SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

HADEA.A – Health and Food
A.2 – EU4Health/SMP Food

GRANT AGREEMENT

Project 101143342 — SPAIN VP2024

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Health and Digital Executive Agency (HADEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION (MAPA), PIC 905557857, established in PASEO DE INFANTA ISABELA, 1, MADRID 28071, Spain,

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator and affiliated entities (if any).

If only one beneficiary signs the grant agreement ('mono-beneficiary grant'), all provisions referring to the 'coordinator' or the 'beneficiaries' will be considered — mutatis mutandis — as referring to the beneficiary.

The parties referred to above have agreed to enter into the Agreement.

By signing the Agreement and the accession forms, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

The Agreement is composed of:

Preamble

Terms and Conditions (including Data Sheet)

Associated with document Ref. Ares(2024)510496 - 23/01/2024

[1] Template published on Portal Reference Documents.
[2] Template published on Portal Reference Documents.
[3] Template published on Portal Reference Documents.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

TERMS AND CONDITIONS

TABLE OF CONTENTS

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

DATA SHEET

1. General data

Project summary:

Project summary
The application covers programmes for avian influenza, Salmonella infections in certain poultry populations (breeding flocks of Gallus gallus, broiler flocks of Gallus gallus, laying flocks of Gallus gallus, breeding flocks of turkeys and fattening flocks of turkeys), and bovine spongiform encephalopathies. Overall, the programmes' actions shall contribute to the general objectives of the Single Market Programme Regulation (EU) 2021/690, Article (3)(2)(e), including by preventing, detecting and/or eradicating animal diseases. More specifically, and in relation to the diseases covered, efforts are focused on: -prevention, early detection, eradication (as appropriate) of disease outbreaks; -control of the prevalence of an animal disease or zoonosis below a sanitary acceptable level / set target, by implementing relevant measures; -measures under EU legislation. Detailed descriptions of specific actions are contained in Annex 1 – Description of the action (part B)."

Keywords:

- Early detection, surveillance, monitoring, control

Project number: 101143342

Project name: SPANISH VETERINARY PROGRAMMES 2024

Project acronym: SPAIN VP2024

Call: SMP-FOOD-2024-VETPROGR-LS-IBA

Topic: SMP-FOOD-2024-VETPROGR-LS-IBA

Type of action: SMP Lump Sum Grants

Granting authority: European Health and Digital Executive Agency

Grant managed through EU Funding & Tenders Portal: Yes (eGrants)

Project starting date: fixed date: 1 January 2024

Project end date: 31 December 2024

Project duration: 12 months

Consortium agreement: Yes

2. Participants

List of participants:

N°	Role	Short name	Legal name	Ctry	PIC	Max grant amount
1	COO	MAPA	MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION	ES	905557857	2 560 899.54
Total						2 560 899.54

Coordinator:

- MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION (MAPA)

3. Grant

Maximum grant amount, total estimated eligible costs and contributions and funding rate:

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Maximum grant amount (Annex 2)	Maximum grant amount (award decision)
2 560 899.54	2 560 899.54

Grant form: Lump Sum

Grant mode: Action grant

Budget categories/activity types: Lump sum contributions

Cost eligibility options: n/a

Budget flexibility: No

4. Reporting, payments and recoveries

4.1 Continuous reporting (art 21)

Deliverables: see Funding & Tenders Portal Continuous Reporting tool

4.2 Periodic reporting and payments

Reporting and payment schedule (art 21, 22):

Reporting					Payments	
Reporting periods			Type	Deadline	Type	Deadline (time to pay)
RP No	Month from	Month to				
					Initial prefinancing	n/a
1	1	12	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

Prefinancing payments and guarantees: n/a

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): No

Restrictions on distribution of initial prefinancing: The prefinancing may be distributed only if the minimum number of beneficiaries set out in the call condititions (if any) have acceded to the Agreement and only to beneficiaries that have acceded.

Interim payment ceiling (if any): 100% of the maximum grant amount

No-profit rule: n/a

Late payment interest: ECB + 3.5%

Bank account for payments:

ES4490000001200253107033

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Conversion into euros: n/a

Reporting language: Language of the Agreement

4.3 Certificates (art 24): n/a

4.4 Recoveries (art 22)

First-line liability for recoveries:

Beneficiary termination: Beneficiary concerned

Final payment: Coordinator

After final payment: Beneficiary concerned

Joint and several liability for enforced recoveries (in case of non-payment):

Limited joint and several liability of other beneficiaries — up to the maximum grant amount of the beneficiary

Joint and several liability of affiliated entities — n/a

5. Consequences of non-compliance, applicable law & dispute settlement forum

Applicable law (art 43):

Standard applicable law regime: EU law + law of Belgium

Dispute settlement forum (art 43):

Standard dispute settlement forum:

EU beneficiaries: EU General Court + EU Court of Justice (on appeal)

Non-EU beneficiaries: Courts of Brussels, Belgium (unless an international agreement provides for the enforceability of EU court judgements)

6. Other

Specific rules (Annex 5): Yes

Standard time-limits after project end:

Confidentiality (for X years after final payment): 5

Record-keeping (for X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Reviews (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Audits (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Extension of findings from other grants to this grant (no later than X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Impact evaluation (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and terms and conditions applicable to the grant awarded for the implementation of the action set out in Chapter 2.

ARTICLE 2 — DEFINITIONS

For the purpose of this Agreement, the following definitions apply:

Actions — The project which is being funded in the context of this Agreement.

Grant — The grant awarded in the context of this Agreement.

EU grants — Grants awarded by EU institutions, bodies, offices or agencies (including EU executive agencies, EU regulatory agencies, EDA, joint undertakings, etc.).

Participants — Entities participating in the action as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties.

Beneficiaries (BEN) — The signatories of this Agreement (either directly or through an accession form).

Affiliated entities (AE) — Entities affiliated to a beneficiary within the meaning of Article 187 of EU Financial Regulation 2018/1046[4] which participate in the action with similar rights and obligations as the beneficiaries (obligation to implement action tasks and right to charge costs and claim contributions).

Associated partners (AP) — Entities which participate in the action, but without the right to charge costs or claim contributions.

Purchases — Contracts for goods, works or services needed to carry out the action (e.g. equipment, consumables and supplies) but which are not part of the action tasks (see Annex 1).

Subcontracting — Contracts for goods, works or services that are part of the action tasks (see Annex 1).

In-kind contributions — In-kind contributions within the meaning of Article 2(36) of EU Financial

[4] For the definition, see Article 187 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 ('EU Financial Regulation') (OJ L 193, 30.7.2018, p. 1): "**affiliated entities** [are]:
(a) entities that form a sole beneficiary [(i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant)];
(b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 136(1) and 141(1) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation".

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Regulation 2018/1046, i.e. non-financial resources made available free of charge by third parties.

Fraud — Fraud within the meaning of Article 3 of EU Directive 2017/1371[5] and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995[6], as well as any other wrongful or criminal deception intended to result in financial or personal gain.

Irregularities — Any type of breach (regulatory or contractual) which could impact the EU financial interests, including irregularities within the meaning of Article 1(2) of EU Regulation 2988/95[7].

Grave professional misconduct — Any type of unacceptable or improper behaviour in exercising one's profession, especially by employees, including grave professional misconduct within the meaning of Article 136(1)(c) of EU Financial Regulation 2018/1046.

Applicable EU, international and national law — Any legal acts or other (binding or non-binding) rules and guidance in the area concerned.

Portal — EU Funding & Tenders Portal; electronic portal and exchange system managed by the European Commission and used by itself and other EU institutions, bodies, offices or agencies for the management of their funding programmes (grants, procurements, prizes, etc.).

CHAPTER 2 ACTION

ARTICLE 3 — ACTION

The grant is awarded for the action **101143342 — SPAIN VP2024** ('action'), as described in Annex 1.

ARTICLE 4 — DURATION AND STARTING DATE

The duration and the starting date of the action are set out in the Data Sheet (see Point 1).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT

5.1 Form of grant

[5] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).
[6] OJ C 316, 27.11.1995, p. 48.
[7] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

The grant is an action grant[8] which takes the form of a lump sum grant for the completion of work packages.

5.2 Maximum grant amount

The maximum grant amount is set out in the Data Sheet (see Point 3) and in the estimated budget (Annex 2).

5.3 Funding rate

Not applicable

5.4 Estimated budget, budget categories and forms of funding

The estimated budget for the action (lump sum breakdown) is set out in Annex 2.

It contains the estimated eligible contributions for the action (lump sum contributions), broken down by participant and work package.

Annex 2 also shows the types of contributions (forms of funding)[9] to be used for each work package.

5.5 Budget flexibility

Budget flexibility does not apply; changes to the estimated budget (lump sum breakdown) always require an amendment (see Article 39).

Amendments for transfers between *work packages* are moreover possible only if:

- the work packages concerned are not already completed (and declared in a financial statement) and
- the transfers are justified by the technical implementation of the action.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE CONTRIBUTIONS

6.1 and 6.2 General and specific eligibility conditions

Lump sum contributions are eligible ('eligible contributions'), if:

(a) they are set out in Annex 2 and

(b) the work packages are completed and the work is properly implemented by the beneficiaries and/or the results are achieved, in accordance with Annex 1 and during in the period set out in Article 4 (with the exception of work/results relating to the submission of the final periodic report, which may be achieved afterwards; see Article 21)

They will be calculated on the basis of the amounts set out in Annex 2.

[8] For the definition, see Article 180(2)(a) EU Financial Regulation 2018/1046: '**action grant**' means an EU grant to finance "an action intended to help achieve a Union policy objective".

[9] See Article 125 EU Financial Regulation 2018/1046.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

6.3 Ineligible contributions

'Ineligible contributions' are:

(a) lump sum contributions that do not comply with the conditions set out above (see Article 6.1 and 6.2)

(b) lump sum contributions for activities already funded under other EU grants (or grants awarded by an EU Member State, non-EU country or other body implementing the EU budget), except for the following case:

(i) Synergy actions: not applicable

(c) other:

(i) country restrictions for eligible costs: not applicable.

6.4 Consequences of non-compliance

If a beneficiary declares lump sum contributions that are ineligible, they will be rejected (see Article 27).

This may also lead to other measures described in Chapter 5.

CHAPTER 4 GRANT IMPLEMENTATION

SECTION 1 CONSORTIUM: BENEFICIARIES, AFFILIATED ENTITIES AND OTHER PARTICIPANTS

ARTICLE 7 — BENEFICIARIES

The beneficiaries, as signatories of the Agreement, are fully responsible towards the granting authority for implementing it and for complying with all its obligations.

They must implement the Agreement to their best abilities, in good faith and in accordance with all the obligations and terms and conditions it sets out.

They must have the appropriate resources to implement the action and implement the action under their own responsibility and in accordance with Article 11. If they rely on affiliated entities or other participants (see Articles 8 and 9), they retain sole responsibility towards the granting authority and the other beneficiaries.

They are jointly responsible for the *technical* implementation of the action. If one of the beneficiaries fails to implement their part of the action, the other beneficiaries must ensure that this part is implemented by someone else (without being entitled to an increase of the maximum grant amount and subject to an amendment; see Article 39). The *financial* responsibility of each beneficiary in case of recoveries is governed by Article 22.

The beneficiaries (and their action) must remain eligible under the EU programme funding the grant

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

for the entire duration of the action. Lump sum contributions will be eligible only as long as the beneficiary and the action are eligible.

The **internal roles and responsibilities** of the beneficiaries are divided as follows:

(a) Each beneficiary must:

(i) keep information stored in the Portal Participant Register up to date (see Article 19)

(ii) inform the granting authority (and the other beneficiaries) immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 19)

(iii) submit to the coordinator in good time:

- the prefinancing guarantees (if required; see Article 23)
- the financial statements and certificates on the financial statements (CFS): not applicable
- the contribution to the deliverables and technical reports (see Article 21)
- any other documents or information required by the granting authority under the Agreement

(iv) submit via the Portal data and information related to the participation of their affiliated entities.

(b) The coordinator must:

(i) monitor that the action is implemented properly (see Article 11)

(ii) act as the intermediary for all communications between the consortium and the granting authority, unless the Agreement or granting authority specifies otherwise, and in particular:

- submit the prefinancing guarantees to the granting authority (if any)
- request and review any documents or information required and verify their quality and completeness before passing them on to the granting authority
- submit the deliverables and reports to the granting authority
- inform the granting authority about the payments made to the other beneficiaries (report on the distribution of payments; if required, see Articles 22 and 32)

(iii) distribute the payments received from the granting authority to the other beneficiaries without unjustified delay (see Article 22).

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including affiliated entities).

However, coordinators which are public bodies may delegate the tasks set out in Point (b)(ii) last

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

indent and (iii) above to entities with 'authorisation to administer' which they have created or which are controlled by or affiliated to them. In this case, the coordinator retains sole responsibility for the payments and for compliance with the obligations under the Agreement.

Moreover, coordinators which are 'sole beneficiaries'[10] (or similar, such as European research infrastructure consortia (ERICs)) may delegate the tasks set out in Point (b)(i) to (iii) above to one of their members. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.

The beneficiaries must have **internal arrangements** regarding their operation and co-ordination, to ensure that the action is implemented properly.

If required by the granting authority (see Data Sheet, Point 1), these arrangements must be set out in a written **consortium agreement** between the beneficiaries, covering for instance:

- the internal organisation of the consortium
- the management of access to the Portal
- different distribution keys for the payments and financial responsibilities in case of recoveries (if any)
- additional rules on rights and obligations related to background and results (see Article 16)
- settlement of internal disputes
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The internal arrangements must not contain any provision contrary to this Agreement.

ARTICLE 8 — AFFILIATED ENTITIES

Not applicable

ARTICLE 9 — OTHER PARTICIPANTS INVOLVED IN THE ACTION

9.1 Associated partners

Not applicable

9.2 Third parties giving in-kind contributions to the action

Other third parties may give in-kind contributions to the action (i.e. personnel, equipment, other goods, works and services, etc. which are free-of-charge), if necessary for the implementation.

Third parties giving in-kind contributions do not implement any action tasks. They may not charge contributions to the action (no lump sum contributions) and the costs for the in-kind contributions are not eligible (may not be included in the estimated budget in Annex 2).

[10] For the definition, see Article 187(2) EU Financial Regulation 2018/1046: "Where several entities satisfy the criteria for being awarded a grant and together form one entity, that entity may be treated as the **sole beneficiary**, including where it is specifically established for the purpose of implementing the action financed by the grant."

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

The third parties and their in-kind contributions should be set out in Annex 1.

9.3 Subcontractors

Subcontractors may participate in the action, if necessary for the implementation.

Subcontractors must implement their action tasks in accordance with Article 11. The beneficiaries' costs for subcontracting are considered entirely covered by the lump sum contributions for implementing the work packages (irrespective of the actual subcontracting costs incurred, if any).

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the subcontractors.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the subcontractors.

9.4 Recipients of financial support to third parties

If the action includes providing financial support to third parties (e.g. grants, prizes or similar forms of support), the beneficiaries must ensure that their contractual obligations under Articles 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping)also apply to the third parties receiving the support (recipients).

The beneficiaries must also ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the recipients.

ARTICLE 10 — PARTICIPANTS WITH SPECIAL STATUS

10.1 Non-EU participants

Participants which are established in a non-EU country (if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)
- for the submission of certificates under Article 24: use qualified external auditors which are independent and comply with comparable standards as those set out in EU Directive 2006/43/EC[11]
- for the controls under Article 25: allow for checks, reviews, audits and investigations (including on-the-spot checks, visits and inspections) by the bodies mentioned in that Article (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.).

[11] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts or similar national regulations (OJ L 157, 9.6.2006, p. 87).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Special rules on dispute settlement apply (see Data Sheet, Point 5).

10.2 Participants which are international organisations

Participants which are international organisations (IOs; if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)

- for the submission of certificates under Article 24: to use either independent public officers or external auditors which comply with comparable standards as those set out in EU Directive 2006/43/EC

- for the controls under Article 25: to allow for the checks, reviews, audits and investigations by the bodies mentioned in that Article, taking into account the specific agreements concluded by them and the EU (if any).

For such participants, nothing in the Agreement will be interpreted as a waiver of their privileges or immunities, as accorded by their constituent documents or international law.

Special rules on applicable law and dispute settlement apply (see Article 43 and Data Sheet, Point 5).

10.3 Pillar-assessed participants

Pillar-assessed participants (if any) may rely on their own systems, rules and procedures, in so far as they have been positively assessed and do not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries.

'Pillar-assessment' means a review by the European Commission on the systems, rules and procedures which participants use for managing EU grants (in particular internal control system, accounting system, external audits, financing of third parties, rules on recovery and exclusion, information on recipients and protection of personal data; see Article 154 EU Financial Regulation 2018/1046).

Participants with a positive pillar assessment may rely on their own systems, rules and procedures, in particular for:

- record-keeping (Article 20): may be done in accordance with internal standards, rules and procedures

- currency conversion for financial statements (Article 21): may be done in accordance with usual accounting practices

- guarantees (Article 23): for public law bodies, prefinancing guarantees are not needed

- certificates (Article 24):

    - certificates on the financial statements (CFS): may be provided by their regular internal or external auditors and in accordance with their internal financial regulations and procedures

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

- certificates on usual accounting practices (CoMUC): are not needed if those practices are covered by an ex-ante assessment

and use the following specific rules, for:

- recoveries (Article 22): in case of financial support to third parties, there will be no recovery if the participant has done everything possible to retrieve the undue amounts from the third party receiving the support (including legal proceedings) and non-recovery is not due to an error or negligence on its part

- checks, reviews, audits and investigations by the EU (Article 25): will be conducted taking into account the rules and procedures specifically agreed between them and the framework agreement (if any)

- impact evaluation (Article 26): will be conducted in accordance with the participant's internal rules and procedures and the framework agreement (if any)

- grant agreement suspension (Article 31): certain costs incurred during grant suspension are eligible (notably, minimum costs necessary for a possible resumption of the action and costs relating to contracts which were entered into before the pre-information letter was received and which could not reasonably be suspended, reallocated or terminated on legal grounds)

- grant agreement termination (Article 32): the final grant amount and final payment will be calculated taking into account also costs relating to contracts due for execution only after termination takes effect, if the contract was entered into before the pre-information letter was received and could not reasonably be terminated on legal grounds

- liability for damages (Article 33.2): the granting authority must be compensated for damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement only if the damage is due to an infringement of the participant's internal rules and procedures or due to a violation of third parties' rights by the participant or one of its employees or individual for whom the employees are responsible.

Participants whose pillar assessment covers procurement and granting procedures may also do purchases, subcontracting and financial support to third parties (Article 6.2) in accordance with their internal rules and procedures for purchases, subcontracting and financial support.

Participants whose pillar assessment covers data protection rules may rely on their internal standards, rules and procedures for data protection (Article 15).

The participants may however not rely on provisions which would breach the principle of equal treatment of applicants or beneficiaries or call into question the decision awarding the grant, such as in particular:

- eligibility (Article 6)

- consortium roles and set-up (Articles 7-9)

- security and ethics (Articles 13, 14)

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

- IPR (including background and results, access rights and rights of use), communication, dissemination and visibility (Articles 16 and 17)
- information obligation (Article 19)
- payment, reporting and amendments (Articles 21, 22 and 39)
- rejections, reductions, suspensions and terminations (Articles 27, 28, 29-32)

If the pillar assessment was subject to remedial measures, reliance on the internal systems, rules and procedures is subject to compliance with those remedial measures.

Participants whose assessment has not yet been updated to cover (the new rules on) data protection may rely on their internal systems, rules and procedures, provided that they ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subject
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the personal data.

Participants must inform the coordinator without delay of any changes to the systems, rules and procedures that were part of the pillar assessment. The coordinator must immediately inform the granting authority.

Pillar-assessed participants that have also concluded a framework agreement with the EU, may moreover — under the same conditions as those above (i.e. not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries) — rely on provisions set out in that framework agreement.

SECTION 2 RULES FOR CARRYING OUT THE ACTION

ARTICLE 11 — PROPER IMPLEMENTATION OF THE ACTION

11.1 Obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement, the call conditions and all legal obligations under applicable EU, international and national law.

11.2 Consequences of non-compliance

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 12 — CONFLICT OF INTERESTS

12.1 Conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the Agreement could be compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect interest (‘conflict of interests’).

They must formally notify the granting authority without delay of any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The granting authority may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28) and the grant or the beneficiary may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 13 — CONFIDENTIALITY AND SECURITY

13.1 Sensitive information

The parties must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing (‘sensitive information’) — during the implementation of the action and for at least until the time-limit set out in the Data Sheet (see Point 6).

If a beneficiary requests, the granting authority may agree to keep such information confidential for a longer period.

Unless otherwise agreed between the parties, they may use sensitive information only to implement the Agreement.

The beneficiaries may disclose sensitive information to their personnel or other participants involved in the action only if they:

(a) need to know it in order to implement the Agreement and

(b) are bound by an obligation of confidentiality.

The granting authority may disclose sensitive information to its staff and to other EU institutions and bodies.

It may moreover disclose sensitive information to third parties, if:

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

(a) this is necessary to implement the Agreement or safeguard the EU financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party

(b) the information becomes publicly available, without breaching any confidentiality obligation

(c) the disclosure of the sensitive information is required by EU, international or national law.

Specific confidentiality rules (if any) are set out in Annex 5.

13.2 Classified information

The parties must handle classified information in accordance with the applicable EU, international or national law on classified information (in particular, Decision 2015/444[12] and its implementing rules).

Deliverables which contain classified information must be submitted according to special procedures agreed with the granting authority.

Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the granting authority.

Classified information may not be disclosed to any third party (including participants involved in the action implementation) without prior explicit written approval from the granting authority.

Specific security rules (if any) are set out in Annex 5.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 14 — ETHICS AND VALUES

14.1 Ethics

The action must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles.

Specific ethics rules (if any) are set out in Annex 5.

14.2 Values

The beneficiaries must commit to and ensure the respect of basic EU values (such as respect for

[12] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

Specific rules on values (if any) are set out in Annex 5.

14.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 15 — DATA PROTECTION

15.1 Data processing by the granting authority

Any personal data under the Agreement will be processed under the responsibility of the data controller of the granting authority in accordance with and for the purposes set out in the Portal Privacy Statement.

For grants where the granting authority is the European Commission, an EU regulatory or executive agency, joint undertaking or other EU body, the processing will be subject to Regulation 2018/1725[13].

15.2 Data processing by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with the applicable EU, international and national law on data protection (in particular, Regulation 2016/679[14]).

They must ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subjects
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the data.

[13] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

[14] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (‘GDPR’) (OJ L 119, 4.5.2016, p. 1).

Associated with document Ref. Ares(2024)510496 - 23/01/2024

The beneficiaries may grant their personnel access to personal data only if it is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiaries must ensure that the personnel is under a confidentiality obligation.

The beneficiaries must inform the persons whose data are transferred to the granting authority and provide them with the Portal Privacy Statement.

15.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 16 — INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS —ACCESS RIGHTS AND RIGHTS OF USE

16.1 Background and access rights to background

The beneficiaries must give each other and the other participants access to the background identified as needed for implementing the action, subject to any specific rules in Annex 5.

‘Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

(a) held by the beneficiaries before they acceded to the Agreement and

(b) needed to implement the action or exploit the results.

If background is subject to rights of a third party, the beneficiary concerned must ensure that it is able to comply with its obligations under the Agreement.

16.2 Ownership of results

The granting authority does not obtain ownership of the results produced under the action.

‘Results’ means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

16.3 Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination and publicity purposes

The granting authority has the right to use non-sensitive information relating to the action and materials and documents received from the beneficiaries (notably summaries for publication, deliverables, as well as any other material, such as pictures or audio-visual material, in paper or electronic form) for policy information, communication, dissemination and publicity purposes — during the action or afterwards.

The right to use the beneficiaries’ materials, documents and information is granted in the form of a royalty-free, non-exclusive and irrevocable licence, which includes the following rights:

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

(a) **use for its own purposes** (in particular, making them available to persons working for the granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)

(c) **editing or redrafting** (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation)

(d) **translation**

(e) **storage** in paper, electronic or other form

(f) **archiving**, in line with applicable document-management rules

(g) the right to authorise **third parties** to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority and

(h) **processing**, analysing, aggregating the materials, documents and information received and **producing derivative works**.

The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned.

If materials or documents are subject to moral rights or third party rights (including intellectual property rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned).

Where applicable, the granting authority will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the [name of granting authority] under conditions."

16.4 Specific rules on IPR, results and background

Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5.

16.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

ARTICLE 17 — COMMUNICATION, DISSEMINATION AND VISIBILITY

17.1 Communication — Dissemination — Promoting the action

Unless otherwise agreed with the granting authority, the beneficiaries must promote the action and its results by providing targeted information to multiple audiences (including the media and the public), in accordance with Annex 1 and in a strategic, coherent and effective manner.

Before engaging in a communication or dissemination activity expected to have a major media impact, the beneficiaries must inform the granting authority.

17.2 Visibility — European flag and funding statement

Unless otherwise agreed with the granting authority, communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge the EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate):

Funded by the
European Union

Co-funded by the
European Union

The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text.

Apart from the emblem, no other visual identity or logo may be used to highlight the EU support.

When displayed in association with other logos (e.g. of beneficiaries or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos.

For the purposes of their obligations under this Article, the beneficiaries may use the emblem without first obtaining approval from the granting authority. This does not, however, give them the right to

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

exclusive use. Moreover, they may not appropriate the emblem or any similar trademark or logo, either by registration or by any other means.

17.3 Quality of information — Disclaimer

Any communication or dissemination activity related to the action must use factually accurate information.

Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):

> "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them."

17.4 Specific communication, dissemination and visibility rules

Specific communication, dissemination and visibility rules (if any) are set out in Annex 5.

17.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 18 — SPECIFIC RULES FOR CARRYING OUT THE ACTION

18.1 Specific rules for carrying out the action

Specific rules for implementing the action (if any) are set out in Annex 5.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

SECTION 3 GRANT ADMINISTRATION

ARTICLE 19 — GENERAL INFORMATION OBLIGATIONS

19.1 Information requests

The beneficiaries must provide — during the action or afterwards and in accordance with Article 7 — any information requested in order to verify eligibility of the lump sum contributions declared, proper implementation of the action and compliance with the other obligations under the Agreement.

The information provided must be accurate, precise and complete and in the format requested, including electronic format.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

19.2 Participant Register data updates

The beneficiaries must keep — at all times, during the action or afterwards — their information stored in the Portal Participant Register up to date, in particular, their name, address, legal representatives, legal form and organisation type.

19.3 Information about events and circumstances which impact the action

The beneficiaries must immediately inform the granting authority (and the other beneficiaries) of any of the following:

(a) **events** which are likely to affect or delay the implementation of the action or affect the EU's financial interests, in particular:

(i) changes in their legal, financial, technical, organisational or ownership situation (including changes linked to one of the exclusion grounds listed in the declaration of honour signed before grant signature)

(ii) linked action information: not applicable

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

19.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 20 — RECORD-KEEPING

20.1 Keeping records and supporting documents

The beneficiaries must — at least until the time-limit set out in the Data Sheet (see Point 6) — keep records and other supporting documents to prove the proper implementation of the action (proper implementation of the work and/or achievement of the results as described in Annex 1) in line with the accepted standards in the respective field (if any); beneficiaries do not need to keep specific records on the actual costs incurred.

The records and supporting documents must be made available upon request (see Article 19) or in the context of checks, reviews, audits or investigations (see Article 25).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 25), the beneficiaries must keep these records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

originals if they are authorised by the applicable national law. The granting authority may accept non-original documents if they offer a comparable level of assurance.

20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, lump sum contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 21 — REPORTING

21.1 Continuous reporting

The beneficiaries must continuously report on the progress of the action (e.g. **deliverables, milestones, outputs/outcomes, critical risks, indicators,** etc; if any), in the Portal Continuous Reporting tool and in accordance with the timing and conditions it sets out (as agreed with the granting authority).

Standardised deliverables (e.g. progress reports not linked to payments, reports on cumulative expenditure, special reports, etc; if any) must be submitted using the templates published on the Portal.

21.2 Periodic reporting: Technical reports and financial statements

In addition, the beneficiaries must provide reports to request payments, in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2):

- for additional prefinancings (if any): **an additional prefinancing report**
- for interim payments (if any) and the final payment: a **periodic report**

The prefinancing and periodic reports include a technical and financial part.

The technical part includes an overview of the action implementation. It must be prepared using the template available in the Portal Periodic Reporting tool.

The financial part of the additional prefinancing report includes a statement on the use of the previous prefinancing payment.

The financial part of the periodic report includes:

- the financial statement (consolidated statement for the consortium)
- the explanation on the use of resources (or detailed cost reporting table): not applicable
- the certificates on the financial statements (CFS): not applicable.

The **financial statement** must contain the lump sum contributions indicated in Annex 2, for the work packages that were completed during the reporting period.

For the last reporting period, the beneficiaries may exceptionally also declare partial lump sum

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

contributions for work packages that were not completed (e.g. due to force majeure or technical impossibility).

Lump sum contributions which are not declared in a financial statement will not be taken into account by the granting authority.

By signing the financial statement (directly in the Portal Periodic Reporting tool), the coordinator confirms (on behalf of the consortium) that:

- the information provided is complete, reliable and true
- the lump sum contributions declared are eligible (in particular, the work packages have been completed, that the work has been properly implemented and/or the results were achieved in accordance with Annex 1; see Article 6)
- the proper implementation and/or achievement can be substantiated by adequate records and supporting documents (see Article 20) that will be produced upon request (see Article 19) or in the context of checks, reviews, audits and investigations (see Article 25).

In case of recoveries (see Article 22), beneficiaries will be held responsible also for the lump sum contributions declared for their affiliated entities (if any).

21.3 Currency for financial statements and conversion into euros

The financial statements must be drafted in euro.

21.4 Reporting language

The reporting must be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

21.5 Consequences of non-compliance

If a report submitted does not comply with this Article, the granting authority may suspend the payment deadline (see Article 29) and apply other measures described in Chapter 5.

If the coordinator breaches its reporting obligations, the granting authority may terminate the grant or the coordinator's participation (see Article 32) or apply other measures described in Chapter 5.

ARTICLE 22 — PAYMENTS AND RECOVERIES — CALCULATION OF AMOUNTS DUE

22.1 Payments and payment arrangements

Payments will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

They will be made in euro to the bank account indicated by the coordinator (see Data Sheet, Point 4.2) and must be distributed without unjustified delay (restrictions may apply to distribution of the initial prefinancing payment; see Data Sheet, Point 4.2).

Payments to this bank account will discharge the granting authority from its payment obligation.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

The cost of payment transfers will be borne as follows:

- the granting authority bears the cost of transfers charged by its bank
- the beneficiary bears the cost of transfers charged by its bank
- the party causing a repetition of a transfer bears all costs of the repeated transfer.

Payments by the granting authority will be considered to have been carried out on the date when they are debited to its account.

22.2 Recoveries

Recoveries will be made, if — at beneficiary termination, final payment or afterwards — it turns out that the granting authority has paid too much and needs to recover the amounts undue.

The general liability regime for recoveries (first-line liability) is as follows: At final payment, the coordinator will be fully liable for recoveries, even if it has not been the final recipient of the undue amounts. At beneficiary termination or after final payment, recoveries will be made directly against the beneficiaries concerned.

Beneficiaries will be fully liable for repaying the debts of their affiliated entities.

In case of enforced recoveries (see Article 22.4):

- the beneficiaries will be jointly and severally liable for repaying debts of another beneficiary under the Agreement (including late-payment interest), if required by the granting authority (see Data Sheet, Point 4.4)
- affiliated entities will be held liable for repaying debts of their beneficiaries under the Agreement (including late-payment interest), if required by the granting authority (see Data Sheet, Point 4.4).

22.3 Amounts due

22.3.1 Prefinancing payments

The aim of the prefinancing is to provide the beneficiaries with a float.

It remains the property of the EU until the final payment.

For **initial prefinancings** (if any), the amount due, schedule and modalities are set out in the Data Sheet (see Point 4.2).

For **additional prefinancings** (if any), the amount due, schedule and modalities are also set out in the Data Sheet (see Point 4.2). However, if the statement on the use of the previous prefinancing payment shows that less than 70% was used, the amount set out in the Data Sheet will be reduced by the difference between the 70% threshold and the amount used.

Prefinancing payments (or parts of them) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency,

Associated with document Ref. Ares(2024)510496 - 23/01/2024

offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

22.3.2 Amount due at beneficiary termination — Recovery

In case of beneficiary termination, the granting authority will determine the provisional amount due for the beneficiary concerned.

This will be done on the basis of work packages already completed in previous interim payments. Payments for ongoing/not yet completed work packages which the beneficiary was working on before termination (if any) will therefore be made only later on, with the next interim or final payments when those work packages have been completed.

The **amount due** will be calculated in the following step:

Step 1 — Calculation of the total accepted EU contribution

Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the beneficiary, on the basis of the beneficiary's lump sum contributions for the work packages which were approved in previous interim payments.

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the 'total accepted EU contribution' for the beneficiary.

The **balance** is then calculated by deducting the payments received (if any; see report on the distribution of payments in Article 32), from the total accepted EU contribution:

{total accepted EU contribution for the beneficiary

minus

{prefinancing and interim payments received (if any)}}.

If the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount due, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered and ask this amount to be paid to the coordinator (**confirmation letter**).

22.3.3 Interim payments

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Interim payments reimburse the eligible lump sum contributions claimed for work packages implemented during the reporting periods (if any).

Interim payments (if any) will be made in accordance with the schedule and modalities set out the Data Sheet (see Point 4.2).

Payment is subject to the approval of the periodic report and the work packages declared. Their approval does not imply recognition of compliance, authenticity, completeness or correctness of their content.

Incomplete work packages and work packages that have not been delivered or cannot be approved will be rejected (see Article 27).

The **interim payment** will be calculated by the granting authority in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the interim payment ceiling

Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the action for the reporting period, by calculating the lump sum contributions for the approved work packages.

After that, the granting authority will take into account grant reductions from beneficiary termination (if any). The resulting amount is the 'total accepted EU contribution'.

Step 2 — Limit to the interim payment ceiling

The resulting amount is then capped to ensure that the total amount of prefinancing and interim payments (if any) does not exceed the interim payment ceiling set out in the Data Sheet (see Point 4.2).

Interim payments (or parts of them) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

22.3.4 Final payment — Final grant amount — Revenues and Profit — Recovery

The final payment (payment of the balance) reimburses the remaining eligible lump sum contributions claimed for the implemented work packages (if any).

The final payment will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

Payment is subject to the approval of the final periodic report and the work packages declared. Their approval does not imply recognition of compliance, authenticity, completeness or correctness of their content.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Work packages (or parts of them) that have not been delivered or cannot be approved will be rejected (see Article 27).

The **final grant amount for the action** will be calculated in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the action for all reporting periods, by calculating the lump sum contributions for the approved work packages.

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the 'total accepted EU contribution'.

Step 2 — Limit to the maximum grant amount

Not applicable

Step 3 — Reduction due to the no-profit rule

Not applicable

The **balance** (final payment) is then calculated by deducting the total amount of prefinancing and interim payments already made (if any), from the final grant amount:

{final grant amount

minus

{prefinancing and interim payments made (if any)}}.

If the balance is **positive**, it will be **paid** to the coordinator.

The final payment (or part of it) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

If the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to recover, the final grant amount, the amount to be recovered and the reasons why

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered (**confirmation letter**), together with a **debit note** with the terms and date for payment.

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

22.3.5 Audit implementation after final payment — Revised final grant amount — Recovery

If — after the final payment (in particular, after checks, reviews, audits or investigations; see Article 25) — the granting authority rejects lump sum contributions (see Article 27) or reduces the grant (see Article 28), it will calculate the **revised final grant amount** for the beneficiary concerned.

The **beneficiary revised final grant amount** will be calculated in the following step:

Step 1 — Calculation of the revised total accepted EU contribution

<u>Step 1 — Calculation of the revised total accepted EU contribution</u>

The granting authority will first calculate the 'revised accepted EU contribution' for the beneficiary, by calculating the 'revised accepted contributions'.

After that, it will take into account grant reductions (if any). The resulting 'revised total accepted EU contribution' is the beneficiary revised final grant amount.

If the revised final grant amount is lower than the beneficiary's final grant amount (i.e. its share in the final grant amount for the action), it will be **recovered** in accordance with the following procedure:

The **beneficiary final grant amount** (i.e. share in the final grant amount for the action) is calculated as follows:

{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action}.

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered (**confirmation letter**), together with a **debit note** with the terms and the date for payment.

Recoveries against affiliated entities (if any) will be handled through their beneficiaries.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

22.4 Enforced recovery

If payment is not made by the date specified in the debit note, the amount due will be recovered:

(a) by offsetting the amount — without the coordinator or beneficiary's consent — against any amounts owed to the coordinator or beneficiary by the granting authority.

In exceptional circumstances, to safeguard the EU financial interests, the amount may be offset before the payment date specified in the debit note.

For grants where the granting authority is the European Commission or an EU executive agency, debts may also be offset against amounts owed by other Commission services or executive agencies.

(b) by drawing on the financial guarantee(s) (if any)

(c) by holding other beneficiaries jointly and severally liable (if any; see Data Sheet, Point 4.4)

(d) by holding affiliated entities jointly and severally liable (if any, see Data Sheet, Point 4.4)

(e) by taking legal action (see Article 43) or, provided that the granting authority is the European Commission or an EU executive agency, by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 100(2) of EU Financial Regulation 2018/1046.

The amount to be recovered will be increased by **late-payment interest** at the rate set out in Article 23.5, from the day following the payment date in the debit note, up to and including the date the full payment is received.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2015/2366[15] applies.

For grants where the granting authority is an EU executive agency, enforced recovery by offsetting or enforceable decision will be done by the services of the European Commission (see also Article 43).

22.5 Consequences of non-compliance

22.5.1 If the granting authority does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the reference rate applied by the European Central Bank (ECB) for its main refinancing operations in euros, plus the percentage specified in the Data Sheet (Point 4.2). The ECB reference rate to be used is the rate in force on the first day of the

[15] Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only on request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

If payments or the payment deadline are suspended (see Articles 29 and 30), payment will not be considered as late.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

22.5.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 28) and the grant or the coordinator may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 23 — GUARANTEES

23.1 Prefinancing guarantee

If required by the granting authority (see Data Sheet, Point 4.2), the beneficiaries must provide (one or more) prefinancing guarantee(s) in accordance with the timing and the amounts set out in the Data Sheet.

The coordinator must submit them to the granting authority in due time before the prefinancing they are linked to.

The guarantees must be drawn up using the template published on the Portal and fulfil the following conditions:

(a) be provided by a bank or approved financial institution established in the EU or — if requested by the coordinator and accepted by the granting authority — by a third party or a bank or financial institution established outside the EU offering equivalent security

(b) the guarantor stands as first-call guarantor and does not require the granting authority to first have recourse against the principal debtor (i.e. the beneficiary concerned) and

(c) remain explicitly in force until the final payment and, if the final payment takes the form of a recovery, until five months after the debit note is notified to a beneficiary.

They will be released within the following month.

23.2 Consequences of non-compliance

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If the beneficiaries breach their obligation to provide the prefinancing guarantee, the prefinancing will not be paid.

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 24 — CERTIFICATES

Not applicable

ARTICLE 25 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

25.1 Granting authority checks, reviews and audits

25.1.1 Internal checks

The granting authority may — during the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing lump sum contributions, deliverables and reports.

25.1.2 Project reviews

The granting authority may carry out reviews on the proper implementation of the action and compliance with the obligations under the Agreement (general project reviews or specific issues reviews).

Such project reviews may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiary concerned and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent, outside experts. If it uses outside experts, the coordinator or beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The coordinator or beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted. The granting authority may request beneficiaries to provide such information to it directly. Sensitive information and documents will be treated in accordance with Article 13.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with the outside experts.

For **on-the-spot visits**, the beneficiary concerned must allow access to sites and premises (including to the outside experts) and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a **project review report** will be drawn up.

The granting authority will formally notify the project review report to the coordinator or beneficiary concerned, which has 30 days from receiving notification to make observations.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Project reviews (including project review reports) will be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

25.1.3 Audits

The granting authority may carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Such audits may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the beneficiary concerned and will be considered to start on the date of the notification.

The granting authority may use its own audit service, delegate audits to a centralised service or use external audit firms. If it uses an external firm, the beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. Sensitive information and documents will be treated in accordance with Article 13.

For **on-the-spot** visits, the beneficiary concerned must allow access to sites and premises (including for the external audit firm) and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a **draft audit report** will be drawn up.

The auditors will formally notify the draft audit report to the beneficiary concerned, which has 30 days from receiving notification to make observations (contradictory audit procedure).

The **final audit report** will take into account observations by the beneficiary concerned and will be formally notified to them.

Audits (including audit reports) will be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

25.2 European Commission checks, reviews and audits in grants of other granting authorities

Where the granting authority is not the European Commission, the latter has the same rights of checks, reviews and audits as the granting authority.

25.3 Access to records for assessing simplified forms of funding

The beneficiaries must give the European Commission access to their statutory records for the periodic assessment of simplified forms of funding which are used in EU programmes.

25.4 OLAF, EPPO and ECA audits and investigations

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

The following bodies may also carry out checks, reviews, audits and investigations — during the action or afterwards:

- the European Anti-Fraud Office (OLAF) under Regulations No 883/2013[16] and No 2185/96[17]
- the European Public Prosecutor's Office (EPPO) under Regulation 2017/1939
- the European Court of Auditors (ECA) under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 257 of EU Financial Regulation 2018/1046.

If requested by these bodies, the beneficiary concerned must provide full, accurate and complete information in the format requested (including complete accounts, individual salary statements or other personal data, including in electronic format) and allow access to sites and premises for on-the-spot visits or inspections — as provided for under these Regulations.

To this end, the beneficiary concerned must keep all relevant information relating to the action, at least until the time-limit set out in the Data Sheet (Point 6) and, in any case, until any ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims have been concluded.

25.5 Consequences of checks, reviews, audits and investigations — Extension of findings

25.5.1 Consequences of checks, reviews, audits and investigations in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to rejections (see Article 27), grant reduction (see Article 28) or other measures described in Chapter 5.

Rejections or grant reductions after the final payment will lead to a revised final grant amount (see Article 22).

Findings in checks, reviews, audits or investigations during the action implementation may lead to a request for amendment (see Article 39), to change the description of the action set out in Annex 1.

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations in any EU grant may also lead to consequences in other EU grants awarded under similar conditions ('extension to other grants').

Moreover, findings arising from an OLAF or EPPO investigation may lead to criminal prosecution under national law.

25.5.2 Extension from other grants

Findings of checks, reviews, audits or investigations in other grants may be extended to this grant, if:

(a) the beneficiary concerned is found, in other EU grants awarded under similar conditions, to

[16] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18/09/2013, p. 1).

[17] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15/11/1996, p. 2).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — within the time-limit for audits set out in the Data Sheet (see Point 6).

The granting authority will formally notify the beneficiary concerned of the intention to extend the findings and the list of grants affected.

If the extension concerns **rejections of lump sum contributions**: the notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings

(b) the request to submit revised financial statements for all grants affected

(c) the correction rate for extrapolation, established on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected, if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

If the extension concerns **grant reductions**: the notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the **correction rate for extrapolation**, established on the basis of the systemic or recurrent errors and the principle of proportionality.

The beneficiary concerned has **60 days** from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method/rate**.

On the basis of this, the granting authority will analyse the impact and decide on the implementation (i.e. start rejection or grant reduction procedures, either on the basis of the revised financial statements or the announced/alternative method/rate or a mix of those; see Articles 27 and 28).

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, lump sum contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 26 — IMPACT EVALUATIONS

26.1 Impact evaluation

The granting authority may carry out impact evaluations of the action, measured against the objectives and indicators of the EU programme funding the grant.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Such evaluations may be started during implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiaries and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent outside experts.

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

26.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the granting authority may apply the measures described in Chapter 5.

CHAPTER 5 CONSEQUENCES OF NON-COMPLIANCE

SECTION 1 REJECTIONS AND GRANT REDUCTION

ARTICLE 27 — REJECTION OF CONTRIBUTIONS

27.1 Conditions

The granting authority will — at interim payment, final payment or afterwards — reject any lump sum contributions which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 25).

The rejection may also be based on the extension of findings from other grants to this grant (see Article 25).

Ineligible lump sum contributions will be rejected.

27.2 Procedure

If the rejection does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the rejection, the amounts and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the rejection (payment review procedure).

If the rejection leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

27.3 Effects

If the granting authority rejects lump sum contributions, it will deduct them from the lump sum contributions declared and then calculate the amount due (and, if needed, make a recovery; see Article 22).

ARTICLE 28 — GRANT REDUCTION

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

28.1 Conditions

The granting authority may — at beneficiary termination, final payment or afterwards — reduce the grant for a beneficiary, if:

(a) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings; see Article 25.5).

The amount of the reduction will be calculated for each beneficiary concerned and proportionate to the seriousness and the duration of the errors, irregularities or fraud or breach of obligations, by applying an individual reduction rate to their accepted EU contribution.

28.2 Procedure

If the grant reduction does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the reduction, the amount to be reduced and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the reduction (payment review procedure).

If the grant reduction leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

28.3 Effects

If the granting authority reduces the grant, it will deduct the reduction and then calculate the amount due (and, if needed, make a recovery; see Article 22).

SECTION 2 SUSPENSION AND TERMINATION

ARTICLE 29 — PAYMENT DEADLINE SUSPENSION

29.1 Conditions

The granting authority may — at any moment — suspend the payment deadline if a payment cannot be processed because:

(a) the required report (see Article 21) has not been submitted or is not complete or additional information is needed

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

(b) there are doubts about the amount to be paid (e.g. ongoing extension procedure, queries about eligibility, need for a grant reduction, etc.) and additional checks, reviews, audits or investigations are necessary, or

(c) there are other issues affecting the EU financial interests.

29.2 Procedure

The granting authority will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day the notification is sent.

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining time to pay (see Data Sheet, Point 4.2) will resume.

If the suspension exceeds two months, the coordinator may request the granting authority to confirm if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the report and the revised report is not submitted (or was submitted but is also rejected), the granting authority may also terminate the grant or the participation of the coordinator (see Article 32).

ARTICLE 30 — PAYMENT SUSPENSION

30.1 Conditions

The granting authority may — at any moment — suspend payments, in whole or in part for one or more beneficiaries, if:

(a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings; see Article 25.5).

If payments are suspended for one or more beneficiaries, the granting authority will make partial payment(s) for the part(s) not suspended. If suspension concerns the final payment, the payment (or recovery) of the remaining amount after suspension is lifted will be considered to be the payment that closes the action.

30.2 Procedure

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Before suspending payments, the granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to suspend payments and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

At the end of the suspension procedure, the granting authority will also inform the coordinator.

The suspension will **take effect** the day after the confirmation notification is sent.

If the conditions for resuming payments are met, the suspension will be **lifted**. The granting authority will formally notify the beneficiary concerned (and the coordinator) and set the suspension end date.

During the suspension, no prefinancing will be paid to the beneficiaries concerned. For interim payments, the periodic reports for all reporting periods except the last one (see Article 21) must not contain any financial statements from the beneficiary concerned (or its affiliated entities). The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

ARTICLE 31 — GRANT AGREEMENT SUSPENSION

31.1 Consortium-requested GA suspension

31.1.1 Conditions and procedure

The beneficiaries may request the suspension of the grant or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the suspension takes effect; this date may be before the date of the submission of the amendment request and
- the expected date of resumption.

The suspension will **take effect** on the day specified in the amendment.

Once circumstances allow for implementation to resume, the coordinator must immediately request another **amendment** of the Agreement to set the suspension end date, the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the amendment. This date may be before the date of the submission of the amendment request.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

During the suspension, no prefinancing will be paid. Moreover, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

31.2 EU-initiated GA suspension

31.2.1 Conditions

The granting authority may suspend the grant or any part of it, if:

(a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings; see Article 25.5)

(c) other:

(i) linked action issues: not applicable

(ii) additional GA suspension grounds: not applicable.

31.2.2 Procedure

Before suspending the grant, the granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to suspend the grant and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

The suspension will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification).

Once the conditions for resuming implementation of the action are met, the granting authority will formally notify the coordinator a **lifting of suspension letter**, in which it will set the suspension end date and invite the coordinator to request an amendment of the Agreement to set the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the lifting of suspension letter. This date may be before the date on which the letter is sent.

During the suspension, no prefinancing will be paid. Moreover, no work may be done. Ongoing work packages must be interrupted and no new work packages may be started.

The beneficiaries may not claim damages due to suspension by the granting authority (see Article 33).

Grant suspension does not affect the granting authority's right to terminate the grant or a beneficiary (see Article 32) or reduce the grant (see Article 28).

ARTICLE 32 — GRANT AGREEMENT OR BENEFICIARY TERMINATION

32.1 Consortium-requested GA termination

32.1.1 Conditions and procedure

The beneficiaries may request the termination of the grant.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the consortium ends work on the action ('end of work date') and
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

The termination will **take effect** on the termination date specified in the amendment.

If no reasons are given or if the granting authority considers the reasons do not justify termination, it may consider the grant terminated improperly.

32.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the lump sum contributions for activities implemented before the end of work date (see Article 22). Partial lump sum contributions for work packages that were not completed (e.g. due to technical reasons) may exceptionally be taken into account.

If the granting authority does not receive the report within the deadline, only lump sum contributions which are included in an approved periodic report will be taken into account (no contributions if no periodic report was ever approved).

Improper termination may lead to a grant reduction (see Article 28).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

32.2 Consortium-requested beneficiary termination

32.2.1 Conditions and procedure

The coordinator may request the termination of the participation of one or more beneficiaries, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing)
- the date the beneficiary ends work on the action ('end of work date')
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

If the termination concerns the coordinator and is done without its agreement, the amendment request must be submitted by another beneficiary (acting on behalf of the consortium).

The termination will **take effect** on the termination date specified in the amendment.

If no information is given or if the granting authority considers that the reasons do not justify termination, it may consider the beneficiary to have been terminated improperly.

32.2.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a **report on the distribution of payments** to the beneficiary concerned

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work

(iii) a second **request for amendment** (see Article 39) with other amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the reports submitted in previous interim payments (i.e. beneficiary's lump sum contributions for completed and approved work packages).

Lump sum contributions for ongoing/not yet completed work packages will have to be included in the periodic report for the next reporting periods when those work packages have been completed.

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If the second request for amendment is accepted by the granting authority, the Agreement is **amended** to introduce the necessary changes (see Article 39).

If the second request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

Improper termination may lead to a reduction of the grant (see Article 31) or grant termination (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

32.3 EU-initiated GA or beneficiary termination

32.3.1 Conditions

The granting authority may terminate the grant or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 40)

(b) a change to the action or the legal, financial, technical, organisational or ownership situation of a beneficiary is likely to substantially affect the implementation of the action or calls into question the decision to award the grant (including changes linked to one of the exclusion grounds listed in the declaration of honour)

(c) following termination of one or more beneficiaries, the necessary changes to the Agreement (and their impact on the action) would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(d) implementation of the action has become impossible or the changes necessary for its continuation would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(e) a beneficiary (or person with unlimited liability for its debts) is subject to bankruptcy proceedings or similar (including insolvency, winding-up, administration by a liquidator or court, arrangement with creditors, suspension of business activities, etc.)

(f) a beneficiary (or person with unlimited liability for its debts) is in breach of social security or tax obligations

(g) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has been found guilty of grave professional misconduct

(h) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed fraud, corruption, or is involved in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

(i) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) was created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin (or created another entity with this purpose)

(j) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.)

(k) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings; see Article 25.5)

(l) despite a specific request by the granting authority, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its affiliated entities or associated partners that is in one of the situations under points (d), (f), (e), (g), (h), (i) or (j) and to reallocate its tasks, or

(m) other:

(i) linked action issues: not applicable

(ii) additional GA termination grounds: not applicable.

32.3.2 Procedure

Before terminating the grant or participation of one or more beneficiaries, the granting authority will send **a pre-information letter** to the coordinator or beneficiary concerned:

- formally notifying the intention to terminate and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the termination and the date it will take effect (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

For beneficiary terminations, the granting authority will — at the end of the procedure — also inform the coordinator.

The termination will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification; ‘termination date’).

32.3.3 Effects

Associated with document Ref. Ares(2024)510496 - 23/01/2024

(a) for **GA termination**:

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the last open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the lump sum contributions for activities implemented before termination takes effect (see Article 22). Partial lump sum contributions for work packages that were not completed (e.g. due to technical reasons) may exceptionally be taken into account.

If the grant is terminated for breach of the obligation to submit reports, the coordinator may not submit any report after termination.

If the granting authority does not receive the report within the deadline, only lump sum contributions which are included in an approved periodic report will be taken into account (no contributions if no periodic report was ever approved).

Termination does not affect the granting authority's right to reduce the grant (see Article 28) or to impose administrative sanctions (see Article 34).

The beneficiaries may not claim damages due to termination by the granting authority (see Article 33).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

(b) for **beneficiary termination**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a **report on the distribution of payments** to the beneficiary concerned

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work

(iii) a **request for amendment** (see Article 39) with any amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the reports submitted in previous interim payments (i.e. beneficiary's lump sum contributions for completed and approved work packages).

Lump sum contributions for ongoing/not yet completed work packages will have to be included in the periodic report for the next reporting periods when those work packages have been completed.

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

If the request for amendment is accepted by the granting authority, the Agreement is **amended** to introduce the necessary changes (see Article 39).

If the request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

SECTION 3 OTHER CONSEQUENCES: DAMAGES AND ADMINISTRATIVE SANCTIONS

ARTICLE 33 — DAMAGES

33.1 Liability of the granting authority

The granting authority cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of the implementation of the Agreement, including for gross negligence.

The granting authority cannot be held liable for any damage caused by any of the beneficiaries or other participants involved in the action, as a consequence of the implementation of the Agreement.

33.2 Liability of the beneficiaries

The beneficiaries must compensate the granting authority for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement, provided that it was caused by gross negligence or wilful act.

The liability does not extend to indirect or consequential losses or similar damage (such as loss of profit, loss of revenue or loss of contracts), provided such damage was not caused by wilful act or by a breach of confidentiality.

ARTICLE 34 — ADMINISTRATIVE SANCTIONS AND OTHER MEASURES

Nothing in this Agreement may be construed as preventing the adoption of administrative sanctions (i.e. exclusion from EU award procedures and/or financial penalties) or other public law measures, in addition or as an alternative to the contractual measures provided under this Agreement (see,

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

for instance, Articles 135 to 145 EU Financial Regulation 2018/1046 and Articles 4 and 7 of Regulation 2988/95[18]).

SECTION 4 FORCE MAJEURE

ARTICLE 35 — FORCE MAJEURE

A party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of other participants involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

CHAPTER 6 FINAL PROVISIONS

ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 Forms and means of communication — Electronic management

EU grants are managed fully electronically through the EU Funding & Tenders Portal ('Portal').

All communications must be made electronically through the Portal in accordance with the Portal Terms and Conditions and using the forms and templates provided there (except if explicitly instructed otherwise by the granting authority).

Communications must be made in writing and clearly identify the grant agreement (project number and acronym).

Communications must be made by persons authorised according to the Portal Terms and Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in their appointment letter (see Portal Terms and Conditions).

[18] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

If the electronic exchange system is temporarily unavailable, instructions will be given on the Portal.

36.2 Date of communication

The sending date for communications made through the Portal will be the date and time of sending, as indicated by the time logs.

The receiving date for communications made through the Portal will be the date and time the communication is accessed, as indicated by the time logs. Formal notifications that have not been accessed within 10 days after sending, will be considered to have been accessed (see Portal Terms and Conditions).

If a communication is exceptionally made on paper (by e-mail or postal service), general principles apply (i.e. date of sending/receipt). Formal notifications by registered post with proof of delivery will be considered to have been received either on the delivery date registered by the postal service or the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

36.3 Addresses for communication

The Portal can be accessed via the Europa website.

The address for paper communications to the granting authority (if exceptionally allowed) is the official mailing address indicated on its website.

For beneficiaries, it is the legal address specified in the Portal Participant Register.

ARTICLE 37 — INTERPRETATION OF THE AGREEMENT

The provisions in the Data Sheet take precedence over the rest of the Terms and Conditions of the Agreement.

Annex 5 takes precedence over the Terms and Conditions.

The Terms and Conditions take precedence over the Annexes other than Annex 5.

Annex 2 takes precedence over Annex 1.

ARTICLE 38 — CALCULATION OF PERIODS AND DEADLINES

In accordance with Regulation No 1182/71[19], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

'Days' means calendar days, not working days.

[19] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8/6/1971, p. 1).

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

ARTICLE 39 — AMENDMENTS

39.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

39.2 Procedure

The party requesting an amendment must submit a request for amendment signed directly in the Portal Amendment tool.

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3). If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why
- the appropriate supporting documents and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The granting authority may request additional information.

If the party receiving the request agrees, it must sign the amendment in the tool within 45 days of receiving notification (or any additional information the granting authority has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date of entry into force or other date specified in the amendment.

ARTICLE 40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES

40.1 Accession of the beneficiaries mentioned in the Preamble

The beneficiaries which are not coordinator must accede to the grant by signing the accession form (see Annex 3) directly in the Portal Grant Preparation tool, within 30 days after the entry into force of the Agreement (see Article 44).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 44).

If a beneficiary does not accede to the grant within the above deadline, the coordinator must — within

SMP Lump Sum MGA — Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510496 - 23/01/2024

30 days — request an amendment (see Article 39) to terminate the beneficiary and make any changes necessary to ensure proper implementation of the action. This does not affect the granting authority's right to terminate the grant (see Article 32).

40.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 39. It must include an accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool.

New beneficiaries will assume the rights and obligations under the Agreement with effect from the date of their accession specified in the accession form (see Annex 3).

Additions are also possible in mono-beneficiary grants.

ARTICLE 41 — TRANSFER OF THE AGREEMENT

In justified cases, the beneficiary of a mono-beneficiary grant may request the transfer of the grant to a new beneficiary, provided that this would not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiary must submit a request for **amendment** (see Article 39), with

- the reasons why
- the accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool and
- additional supporting documents (if required by the granting authority).

The new beneficiary will assume the rights and obligations under the Agreement with effect from the date of accession specified in the accession form (see Annex 3).

ARTICLE 42 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE GRANTING AUTHORITY

The beneficiaries may not assign any of their claims for payment against the granting authority to any third party, except if expressly approved in writing by the granting authority on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the granting authority has not accepted the assignment or if the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the granting authority.

ARTICLE 43 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

43.1 Applicable law

Associated with document Ref. Ares(2024)510496 - 23/01/2024

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

Special rules may apply for beneficiaries which are international organisations (if any; see Data Sheet, Point 5).

43.2 Dispute settlement

If a dispute concerns the interpretation, application or validity of the Agreement, the parties must bring action before the EU General Court — or, on appeal, the EU Court of Justice — under Article 272 of the Treaty on the Functioning of the EU (TFEU).

For non-EU beneficiaries (if any), such disputes must be brought before the courts of Brussels, Belgium — unless an international agreement provides for the enforceability of EU court judgements.

For beneficiaries with arbitration as special dispute settlement forum (if any; see Data Sheet, Point 5), the dispute will — in the absence of an amicable settlement — be settled in accordance with the Rules for Arbitration published on the Portal.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 22 and 34), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice — under Article 263 TFEU.

For grants where the granting authority is an EU executive agency (see Preamble), actions against offsetting and enforceable decisions must be brought against the European Commission (not against the granting authority; see also Article 22).

ARTICLE 44 — ENTRY INTO FORCE

The Agreement will enter into force on the day of signature by the granting authority or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

JOSE LUIS SAEZ LLORENTE with ECAS id nsaezjos signed in the Participant Portal on 24/01/2024 at 08:44:14 (transaction id SigId-18351-h1HzfoliepVJsIYpUrAEDE8VKQvO0Ki8YSkYzf2aEB3D9IrF5o8LCQ7FDNCTe3CVS0miNFltOFNJcbj0MsZ1lT-yntOf97TTHq2YjhvtFtWhO-OBDubBNkN0rXyc8RcfTcwrgUzPLVIyHaKpt1Fj0nVX67ZGxvno5XLzIHnNrBzGxSSYQnjti5zgd8sUYzuiI2Kd9). Timestamp by third party at 2024.01.24 08:44:20 CET

For the granting authority

Signed by Agnes MATHIEU-MENDES with ECAS id mathiag as an authorised representative on 24-01-2024 16:48:30 (transaction id SigId-28898-SElZijxVB1VSwzzrwFNltWZ9mMy3ZfI082X2TzqkCAxZ6KulVx2ahJTmte8nzuC2q4Uhu5RNZm9M13psyzv3KsJ-yntOf97TTHq2YjhvtFtWhO-QDPBCaFNWk4jyEwlqyEmKBq9xDMkdczhlsNytpWkCl3XOPZVFfiVh1I7455PAhNnpsztUcrzON21R6pdnrD5iG) 2024.01.24 16:48:36 CET

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX 1

Single Market Programme (SMP)

Description of the action (DoA)

Part A

Part B

Associated with document Ref. Ares(2024)510496 - 23/01/2024

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

Part A of the Description of the Action (DoA) must be completed directly on the Portal Grant Preparation screens.

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101143342
Project name:	SPANISH VETERINARY PROGRAMMES 2024
Project acronym:	SPAIN VP2024
Call:	SMP-FOOD-2024-VETPROGR-LS-IBA
Topic:	SMP-FOOD-2024-VETPROGR-LS-IBA
Type of action:	SMP-LS
Service:	HADEA/A/02
Project starting date:	fixed date: 1 January 2024
Project duration:	12 months

TABLE OF CONTENTS

Associated with document Ref. Ares(2024)510496 - 23/01/2024

PROJECT SUMMARY

Project summary

Grant Preparation (General Information screen) — Provide an overall description of your project (including context and overall objectives, planned activities and main achievements, and expected results and impacts (on target groups, change procedures, capacities, innovation etc)). This summary should give readers a clear idea of what your project is about.

Use the project summary from your proposal.

The application covers programmes for avian influenza, Salmonella infections in certain poultry populations (breeding flocks of Gallus gallus, broiler flocks of Gallus gallus, laying flocks of Gallus gallus, breeding flocks of turkeys and fattening flocks of turkeys), and bovine spongiform encephalopathies.
Overall, the programmes' actions shall contribute to the general objectives of the Single Market Programme Regulation (EU) 2021/690, Article (3)(2)(e), including by preventing, detecting and/or eradicating animal diseases.
More specifically, and in relation to the diseases covered, efforts are focused on:
-prevention, early detection, eradication (as appropriate) of disease outbreaks;
-control of the prevalence of an animal disease or zoonosis below a sanitary acceptable level / set target, by implementing relevant measures;
-measures under EU legislation.
Detailed descriptions of specific actions are contained in Annex 1 – Description of the action (part B).”

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	MAPA	MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION	ES	905557857

LIST OF WORK PACKAGES

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
WP1	AVIAN INFLUENZA SURVEILLANCE PROGRAMME 2024	1 - MAPA	1.00	1	12	D1.1 – AI_final report D1.2 – AI_intermediate report
WP2	Salmonella control programme 2024	1 - MAPA	1.00	1	12	D2.1 – Salmonella_final report D2.2 – Salmonella_intermediate report
WP3	BSE programme 2024	1 - MAPA	1.00	1	12	D3.1 – BSE_final report D3.2 – BSE_intermediate report

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Work package WP1 – AVIAN INFLUENZA SURVEILLANCE PROGRAMME 2024

Work Package Number	WP1	**Lead Beneficiary**	1 - MAPA
Work Package Name	AVIAN INFLUENZA SURVEILLANCE PROGRAMME 2024		
Start Month	1	**End Month**	12

Objectives
The main objectives of the programme in Spain are to demonstrate freedom from the disease,and the early detection of the circulation of avian influenza virus, both strains of high and lowpathogenicity, by a surveillance system that includes a passive and an active component.

Description
Active surveillance component has the objective of demonstration of freedom and contributeto the early detection of HPAI through the detection of subclinical infections of LPAI ofsubtypes H5 and H7 that can easily spread between poultry flocks and mutate into HPAI, andthe detection of infections with HPAI in species which do not normally show significant clinical signs. The passive component aims specifically at the early detection though contributing to thereporting and immediate investigation by the Official Veterinary Services (OVS) of any sign ofdisease or abnormal mortality in poultry, captive or wild birds.

Work package WP2 – Salmonella control programme 2024

Work Package Number	WP2	**Lead Beneficiary**	1 - MAPA
Work Package Name	Salmonella control programme 2024		
Start Month	1	**End Month**	12

Objectives
Reduction of prevalence of infected flcks bellow EU target

Description
Control programmes in poultry populations of breeding flocks of Gallus gallus and turkeys, laying hens, broilers and fattening turkeys.

Work package WP3 – BSE programme 2024

Work Package Number	WP3	**Lead Beneficiary**	1 - MAPA
Work Package Name	BSE programme 2024		
Start Month	1	**End Month**	12

Objectives
In 2024 the specific objective for the BSE programme is to continue to comply with requirements in order to maintain Spain’s classification as a country with negligible BSE riskstatus, achieved in 2016.

Description
MonitorING OF the epidemiological situation in cattle population in relation to BSE, and to detect the presence of BSE disease and, when necessary, implement the

Associated with document Ref. Ares(2024)510496 - 23/01/2024

appropriate control and eradication measures.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

STAFF EFFORT

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	Total Person-Months
1 - MAPA	1.00	1.00	1.00	3.00
Total Person-Months	1.00	1.00	1.00	3.00

Associated with document Ref. Ares(2024)510496 - 23/01/2024

LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

The labels used mean:

Public — fully open (⚠ automatically posted online)
Sensitive — limited under the conditions of the Grant Agreement
EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	AI_final report	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	12
D1.2	AI_intermediate report	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	8
D2.1	Salmonella_final report	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	12
D2.2	Salmonella_intermediate report	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	8
D3.1	BSE_final report	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	12
D3.2	BSE_intermediate report	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	8

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Deliverable D1.1 – AI_final report

Deliverable Number	D1.1	Lead Beneficiary	1 - MAPA
Deliverable Name	AI_final report		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	12	Work Package No	WP1

Description
Final report

Deliverable D1.2 – AI_intermediate report

Deliverable Number	D1.2	Lead Beneficiary	1 - MAPA
Deliverable Name	AI_intermediate report		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	8	Work Package No	WP1

Description
INTERMEDIATE REPORT 6 FIRST MONTHS

Deliverable D2.1 – Salmonella_final report

Deliverable Number	D2.1	Lead Beneficiary	1 - MAPA
Deliverable Name	Salmonella_final report		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	12	Work Package No	WP2

Description
Final report

Deliverable D2.2 – Salmonella_intermediate report

Deliverable Number	D2.2	Lead Beneficiary	1 - MAPA
Deliverable Name	Salmonella_intermediate report		
Type	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	8	Work Package No	WP2

Description
INTERMEDIATE REPORT 6 FIRST MONTHS

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Deliverable D3.1 – BSE_final report

Deliverable Number	D3.1	**Lead Beneficiary**	1 - MAPA
Deliverable Name	BSE_final report		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	12	**Work Package No**	WP3

Description
Final report

Deliverable D3.2 – BSE_intermediate report

Deliverable Number	D3.2	**Lead Beneficiary**	1 - MAPA
Deliverable Name	BSE_intermediate report		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	8	**Work Package No**	WP3

Description
INTERMEDIATE REPORT FRST 6 MONTHS

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	SIX-MONTHLY TECHNICAL REPORT	WP2, WP3, WP1	1 - MAPA	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.	2
2	FINAL TECHNICAL REPORT	WP2, WP3, WP1	1 - MAPA	Technical monitoring data is collected by at the end so that it is possible to see the evolution at that moment and to correct any deviation if necessary.	12

LIST OF CRITICAL RISKS

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
1	obtain enough samples for passive surveillance (dead birds)	WP1	AWARENESS CAMPAIGNS
2	foreseen in advance the number of farms to be depopulated and the associated compensation in breeding hens	WP2	UPDATE INTHE INTERIM REPORT
3	DETECT ANIMALS WITH COMPATIBLE CLINICAL SIGNS, IF ANY	WP3	AWARENESS CAMPAINGS

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded programme for the surveillance of Avian Influenza in poultry and wild birds for 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))
Avian Influenza surveillance Programme

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation*).

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	**SPAIN**
Disease	**AVIAN INFLUENZA**
Species	**Poultry** ☒ **Wild birds** ☒
Implementation Year	**2024**

CONTACT PERSON on AI programme :

Name	Germán Cáceres Garrido
e-mail	gcaceres@mapa.es
Job type within the CA	Head of epidemiology area

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Avian Influenza Programme – 2024

RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:

- **Commission Delegated Regulation (EU) 2020/689** on 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases **(**OJ L 174, 3.6.2020, p. 211–340)

The main objectives of the programme in Spain are to demonstrate freedom from the disease, and the early detection of the circulation of avian influenza virus, both strains of high and low pathogenicity, by a surveillance system that includes a passive and an active component.

Active surveillance component has the objective of demonstration of freedom and contribute to the early detection of HPAI through the detection of subclinical infections of LPAI of subtypes H5 and H7 that can easily spread between poultry flocks and mutate into HPAI, and the detection of infections with HPAI in species which do not normally show significant clinical signs.

The passive component aims specifically at the early detection though contributing to the reporting and immediate investigation by the Official Veterinary Services (OVS) of any sign of disease or abnormal mortality in poultry, captive or wild birds.

(maximum 200 characters)

1.2 Needs and specific objectives

Please give a short description of the programme and in particular how the Objectives for surveillance in poultry and wild birds were met (e.g. please provide a short description of the designed surveillance and indicators to meet each of the objective)

1. Early detection of highly pathogenic avian influenza (HPAI) in poultry.
2. Early detection of HPAI in wild birds providing for:
   (a) an early warning for possible HPAI introduction into poultry, in particular when viruses enter the Union through migratory movements of wild birds;
   (b) information for the assessment of risks for virus spread following findings of HPAI in wild birds.
3. Detection of HPAI in poultry species which generally do not show significant clinical signs.
4. Detection of circulating low pathogenic avian influenza viruses (LPAIV) that may easily spread between poultry flocks in particular in areas with a high density of poultry establishments in view of their potential to mutate to HPAI in order to:
   (a) identify clusters of infection with LPAIV; and
   (b) monitor the risk of spread of LPAIV by movements of poultry and by fomites in certain production systems at risk.
5. Contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk.

1) Early detection of highly pathogenic avian influenza (HPAI) in poultry is based in passive surveillance, with reporting and immediate investigation by the Official Veterinary Services of any sign of disease or abnormal mortality in domestic birds. The monitoring of production parameters (e.g. increased mortality, decreased feed and water consumption, presence of clinical signs suggestive of respiratory disease or reduced laying).

It will be always implemented throughout the national territory and, being reinforced in those places and at those periods where/when the risk is higher in accordance with the same risk assessment systems established for the active surveillance component.

2) Early detection of HPAI in wild birds. It will be always implemented throughout the national territory and, being reinforced in those places and at those periods where/when the risk is higher in accordance with the same risk assessment systems established and described for the active surveillance component.

This information is integrated in the risk analysis model, in order to create weekly reports, with a risk evaluation per district, that are available for the CA for the decision-making process.

3) Detection of HPAI in poultry species which generally do not show significant clinical signs The active surveillance component, includes the sampling in the following categories: ducks (fattening and breeders), geese (fattening and breeders), quails and poultry of the order Anseriformes species for supplying game, based on our risk-based surveillance system, especially in high-risk periods.

4) Detection of circulating low pathogenic avian influenza viruses (LPAIV): The active surveillance component, includes the sampling in laying hen, free range laying hens, turkeys for fattening and breeding and poultry of Galliformes species for supplying game. The sampling, when possible, shall apply to poultry establishments for which the competent authority has assessed the repeated occurrence of aggregations (either in time or space) in the past or in which the occurrence is more likely, based on our risk-based surveillance system and in high-risk periods.

5) Contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk: Within the Wildlife Surveillance Program, samples will be taken from wild carnivores (especially foxes and wolves) in those cases of mortality or presence of clinical signs compatible with HPAI, particularly in areas and periods where there is a risk of transmission of the disease because of circulation in wild birds.

In American mink farms, samples shall be taken in case of abnormal mortalities, as well as in case there is presence of any respiratory, neurological or any other symptomatology that may be compatible with HPAI, especially in those areas and periods in which there is a risk of HPAI transmission because of circulation in wild birds.

In domestic swine farms, a follow-up will be established in case that for clinical or epidemiological reasons there is a suspicion of infection of animals with HPAI virus, particularly in those areas and periods in which there is a special risk of HPAI transmission.

(maximum 500 characters)

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?

The surveillance programme has been updated and modified, according to the regulatory requirements of the new animal health law which came into force in April 2021, and its subsequent modifications, and, according to the results obtained and their subsequent analysis.

The results of this surveillance programme, in particular in wildlife, are useful for other countries in the area to use in their risk analysis of HPAI introduction into their respective territories.

Additionally, the programme has been updated according to the inputs and results obtained from the risk analysis tool (Diflusion modelling tool), so that each year these resources can be optimised more and better.

The modelling tool has been shared with countries that have shown interest about it.

(maximum 500 characters)

1.4 Target population and area of the implementation

Describe areas of the implementation of the programme activities (e.g. passive surveillance; active surveillance (clinical examination of herds; sero-surveillance); vaccination (if implemented). If possible, provide maps in the Annex.

If applicable, explain factors/considerations taken into account when deciding on the surveillance type and area of its implementation; in case of vaccination, explain boundaries and size of the vaccination area.

Describe target animals and animal population size both for poultry and wild birds (species, number of holdings or herds or establishment as appropriate and animals) - Fill in **Table 1** (as appropriate) **in the Annex** to this Form.

Passive surveillance component

The passive component aims at the early detection through reporting and immediate investigation by the Official Veterinary Services (OVS) of any sign of disease or abnormal mortality in domestic birds. It must be always implemented throughout the national territory and, being reinforced in those places and at those periods where/when the risk is higher in accordance with the same risk assessment systems established and described for the active surveillance component. This information must be reported by vets and/or farmers attending the holding.

Active surveillance component: In accordance with Annex II to Commission Delegated Regulation (EU) 2020/689 of 17 December 2019, establishments shall be selected based on risk criteria according to the following principles:

Firstly, the total number of holdings foreseen for Spain is distributed among the 17 Autonomous Communities proportionally to the number of poultry holdings in each of them for each category of poultry covered by the programme, so that the sampling is representative throughout the territory.

To select establishments for targeted surveillance the CA must consider the risk of horizontal transmission of the virus due to the structure and complexity of the production system as well as movements between farms, in particular where there is a high density of farms in the area. Specific consideration shall be given to the following risk factors at the level of the establishment:

(a) The species present on the establishment;

(b) The production cycle and duration of production;

(c) The presence of different poultry species;

(d) The presence of poultry flocks of different ages;

(e) The presence of long-lived poultry;

(f) The practice of all-in-all-out;

(g) The length of the waiting period between flocks; and

(h) Biosecurity practices and poultry housing conditions.

In order to make the selection of holdings to be sampled on the basis of risk, in addition to the criteria mentioned above, the OVS shall take into account when selecting holdings the outcome of two complementary risk assessments carried out at national level:

- On the one hand, sampling shall be primarily directed, in the case of holdings with an open-air production system, towards holdings located in municipalities included in the special risk areas and special surveillance zones established for each Autonomous Community in Annexes II and III of Order APA/782/2022 of 5 August amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza. Map 1 in annex IV shows the municipalities included in the 'special risk areas (Annex II) and the municipalities included in the 'special surveillance zones' (Annex III) of the mentioned Order.

- On the other hand, and complementarily, the selection of holdings shall be based on the outputs of the risk assessment tool/model, Diflusion, developed and used by MAPA in collaboration with the National Institute for Agricultural and Food Research and Technology in the MAPA-INIA 2019 Management Assignment. The number of holdings assigned to each Autonomous Community will be selected considering the level of regional risk, so that sampling will be more intense in the regions with higher risk compared to those with lower risk. Diflusion is based on a multi-criteria decision analysis tool -TOPSIS (Technique for Order Performance by Similarity to Ideal Solution). This tool allows the identification of livestock districts with a higher risk of HPAI introduction based on six parameters:

- The census of wild waterfowl in national wetlands, counting annual count data (according to 2007 and 2013 data from the Spanish Ornithological Society) of waterfowl of 42 species considered at risk for the introduction of HPAI in Spain.
- HPAI outbreaks in Europe and migratory bird movements, retrospectively determining possible HPAI entry alerts due to the migratory movement of the 42 wild bird species selected as at risk for the introduction of influenza into Spain, from areas where HPAI outbreaks were reported in Europe in 20 years.
- Survival of the virus, evaluating the days of survival based on monthly temperatures from 2,216 national weather stations requested from the Spanish Meteorological Agency (AEMET). In the case of the risk analysis, the maximum number of days that the virus can survive at the minimum temperature between November and April were included.
- The density of poultry holdings based on data extracted from SITRAN.
- INTRA (incoming) commercial movements of poultry with EU.
- Domestic poultry movements..

The map resulting from weighting the parameters following the comparison technique and including these weightings in the TOPSIS method is included in the map below, categorising the Spanish livestock districts according to the level of risk in 5 categories. Map 2 is provided in Annex IV.

Vaccination

At present, vaccination of domestic birds is not authorised in Spain.

However, there is a Vaccination Plan for zoos, which details the requirements and subsequent surveillance for vaccinating this type of establishments, given their singularity and risk: Plan de vacunación preventiva frente a la Influenza aviar en núcleos zoológicos

Target animals and animal population

- Poultry

For the purpose of the active surveillance, the following types or categories of poultry holdings are considered:

- Laying hens, free-range laying hens, breeding turkeys, fattening turkeys, poultry of Galliformes species for the supply of game birds to be released into the wild, for the detection of sub-clinical infections of Low Pathogenic Avian Influenza subtypes H5 and H7.

- Breeding ducks, breeding geese, fattening ducks, fattening geese, poultry of species of the order Anseriformes for supplying game birds to be released into the wild and quail, for the detection of HPAI or LPAI in poultry species that normally do not show significant clinical signs.

However, although not included a specific category in the programme, the following categories of poultry may also be sampled in exceptional circumstances:

a) Broilers, if they are kept in significant numbers, in extensive conditions, or are considered to be at higher risk of becoming infected with avian influenza.

b) Backyard poultry, only when the risk assessment justifies its inclusion.

c) Others, only when justified by risk assessment.

Regarding the last data poultry population, the avian census in Spain is 346.5 million animals (in January 2023). According to SITRAN, most of this census, up to a total of 329,31 million birds, corresponds to the species Gallus gallus (mainly for meat production). The spatial distribution therefore can be considered as the territorial distribution of the total number of breeding birds, with Galicia, Castilla La Mancha, Aragon, Castilla y León and Catalonia standing out regarding census.

For turkey production, the national census is 16.5 million heads, with Galicia, Andalusia and Catalonia, and to a lesser extent the Levante area, being the main producers and where the census is predominantly present.

In duck production, there are 676.000 birds. There are two different productions, in the north (Navarre, Aragon and Catalonia) the production is mainly linked to the production of foie, while the production in the central area, which is also important, is more closely linked to the production of duck meat.

A report with maps and figures is provided in the Annex.

- Wild birds

The system should focus on wild birds, especially migratory waterfowl and specifically those having shown a higher risk of infection and therefore having the capacity to transmit the highly pathogenic avian influenza virus, known as 'target species' (EFSA-G-2017-00649 report) and in addition target species that have a higher risk in Spain according to their census, migratory routes studies and last year's declarations.

Every year, Spain hosts more than 1.500.000 winter migratory water birds.

According to the number of species and census of wintering water birds obtained from the Spanish Ornithological Society (SEO, 2013-2019), the higher risk areas in Spain are:

- Doñana: with 360 species of birds, from which 127 reproduce habitually in the Park. Doñana receives over 500.000 wintering waterfowl each year and is on the migration path of over 6 million birds (including storks, seagulls among others).
- Delta del Ebro: is home to 27.000 pairs of nesting waterfowl. It receives between 250000 and 300.000 wintering birds each year, including more than 85 water bird species and represents a zone of moulting, feeding and resting during seasonal migrations.
- Ampordan Aigüamolls: It receives 15.000-20.000 wintering aquatic birds every year and has an important biodiversity with more than 60 water birds species.
- Albufera de Valencia: It receives 80.000 wintering birds each year, including more than 60 water bird species highlighting anatidae, coots, and gulls.

More information available in SEO Website: https://seo.org/resultados-seguimiento-de-aves/

and in MAPA Website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/informeanalisisderiesgo2019cisaia_tcm30-449218.pdf

1.5 Epidemiological situation

Describe the current epidemiological situation, mention risks/factors which may contribute disease introduction and spread; indicate likelihood for disease introduction and spread from the neighbouring countries.

Provide results of disease surveillance over the last five years for both poultry and wild birds - Fill in **Table 2** (as appropriate) **in the Annex** to this Form.

POULTRY

During the years 2018-2021, no outbreak of highly pathogenic avian influenza was detected in avian farms in Spain.

On January 18, 2022, the Central Veterinary Laboratory of Algete confirmed the detection of the highly pathogenic avian influenza virus H5N1 in a broiler turkey farm located in the livestock region of Cantalejo, province of Segovia. Throughout 2022, 37 outbreaks have been reported in domestic birds: 30 in Andalusia, 3 in Castilla y León, 2 in Castilla-La Mancha and 1 in Extremadura. All the cases were subtyped as H5N1. In 2023 until the end of May, only one H5N1 case has been reported in a broiler turkey farm in the province of Lleida.

The greatest risk for the introduction of HPAI in poultry is the direct or indirect contact with infected wild birds, particularly during the high risk period, therefore biosecurity measures are established in the special surveillance zones and special risk areas according to national Order 2442/2006, and at certain times of the year additional measures are activated (such as confinement of animals, or prohibit concentrations) when the risk is determined as high to prevent the introduction of the disease.

CAPTIVE BIRDS

During the years 2018-2021 no outbreak of highly pathogenic avian influenza was detected in captive birds. Three cases have been detected in captive birds in 2022.

A voluntary preventive vaccination programme in zoos has been established in zoos because of their specificities and singularity.

WILD BIRDS

During the years 2018 and 2019, the disease was not detected in wild birds in Spain.

In the 2020-2021 season, 3 outbreaks of HPAI H5N8 were detected in wild birds in Cantabria (a peregrine falcon in the Natural Park of the Marshes of Santoña, Victoria and Joye), Girona (3 storks and a goose in the Natural Park dels Aiguamolls de l'Empordà) and Zamora (a common goose in the Laguna Grande de Villafáfila).

During the year 2022, a total of 149 outbreaks have been reported in wild birds and 3 in captive birds. In total, at least 29 different species have been affected, being the most represented, Atlantic gannets (35.84%), white storks (13.29%) and geese (12.14%). As for its location, 14 Autonomous Communities have confirmed positives in the Central Veterinary Laboratory of Algete (Andalusia, Aragón, Asturias. Cantabria, Castilla La Mancha, Castilla y León, Cataluña, Extremadura, Galicia; La Rioja, Madrid, Murcia, Navarra and País Vasco).

In 2023, until May 15, a total of 19 outbreaks are counted, 6 in Aragon, 5 in Catalonia, 4 in the Basque Country, 2 in Castilla y León, 1 in Castilla-La Mancha and 1 in Galicia.

The major risk of incursion is the migration routes of wild birds from Northern and Central Europe to Spain, but in 2022 and endemic pattern was also shown during summer.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes / impact. They have to be adapted to disease situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Disease surveillance

Describe disease surveillance (e.g. active (clinical examination of herds; sero-surveillance); passive). For each type of surveillance to be implemented describe: calculations of targets (per risk area if applicable), criteria to include a holding (or herd) and an animal in active surveillance; how holdings will be selected; frequency and timeline of the implementation of clinical examinations (including interval between visits); sampling scheme / sampling strategy, type of samples, who performs clinical examination and sampling; documented procedures for clinical examination, sampling, collection and delivery of samples.

Describe case definition.

POULTRY ACTIVE SURVEILLANCE

In the framework of active poultry surveillance, the number of holdings of each category present in each Autonomous Community is collected. Based on the total, the number of holdings corresponding to each territory is calculated in such a way as to guarantee the detection of at least one infected holding, assuming a minimum prevalence of 5% with a confidence interval of 95% (in poultry except geese and ducks) and with a confidence interval of 99% for the latter.

Holdings to be sampled are selected within each Autonomous Community based on a risk-based prioritisation systems including three complementary elements:

- Prioritisation of poultry holdings located in municipalities included in special risk areas and special surveillance zones defined in Spain through Order APA/782/2022 of 5 August amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza;

- Prioritisation of holdings located in higher-risk livestock districts characterised through a risk analysis model based on the TOPSIS method

- Prioritisation based on the criteria included in Annex II of Commission Delegated Regulation (EU) 2020/689 of 17 December 2019.

The place of sampling will be the holding, and each holding selected is sampled once a year. The sampling is performed by official or authorised vets.

The sampling procedure: For active surveillance, random serum and blood samples shall be collected depending on production categories and species from a total of 5-10 birds per poultry holding (except ducks, geese and quails and Anseriformes where 20 samples per holding are taken). In case of several sheds, samples shall be taken from at least five birds per shed. Accordingly, 20 samples shall be taken from laying and breeding hens if there is more than one shed on each holding.

Sampling shall be carried out preferably in adult animals, avoiding sampling in new-born animals or animals recently introduced in the holding.

Virological sampling shall not be used as an alternative to serological sampling, except in the case of farmed game birds where serological sampling is not possible, and except in species which generally do not show significant clinical signs.

Sampling shall be carried out between 1 January and 31 December 2024. The sampling period shall be adapted to the seasonality of production. It is recommended the use of samples collected for other purposes, in order to increase the efficiency of the economic and human effort made. It may also be adapted to other types of periodicities identified at local level that may imply a higher risk. Consideration shall also be given to targeting sampling to the periods of highest risk of virus circulation, which are usually between October and April.

POULTRY PASSIVE SURVEILLANCE

Once a suspicion is notified to the official veterinary services and in compliance with the national contingency plan (practical operational manual) for avian influenza, official vets from the competent animal health authorities of the Autonomous Community involved shall assess the risk, visit as soon as possible the farm and take the following action:

a) Clinical examination of the animals, necropsy and epidemiological survey.

b) Collection of official samples and send them to the official laboratory

c) Census of all animals including dead on the farm

d) Communication to the owner of the conditions of immobilisation

e) Official communication of the suspicion

Depending on the results of the tests carried out in the official labs, the steps laid down in the Manual for Avian Influenza shall be followed. Documents and sampling procedures are state in the manual: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022_tcm30-437988.pdf

WILD

Wild passive surveillance is based on virological sampling, hence there is the need for cloacal and tracheal or oropharyngeal swabs and/or tissue samples (brain, heart, lungs, trachea, kidney and intestines). The passive-surveillance component is based on the timely notification and laboratory sampling of dead or dying birds found and should focus specifically on waterfowl.

Sampling shall take place between 1 January and 31 December of each year and results shall be communicated every six months via the RASVE website. All results (serological and virological) obtained by authorised regional laboratories shall be reported to the Sub-Directorate General for Animal Health and Hygiene and Traceability, which shall then forward them to the European Commission.

The case definition is established according to Annex I of Regulation 689/2020.

An animal or a group of animals must be considered, by the competent authority, as a confirmed case of HPAI when:

(a) the disease agent responsible for HPAI, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;

(b) nucleic acid specific to the disease agent for HPAI, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or

(c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.

For the purposes of this case definition, the disease agent responsible for HPAI must be either:

(a) an influenza A virus of H5 and H7 subtypes or any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1,2; or

(b) an influenza A virus of H5 and H7 subtypes with a sequence of multiple basic amino acids present at the cleavage site of the haemagglutinin molecule (HA0) that is similar to that observed for other HPAI isolates.

Case of LPAI: any influenza A virus of H5 and H7 subtypes that are not HPAI viruses.

2.1.2 Laboratory testing

Describe tests and testing schemes/hierarchy used; in particular explain the testing scheme.

Mention testing laboratories and tests they perform.
Describe assurance of the quality of the results produced by these laboratories (it is sufficient to indicate laboratory quality assurance schemes in place).

Fill in **Table 1** (as appropriate) **in the Annex** to this Form.

The analysis of the samples shall comply with the following conditions:

(a) The analysis of the samples shall be carried out by laboratories designated by the corresponding Autonomous Communities, working under the control of the National Reference Laboratory (NRL). The NRL shall provide the necessary technical support and reference materials to the official regional laboratories, and organize periodically Proficiency Test (PT) for the control and harmonization of ELISA and RT-PCR diagnostic methods. All the designated laboratories are accredited according ISO17025 or work under quality assurance

system including participation in the PT organized by NRL. All the AIV diagnostic techniques employed by the NRL are accredited according ISO 17025

(b) The analysis of samples shall comply with Annex II Delegated Regulation 689/2020.

(c) Samples collected in the framework of the targeted surveillance plan for LPAI and supplementary surveillance for HPAI in poultry species not normally showing significant clinical signs shall be subjected to laboratory testing by serological (ELISA for antibodies detection against Influenza A virus) or virological (M gene RT-PCR) methods in the authorised laboratories .

(e) In case of ELISA or M gene RT-PCR positive results, samples must be sent to National Reference Laboratory to be analyzed by Hemaglutinin H5/H7 Inhibition test in the case of serum samples, or specific RT-PCRs (H5, H7, H9, N1, N5, N8) in the case of swab/tissue samples, using the procedures recommended by AIV EURL. In case of positive H5, H7 serological results, further samples (at least 20 serological and 20 virological tracheal and cloacal swaps samples or tissues from at least 5 sick or dead birds) shall be taken and submitted to the National Reference Laboratory for virological analysis by M gene and specific PCR (H5, H7, H9, N1, N5, N8), sequencing for pathotyping, chick embryo inoculation, etc.

(d) Samples must be subjected to laboratory testing by virological methods (M gene RT-PCR) when taken for the early detection of HPAI in poultry, captive and wild birds, and for the follow-up of seropositive results. In case of M gene RT-PCR positive results, samples must be sent to National Reference Laboratory to be analyzed by specific RT-PCRs (H5, H7, H9, N1, N5, N8). Pooling of similar swab samples from the same anatomical site in domestic animals is considered.

(f) Any positive result (H5, H7) shall be investigated by conducting an epidemiological survey following the guidelines indicated in the National Contingency Plan for the control of AI:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022_tcm30-437988.pdf

(g) All results (serological and virological) obtained by the approved official regional laboratories shall be sent to the Sub-Directorate General for Animal Health and Hygiene and Traceability on a six-monthly basis, using a communication module within RASVE application created for this purpose, who in turn shall send the whole data-set to the European Commission.

(h) The NRL shall forward to the Community Reference Laboratory all avian influenza viruses of H5 or H7 subtypes or other influenza viruses that may pose a significant threat for health, so that a virus repository can be established to allow future developments of diagnostic techniques and molecular epidemiology follow-up.

Tests shall comply with the procedures detailed in the Diagnostic Manual, adapted as appropriate should the CRL so decide. Accordingly, virological tests shall include: M gene and specific RT-PCRs, sequencing for pathotyping, and inoculation of chicken embryos.

Special care shall be taken when storing and transporting samples to prevent their deterioration: among other things, they should be refrigerated and sent to the laboratory immediately. Swabs should be completely immersed in a phosphate-buffer medium (PBM)

with antibiotics or, in the absence of this, in a physiological serum with antibiotics. If no PBM or physiological serum is available, a commercial medium can be used that is specifically designed to transport viruses, but under no circumstances, media designed for bacterial should be used. A commercial medium can be used that is specifically designed to transport viruses, try to avoid the use of inactivating media that prevent virus isolation in case of positive samples.

2.1.3 Measures in case of disease suspicion and confirmation

Describe measures to be implemented in case of disease suspicion and confirmation (detailed references to the provisions of relevant Union legislation to be implemented in case of disease suspicion and confirmation are sufficient).

Spanish Animal Health Law 8/2003, of April 24, establishes in Article 5 that any person, physical or legal, public or private, will be obliged to notify the competent authority, immediately and, in any case, in the manner and within the established deadlines, all the sources of knowledge of diseases of an epizootic nature, as well as of any pathological process that causes the suspicion of being a notifiable disease.

The disease is listed in COMMISSION IMPLEMENTING REGULATION (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system. Furthermore, pursuant to Article 7 of Order APA 2442/2006 of 27 July 2006, all persons, in particular veterinarians, wild bird protection organisations, hunting associations, etc. must immediately report any abnormal deaths, in particular those of waterfowl, to the relevant health authorities.

Once the suspicion is notified to the official veterinary services and in compliance with the national contingency plan (practical operational manual) for avian influenza, official vets from the competent animal health authorities of the Autonomous Community involved shall assess the risk, visit as soon as possible the farm and take the following action:

a) Clinical examination of the animals, necropsy and epidemiological survey.

b) Collection of official samples and send them to the official laboratory

c) Census of all animals including dead on the farm

d) Communication to the owner of the conditions of immobilisation

e) Communication of the suspicion to higher levels

Depending on the results of the tests carried out in the official labs, the steps laid down in the Manual for Avian Influenza shall be followed. If the disease is confirmed in the NRL, it shall be reported immediately to the Sub-Directorate General for Animal Health and Hygiene and Traceability, which shall report the information urgently to the European Commission, and the

following measures laid down in the EU Delegated Regulation 687/2020are immediately adopted:

- Immobilization of the farm since moment of suspicion.
- Epidemiological investigation: movements out/in. Likely source, possible contact with wild birds, presence of lagoons with water wild birds close by.
- Census of animals and risk - products located in the affected farms.
- Stamping out: Culling of animals in the affected farms.
- Disposal of animals, litter and bedding straw (Rendering plant Category I or burial) in the affected farms.
- Zoning: surveillance 10km and protection 3km zones and movement restrictions. Inspection of holdings in the restriction zone.
- Preliminary and final cleaning and disinfection in the affected farms.

All the measures, in case of suspicion and confirmation of AI, are detailed in the specific Manual available in MAPA Website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022_tcm30-437988.pdf

2.1.4 Data collection, management and analysis

Describe surveillance data collection, management and analysis, including spatial analysis (mapping, if any) of activities under both active and passive surveillance (to contribute identify possible gaps in disease surveillance).

All results (serological and virological) obtained by the approved official regional laboratories and the NRL shall be sent to the Sub-Directorate General for Animal Health and Hygiene and Traceability on a six-monthly basis, using a communication module within RASVE application created for this purpose. From the Sub-Directorate General for Animal Health and Hygiene and Traceability, the reported data are analysed and verified. Once the information has been verified, a report is carried out that will collect the results of the program implemented during the last year.

These results are presented and analysed once a year in Rasve Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme. The results of the program are also shared with the national sector associations in a specific meeting after the results are endorsed by the Rasve Committee.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians other stakeholders as relevant) involved in the planning and

implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

According to the Spanish Legal framework, the Autonomous Communities are the competent authority for the implementation of the program, while the National Government has the competence to establish the bases and national coordination in animal health.

The Animal Health Services of each Autonomous Community are responsible then for implementation of the AI programme in their respective regions.

The NRL for Avian Influenza (Central Veterinary Laboratory in Algete), is under the Directorate General for Health in Primary Production of the Ministry of Agriculture, Fisheries and Food; and the Sub-Directorate General for Animal Health and Hygiene and Traceability (also under the same DG) is the authority in charge of the supervision and coordination of the activities carried out by the Autonomous Communities.

In the case of wild birds, the Competent Authorities also require the collaboration of the natural environment and hunting authorities, which will receive the necessary information on the epidemiological situation of the disease, particularly in those cases that present a higher risk of introduction and spread of the avian influenza virus in Spain. The central competent natural environment and hunting authorities and the Autonomous Communities will in turn pass this information on to hunting and ornithology organisations and wild birds recue centres. Samples taken from dead or sick birds will be forwarded to the corresponding Animal Health Laboratories of the respective Autonomous Communities via the Official Veterinary Services or via the departments responsible for the natural environment, depending on the distribution of responsibilities in each Autonomous Community.

Avian influenza is included in the list of notifiable diseases according to COMMISSION IMPLEMENTING REGULATION (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system, and under Article 5 of Law 8/2003, national Animal Health Act, all natural or legal persons, public or private — thus including official or private veterinarians, livestock farmers, hunters, environmental health officers, laboratories, etc. — must duly inform the competent authority of any suspicion of diseases contained in the list of notifiable diseases.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned

controls and verifications, and monitoring of the achievement of targets (activity[1] indicators) - please describe for different programme activities; mention frequency of such controls. *What enforcement mechanisms will be initiated in case of failure of reaching the planned targets / to ensure continuous improvement.* *Describe the evaluation of the progress[2] indicators (quantitative or qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.*
National surveillance programme for each year is elaborated by MAPA in coordination with the 17 Autonomous Regions OVS. Surveillance results are collected every six months (in July for the first semester, and in January for the second semester), that are analysed together with the CAs of the Autonomous Regions in the framework of the monthly animal health coordination meeting in the frame of the Rasve Committee. In case targets are not met, there is an indicator, the number of samples or the number of holding to be taken/visited that if is not achieved, the reason is analysed, to try to find a solution (for example select and replace with inclusion of additional holdings). The number of holdings per category to prepare the programme for next year is decided one year in advance, and there could be some differences between the farms active when deciding and the farms active at the moment of sampling. As mentioned, the overall results of the programmes are analysed with the CAs of the Autonomous Regions (in April/May) and with the affected sector once a year (in May/June).

2.4 Risk management

Critical risks and risk management strategy *Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.* *Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.* ***Note:** Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*		
Risk No	Description	Proposed risk-mitigation measures

[1] Example of activity indictors: number of holdings checked; number of animals samples; number of samples tested, etc.

[2] Example of progress indicators: number of samples tested under passive surveillance higher than the last year, indicating higher likelihood of early detection of possible introduction of disease (new disease outbreaks).

1	**Unexpected problem in certain region, that may not have enough human/financial resources because of other priorities such as disease circulation any Cat A disease . Medium risk.**	**Try to find financial and human support.** **If no possible, try to derive the affected sampling to the closest region or Autonomous Community to carry out the sampling to comply with national targets.**
2	**Lack of reporting of suspicions, inefficient passive surveillance. Low risk.**	**Continuous training and awareness campaigns aimed at the sector (farmers) and private veterinarians.** **Transparent and constant risk-communication, update epidemiological situation reports.** **Maintain regular meetings with the sector**
3	**Maintenance of disease in a certain area out of the high risk periods. High risk.**	**Immediately inform the Autonomous Regions so that surveillance can be increased in these periods not foreseen in the programme.** **Activate biosecurity measures of the national Order if needed.**

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Six-monthly technical report	July 2024	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.
Six-monthly technical report	January 2025	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.

Annual report meeting with the regional authorities	April/May 2025	A report is presented and analysed once a year in Rasve Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme.
Annual report meeting with the sector	May/June 2025	A report is presented and analysed once a year with the sector in May/June of the following year, in order to identify the gaps detected and to try to fix them for the following programme.

3. IMPACT

3.1 Impact and ambition

*Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view).*

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

***Possible examples**: increased likelihood of early detection and response in case of disease occurrence, contributes decrease in preventable losses in animal production and loses due to trade restrictions.*

The surveillance programme has a direct impact on the early detection of HPAI:

- Passive surveillance is identified as a key tool to detect HPAI in poultry, captive birds and wild birds.

- Active surveillance is established as a very good tool for the detection of HPAI in species that do not show clinical symptomatology.

- Active surveillance is established as a very good tool for the detection of LPAI.

Furthermore, as it has an impact on early detection, the economic impact is also considered very important for the CA and the sector, as the consequences of a lack of early detection could lead to a further spread of the virus in farms, and so a bigger and more complicated outbreak, which would consequently imply:

- Increase number of farms affected with increased birds to be culled and carcasses and risk-products disposed.

- Increased budget and personal needed for outbreak management

- Increased number of farms immobilised in Restriction Zones and increase farms subject to preventive empty of birds that are sent to the SH before slaughtering weight.

- Increased export problems and restrictions by thirds countries.

- Greater number of businesses and families affected for a longer period of time.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

Information in the EU on funding for both national programmes and emergencies is available at the following link:

https://www.mapa.gob.es/es/ganaderia/legislacion/legislacion_sanidad_animal.aspx

Likewise, all information on HPAI, epidemiological situation, surveillance programme, measures, etc., is available at the following link:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/influenza-aviar/influenza_aviar.aspx

All relevant epidemiological information and events is constantly updated in the Website and also sent via mail to the CA of the regions, and stakeholders involved with an established list of contact emails of: Regional OVS; Other central Ministries units, Poultry production and hunter associations, Environmental police (SEPRONA))

Publication of event reports in the website (RASVE News): https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/default.aspx

Regularly updated report on avian influenza situation in the world with special emphasis on EU and Spain: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/informeia_2022-05-18_tcm30-584890.pdf

Wild bird's surveillance guide included in the evet reports to enhance passive surveillance in wild populations: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/guiavigilanciasanitariafaunasilvestre_tcm30-511596.PDF

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?
It is considered necessary to maintain HPAI surveillance efforts, both passive and active, to ensure early detection of the disease. HPAI is an endemic disease that persists in wild birds and usually occurs in episodes on a cyclical basis, so it is essential to maintain this surveillance programme on a long-term basis. The resources needed will depend on the epidemiological situation of the disease in each season, as the sampling effort (especially in passive surveillance) is directly related to the disease circulation.

ANNEX

I. **Baseline population data and Targets for 2024**
II. **History of disease occurrence**
III. **Implementation of applicable rules and regulation**
IV. **Maps (as relevant)**

I. Baseline population data and targets for 2024

Table 1a: Poultry holdings[3] (except ducs, geese and farmed game birds (waterfowl eg. Mallards) to be samples (insert as appropriate for the programme)

In the column "Total number of samples", please put 0 if the same samples have already been counted for another laboratory analysis (example : for HI-H5 and HI –H7 test, only 1 sample should be counted)

Laying hens

Number	Region (NUTS-2)[4]	Total number of holdings[5]	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis[6]
Holding	SPAIN	1.036	60	20	1.200	1.200	ELISA
	SPAIN	0	0	0	0	100	HI-TEST (H5)
	SPAIN	0	0	0	0	50	HI-TEST (H7)
	SPAIN	0	0	0	100	20	PCR TEST
	TOTAL	1.036	60	20	1.300	1.370	

[3] Holdings or herds or flocks or establishments as appropriate.
[4] Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested
[5] Total number of holdings of one category of poultry in concerned NUTS 2 region.
[6] Please choose between: **ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test**

Free range laying hens

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	721	60	10	600	600	ELISA
	SPAIN	0	0	0	0	60	HI-TEST (H5)
	SPAIN	0	0	0	0	30	HI-TEST (H7)
	SPAIN	0	0	0	60	12	PCR TEST
	TOTAL	721	60	10	660	702	

Turkey breeders

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	14	14	10	140	140	ELISA
	SPAIN	0	0	0	0	30	HI-TEST (H5)
	SPAIN	0	0	0	0	15	HI-TEST (H7)
	SPAIN	0	0	0	30	6	PCR TEST
	TOTAL	14	14	10	170	191	

Fattening turkeys

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	733	60	10	600	600	ELISA
	SPAIN	0	0	0	0	100	HI-TEST (H5)
	SPAIN	0	0	0	0	50	HI-TEST (H7)
	SPAIN	0	0	0	100	20	PCR TEST
	TOTAL	733	60	10	700	770	

Farmed game birds (gallinaceous)

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	309	60	10	600	600	ELISA
	SPAIN	0	0	0	0	200	HI-TEST (H5)
	SPAIN	0	0	0	0	100	HI-TEST (H7)
	SPAIN	0	0	0	200	40	PCR TEST

	TOTAL	309	60	10	800	940	

Farmed game (waterfowl)

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	79	42	20	840	840	ELISA
	SPAIN	0	0	0	0	300	HI-TEST (H5)
	SPAIN	0	0	0	0	150	HI-TEST (H7)
	SPAIN	0	0	0	150	30	PCR TEST
	SPAIN	0	0	0	0	3	Virus isolation test
	TOTAL	79	42	20	990	1.323	

Other please specify here: quails

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	118	53	20	1.060	1.060	ELISA

	SPAIN	0	0	0	0	400	HI-TEST (H5)
	SPAIN	0	0	0	0	200	HI-TEST (H7)
	SPAIN	0	0	0	400	80	PCR TEST
	TOTAL	118	53	20	1.460	1.740	

Ratites

No representation

Broilers (only when at risk)

No representation

Backyard flocks

No representation

Chicken breeders

No representation

Totals	Total number of tests	Total number of samples
Total poultry 2024	7.036	6.080

Table 1b: DUCKS, GEESE AND FARMED GAME BIRDS (WATERFOWL eg. MALLARD) HOLDING[7] to be sampled

(insert as appropriate for the programme)

In the column "Total number of samples", please put 0 if the same samples have already been counted for another laboratory analysis (example : for HI-H5 and HI –H7 test, only 1 sample should be counted)

Duck breeders

Number	Region (NUTS-2)[8]	Total number of holdings[9]	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis[10]
Holding	SPAIN	9	9	20	180	180	ELISA
	SPAIN	0	0	0	0	50	HI-TEST (H5)
	SPAIN	0	0	0	0	25	HI-TEST (H7)
	SPAIN	0	0	0	50	10	PCR TEST
	TOTAL	9	9	20	230	265	

[7] Holdings or herds or flocks or establishments as appropriate.
[8] Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested
[9] Total number of holdings of one category of poultry in concerned NUTS 2 region.
[10] Please choose between: **ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test**

Fattening ducks

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	64	59	20	1180	1180	ELISA
	SPAIN	0	0	0	0	400	HI-TEST (H5)
	SPAIN	0	0	0	0	200	HI-TEST (H7)
	SPAIN	0	0	0	200	40	PCR TEST
	SPAIN	0	0	0	0	3	Virus isolation test
	TOTAL	64	59	20	1.380	1.823	

Geese breeders

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	5	20	100	100	100	ELISA
	SPAIN	0	0	0	0	50	HI-TEST (H5)
	SPAIN	0	0	0	0	25	HI-TEST (H7)

	SPAIN	0	0	0	50	10	PCR TEST
	TOTAL	5	20	100	150	185	

Fattening geese

Number	Region (NUTS-2)	Total number of holdings	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis
Holding	SPAIN	27	27	20	540	540	ELISA
	SPAIN	0	0	0	0	200	HI-TEST (H5)
	SPAIN	0	0	0	0	100	HI-TEST (H7)
	SPAIN	0	0	0	200	40	PCR TEST
	TOTAL	27	27	20	740	880	

Totals	Total number of tests	Total number of samples
Total ducks and geese and farmed game birds 2024	3.153	2.500

TOTALS for Poultry (Table 1a) & Ducks and Geese (Table 1b) and farmed game birds for year: 2024

Poultry & Ducks/Geese/farmed game birds	Total number of tests
Grand Total	11.385
Grand Total ELISA	7.040
Grant Total agar	0
Grand Total HI tests (H5)	1.890
Grant Total HI tests (H7)	915
Grant Total Virus Isolation test	6
Grant Total PCR test	308
Grant Total Sampling	8.580

Table 1c: WILD BIRDS focussed on target species

Targets for year: 2024

Region (NUTS-2)[11]	Total number of wild birds to be sampled	Estimated total number of wild birds to be sampled for passive surveillance	Type of test[12]	Number of tests
Spain	3.000	3.000	PCR	6.000
Spain	0	0	VIRUS ISOLATION TEST	100
(add row if necessary)				
TOTAL	3.000	3.000		6.100

	Total number of tests
Total number of tests	**6.100**
Total Virus isolation tests	**100**
Total PCR tests	**6.000**
Total Other tests	**0**

[11] Refers to the place of collection of birds/samples. In case NUTS 2 (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member State is requested. Please fill-in these values directly in the field.
[12] Please choose between: **Virus isolation test, PCR test, Other please specify here**

Total number of wild birds to be sampled for passive surveillance	**3.000**

II. History of disease outbreaks

Table 2: Poultry and wild birds' outbreaks

Outbreaks				
Year	Poultry (No. holdings)		Wild birds (No. birds)	
	Checked	Positive	Examined	Positive
2023	NO DATA AVAILABLE UNTIL 07.2023	1 (Until may 2023)	NO DATA AVAILABLE UNTIL 07.2023	19 (Until may 2023)
2022	695	37	3.040	149
2021	735	0	1.225	2
2020	668	0	711	1
2019	837	0	1.896	0

III. Implementation of applicable rules and regulation

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE DETECTION AND ELIMINATION OF THE DISEASE)

EU countries

Implementation of applicable regulations - please tick the box as appropriate. In case of deviations, please describe / justify.

1.	**Regulation (EU) 2016/429** of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, pp. 1-208)	**Yes**	*Description of deviation/Justification (when relevant):*
2.	**Commission Delegated Regulation (EU) 2020/687** of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, pp. 64-139).	**Yes**	*Description of deviation/Justification (when relevant):*
3.	**Commission Implementing Regulation (EU) 2020/2002** of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system (OJ L 412, 8.12.2020, pp. 1-28).	**Yes**	*Description of deviation/Justification (when relevant):*
4.	**Commission Implementing Regulation (EU) 2020/690** of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established (OJ L 174, 3.6.2020, pp. 341-344)	**Yes**	*Description of deviation/Justification (when relevant):*
5.	**Commission Delegated Regulation (EU) 2020/689** on 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the	**Yes**	*Description of deviation/Justification (when relevant):*

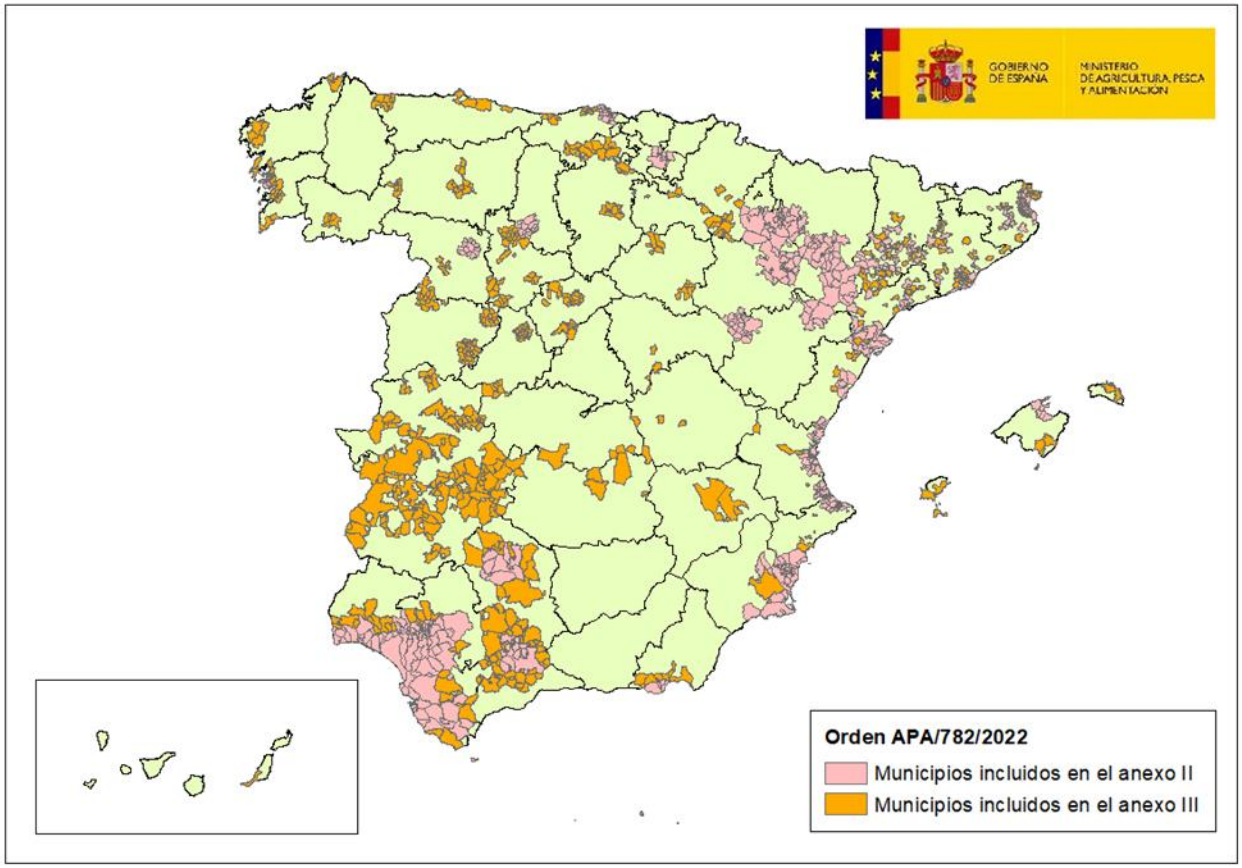
	Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211–340)		

IV. Maps (as relevant)

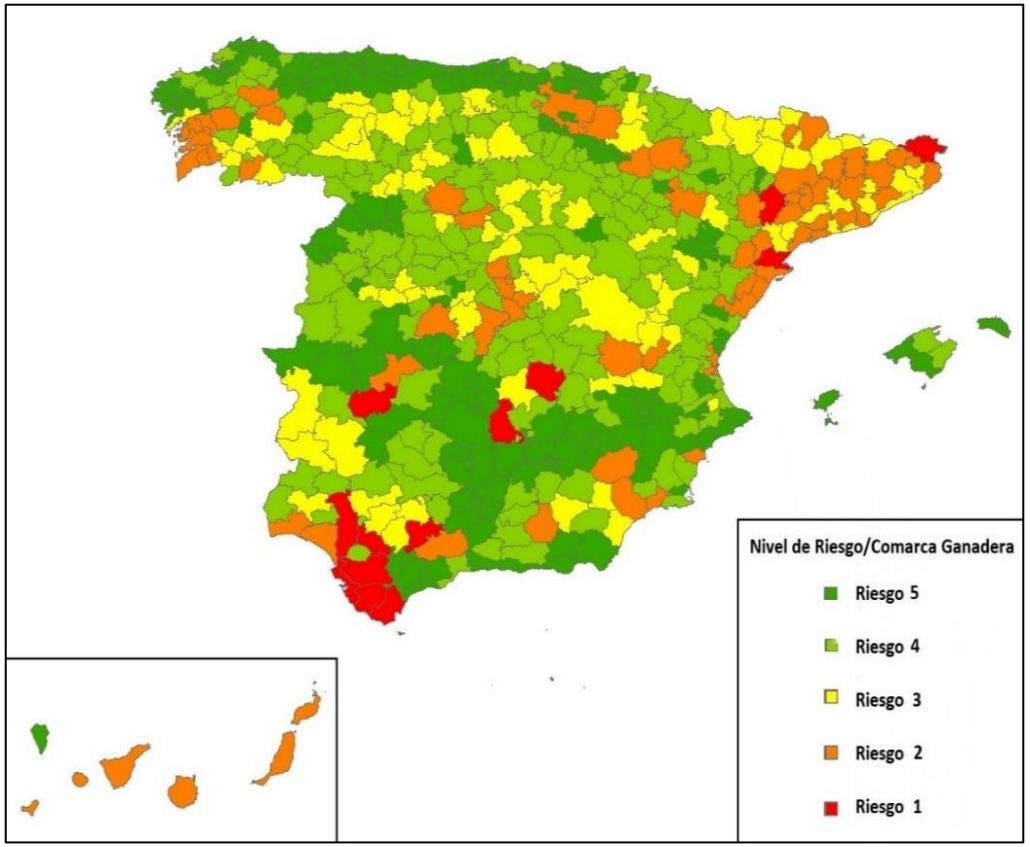
Nº of holdings per types or categories and Autonomous Community. May 2023 -for 2024 IA Program

CCAA	Laying Hens	Free range laying hens	Fattening turkeys	Breeding Turkeys	Farm gallinaceus (game birds)	Quails	Farm game birs Anatidae	Fattening ducks	Breeding ducks	Fattening geese	Breeding geese
Andalucía	74	85	343	4	65	7	42	1	0	1	0
Aragón	25	42	29	0	3	13	0	3	0	0	0
Asturias	5	8	0	0	0	0	0	0	0	0	0
Baleares	3	39	0	0	2	0	0	0	0	0	0
Canarias	188	33	0	0	3	4	0	0	0	0	0
Cantabria	8	13	0	0	1	1	0	0	0	0	0
Castilla La Mancha	194	76	6	0	47	3	0	2	0	0	0
Castilla y León	62	50	30	0	58	11	0	7	2	1	3
Cataluña	159	145	142	10	39	68	0	25	3	16	0
Extremadura	5	16	24	0	35	5	0	0	0	2	0
Galicia	187	79	63	0	8	0	0	2	0	2	0
Madrid	10	5	0	0	9	1	0	0	0	2	1
Murcia	18	7	17	0	8	0	0	0	0	0	0
Navarra	13	17	0	0	10	0	0	20	2	0	0
País Vasco	14	68	0	0	2	2	0	1	1	0	0
La Rioja	7	2	0	0	3	2	0	0	0	0	1
Valencia	64	36	79	0	16	1	0	3	1	3	0
Ceuta											
Melilla											
TOTAL	***1.036***	***721***	***733***	***14***	***309***	***118***	***42***	***64***	***9***	***27***	***5***

Zones at special risk, updated in 2022 through Orden APA/782/2022*, that modified Order APA/2442/2006, from 27th of July, that provides specific protection measures against avian influenza, and it is shown in the map as follows:*



The map resulting from weighting the parameters following the comparison technique and including these weightings in the TOPSIS method is included in the map below, categorising the Spanish livestock districts according to the level of risk in 5 categories.



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Zoonotic *Salmonella* Programme
Control programme – Reduction of prevalence of *Salmonella* serotypes in Breeding flocks of *Gallus gallus*

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	Spain
Disease	**ZOONOTIC SALMONELLA**
Animal population/Species	**Breeding flocks *Gallus gallus***
Implementation Year	**2024**

CONTACT PERSON on Zoonotic *Salmonella* programme :

Name	Soledad Collado
e-mail	scollado@mapa.es
Job type within the CA	Head of Service of Zoonoses

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Salmonella in Breeding flocks *Gallus gallus* Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Regulation (EU) No 200/2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*,
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes ☒ No ☐

If no, please explain:

(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Yes ☒ No ☐

If no, please explain:

The objective of the National Programme is to control the presence of five serotypes with public health significance: *S*. Enteritidis, *S*.Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, *S*. Virchow and *S*. Hadar in breeding flocks of *Gallus gallus*, and to reduce its prevalence to that targeted by the Community, i.e. to a maximum of 1% in flocks with more than 250 adult birds.

Definition of a positive case

A breeding flock shall be considered positive for the purpose of ascertaining the achievement of the Union target:

a) when the presence of the relevant Salmonella serotypes, other than vaccine strains, has been detected in one or more samples taken from the flock, or

b) when residues of antimicrobials or bacterial growth inhibitors have been detected in the flock.

• A positive breeding flock shall only be counted once regardless of how often the relevant *Salmonella* serotypes have been detected in this flock during the production period or whether the sampling was carried out at the initiative of the food business operator or by the competent authority. However, if sampling during the production period is spread over two calendar years, the result of each year shall be reported separately. In the event that a positive result is detected, and the competent authority decided to perform a confirmatory analysis, the final valid result shall be the result of the said confirmatory analysis.

(maximum 500 words)

For a MS with less than 100 adult breeding flocks of *Gallus gallus* the target is to have no more than one such flock remaining positive for the relevant *Salmonella* serovars per year.

Yes ☒ No ☐

If no, please explain:

Spain has more than 100 adult breeding flocks.

(maximum 500 words)

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other

countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as Salmonella, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies that had the scientific assessment of EFSA for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence.

Therefore, the project is a continuation of the previous programmes for the control of Salmonella annually presented to the EU from the establishment of the objective of reduction of the prevalence, who was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to rise the level of public health and animal health in the EU, that at the same time enable the rational development of the farming sector and provides a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme has an harmonised surveillance, the results are comparable between MSs is based in an EU harmonised system, the results are comparable between MSs, and allow the analysis of the spatial and temporal trend at EU level.

It also has an international dimension, as it boostes the confidence not only of the EU Member States and its consumers but also of Third Countries, who can trust in a solid system which ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and economics, giving benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

This programme will be implemented on all breeding flocks of *Gallus gallus*

Yes ☒ No ☐

If no, please explain on which flocks: ***(maximum 500 words)***

Fill in **Table 1**) **in the Annex** to this Form.

This programme will be implemented on the whole territory of the Member State

Yes ☒ No ☐

If no, please explain:

It will be implemented in all holdings of *Gallus gallus* breeding hens (both adult breeding and rearing hens).

On breeding hen holdings where the producer directly supplies small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer, at least one FBO control should be done per year in all the flocks present in the farm at that moment. The competent authorities of the Autonomous Communities shall take any action required to ensure control and monitoring of salmonellosis with public health significance.

This programme will not be implemented at holdings that produce primary products for own consumption (for private domestic use).

Holdings to which the programme will apply must be authorised and registered by the competent authorities. For the purposes of the programme an epidemiological unit shall be considered to be a breeding flock, defined as all poultry of the same health status kept on the same premises or within the same enclosure; in the case of housed poultry, this includes all birds sharing the same airspace, in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of breeding hens shall be identified individually. To identify the flocks on a holding the REGA code will be used, consisting of a capital letter corresponding to the shed (this letter must be written on the entrance door to the shed) and the date of entry of the birds into that shed, in the format mmyyyy. REGA+ SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mmyyyy).

(maximum 500 words)

1.5 Notification of detection of target *Salmonella* serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ☒ No ☐

If yes, please describe the procedure briefly.

If no, please explain:

Any natural or legal person, especially veterinarians, must notify the competent authorities of any confirmed (or suspected) cases of salmonellosis, regardless of whether or not they are related to measures in the framework of the national programmes for the control of salmonella. To that end, all confirmed or suspected results from samples taken and analysed

by operators outside the framework of the PNCS must be reported in the same way as if they fell within the framework of the PNCS.

When *Salmonella* spp is isolated in samples taken in the course of operator own checks, the laboratories shall serotype them in order to be able to distinguish at least between the serotypes covered by this programme and other *Salmonella* spp serotypes. The laboratory may carry out the serotyping itself or send the samples to another laboratory authorised under the PNCS in accordance with point 12 of this Programme for serotyping. If the serotyping shows positive for one of the serotypes in question or for any other serotype, or if their presence cannot be ruled out, and the initial sample was taken in an own check, it must be reported to the competent authority as soon as possible, and never later than 24 hours after the laboratory or the operator of the holding operator receives the results of the analysis.

As soon as the operator becomes aware of the existence of a positive result, he shall be responsible for taking the appropriate measures, as set out in this programme for cases where any of the Salmonella serotypes covered by the programme are detected. The competent authority may exceptionally carry out a confirmatory analysis if it considers this appropriate.

All the results of own checks must be recorded using the dedicated computer application used by the authorised laboratories to communicate results, without prejudice to the contents of the previous paragraph. To ensure suitable traceability of the samples taken during own checks and official monitoring and in order to ensure suitable computer processing of the sampling data for this programme, the sampled flocks shall be identified as specified in Point 3 of the Programme.

The competent livestock service and health authorities must keep each other suitably informed of the positive results.

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.
Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on S. Enteritidis and S. Typhimurium. During 2004, the monitoring and data collection of Gallus gallus breeding flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents. Since the beginning of the implementation of the *Salmonella* Control Programme in breeding hens until nowadays, the prevalence of *Salmonella* has dropped from 2,3% (2007) to 0,36%

(2022), which corroborates the effectiveness of the programme. The most prevalent salmonellas with importance in public health in 2022 are *S*. Enteritidis and *S*. Infantis, followed by *S*. monophasic Typhimurium, *S*. Typhimurium and *S*. Virchow.

The evolution of the prevalence of Salmonella under control in breeding flocks of *Gallus gallus* is shown in the graph of the evolution of the prevalence 2007-2022 (target serotypes).

In 2022 the most prevalent control serotypes were S. Enteritidis and S. Infantis, followed by S. Typhimurium monophasic, S. Typhimurium and S. Virchow and the prevalence of adult flocks positive to control serotypes (considering official and industry sampling and egg and meat production lines) was 0.36%, thus remaining within the EU target.

The production sector of breeding flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining an extremely high level of biosecurity measures before and after a positive result (as the introduction of birds and incubated eggs Salmonella-free, introduction of feed, keeping strict hygiene practices between flocks, correct training and awareness of all workers, limiting external visits, frequent rodent control, thoroughly cleaning and disinfection techniques and adequate verification analysis, adequate facilities maintenance, by-products and manure management, etc).

Furthermore, the mandatory slaughtering and destruction of the birds and eggs in case of a positive target serotype, with the consequent compensation of the costs, could suppose a technical and financial problem both for the farmer and for the CA, depending on the number and the age of the birds.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the *Salmonella* in Breeding *Gallus gallus* situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.
Yes ☒ No ☐

If yes, please make a short description of the most relevant biosecurity measures applied in order to prevent *Salmonella* contamination of their flock and please quote the document describing them, if any. Also please specify if biosecurity is part of the salmonella programmes or if there is national legislation in place for the implementation of biosecurity.

Specify if there is a national guidance available for the biosecurity measures to be implemented and if this guidance is easily accessible by the FBO's. If no, please describe.
Biosecurity measures are part of the SNCP and there are national rules reinforcing them (Royal Decree 637/2021, establishing basic rules for the management of poultry farms and national Animal Health Law 8/2003, that states general rules related with prevention, control and eradication measures, sector health organisation, authorisation and marketing of animal health and animal feed products, and the fees, inspections and sanctions in case of shortcomings). These rules are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic Salmonella in breeding farms and a general national work guideline for the prevention and control of Salmonella in all poultry populations, published to sum up the legal measures established in the legal provisions. The guidelines and the information of general biosecurity are public and available at the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/ https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx Within all these regulations, it is specified that the holder of the poultry farm must take protected husbandry measures to control the entry or contamination by Salmonella spp in the farm, and in particular that: - the design and maintenance of the farm facilities is adequate. - appropriate rodent control measures are carried out. - adequate washing, cleaning and disinfection measures are carried out in the rearing sheds, production sheds, annexed structures and other structures, production facilities, annexed structures, as well as the material and utensils used in production activities. - adequate measures are adopted to prevent the transmission of Salmonella spp. through drinking water. - appropriate measures are taken to prevent the presence of Salmonella spp in raw materials and feedstuffs. Therefore, without prejudice to the provisions of Royal Decree 637/2021, of July 27, establishing the basic rules for the management of poultry farms, the owner of the farm must take the necessary measures to control the entry or contamination by *Salmonella* spp in the farm, as described in section 14 of the national program. Biosecurity measures will be verified in accordance with a protocol included in the programme for checking biosecurity measures on breeding poultry holdings (see protocol in the programme available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx).

These checks will take place in the course of each of the official inspections provided for on the holdings, at the frequency indicated in the programme. The data gathered in such surveys must be recorded using the MAPA computer application for official inspections, in the 'biosecurity' section.

If, in the course of an inspection, shortcomings in the biosecurity measures are detected, this will be made known to the owner of the holding by means of a report in at least triplicate for the owner of the holding and his legal representative or the person in charge of the animals, setting out all the shortcomings and the deadlines set for them to be remedied.

The veterinary officer shall adopt a proportionate and progressive approach in his work to enforce biosecurity rules and measures.

The competent authority may, if necessary, make use of the measures established in Chapter IV, Title V, of Law 8/2003, the Animal Health Act. This is without prejudice to other measures or penalties which may be adopted in respect of that flock or throughout the holding, depending on the type of shortcoming. The measures to be adopted to prevent health risks depend on the seriousness of the shortcoming and may range from shutting down the holding to the loss of the health authorisation for operating a holding.

The procedure will be followed to check and improve biosecurity measures in the holdings (biosecurity survey included in the programme and available in MAPA's website).

2.1.2 Minimum sampling requirements for food business operators

Samples at the initiative of the FBO must be taken and analysed to test for the target *Salmonella* serovars respecting the following minimum sampling requirements:

a. Rearing flocks: day-old chicks, four-week-old birds, two weeks before moving to laying phase or laying unit
b. Adults breeding flocks: depending if the MS achieved the EU target for more than 2 years

☐ Every second week during the laying period (at the holding and at the hatchery)
☒ Every three weeks during the laying period at the holding. Sampling frequency remains at every 2nd week at the hatchery (derogation of point 2.1.1 of Annex to Regulation (EC) No 200/2010)

Indicate also who takes the FBO samples

Sampling shall be carried out in accordance with the minimum requirements laid down in Part B of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Zoonosis / Zoonotic agent *Salmonella* spp with public health significance (ST, SE, SH, SV, SI)

Stages of production to be covered by sampling

Rearing:

I. day-old chicks

II. 4-week-old birds

III. two weeks before transfer to the laying unit or the start of the laying phase

Adults:

II. Every 2 weeks during the laying phase

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding Salmonella, as reflected in section 14 of the program.

The owner of the holding shall be responsible for carrying out own checks (FBO controls), including sampling, in the form and under the conditions provided for by this programme. Sampling may be carried out by qualified staff from the laboratory which performs the analyses. The veterinarian responsible for the holding will ensure that the sampling protocol is in accordance with the conditions laid down in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

Since the Community target has been reached at national level for at least two consecutive calendar years in Spain, the frequency of sampling on the holding may be extended to every three weeks, at the discretion of the competent authority and in accordance with Commission Regulation (EC) 213/2009, amending Regulation (CE) 2160/2009. Each Autonomous Community is responsible for authorising the extension of the frequency of sampling in its territory.

The owner of the holding shall keep the results of the analysis for a period of at least three years, during which time they will be at the disposal of the competent authority. Recording of results in the Ministry own-check application.

The data and information obtained from holdings where official sampling is performed (Annex: SELF-CONTROL sampling) and the laboratory results shall be recorded in the application of the National programme for the control of Salmonella https://servicio.mapa.gob.es/

The results of the self-control samples (FBO samples) must be recorded in the self-control software application, together with the required accompanying data, within one month of the laboratory analysis result being obtained; the results must be obtained within 10-15 days of the sampling, on average, except in exceptional circumstances. All the data from the sampling sheet must be filled in correctly: if any information is missing the samples cannot be recorded in the application. All samples and data relating to sampled flocks that are not recorded in the Ministry applications (official monitoring and own checks) will not be valid within the framework of the PNCS. The above notwithstanding, all positive results for *Salmonella* considered to have public health significance must be notified as specified in the PNCS.

2.1.3 Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 200/2010

Yes ☒ No ☐

If no, please explain

A. MINIMUM SAMPLING REQUIREMENTS FOR SELF-CONTROLS (FBO CHECKS)

Sampling must observe the minimum sampling requirements laid down in Part B of ANNEX II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and in the ANNEX to Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks, and Commission Regulation (EC) No 213/2009 amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) 2019/268 of 15 February 2019 amending Regulations (EU) No 200/2010, (EU) No 517/2011, (EU) No 200/2012 and (EU) No 1190/2012 as regards certain methods for Salmonella testing and sampling in poultry.

A.1. Sampling in adult breeding flocks (both own checks and official controls)

Sampling will involve obtaining sufficient faecal samples to detect 1% of infected birds in the flock with a 95% confidence limit. To that effect, the samples shall comprise one of the following:

a) Pooled faeces obtained from individual samples of fresh faeces weighing not less than 1 g, taken at random from various parts of the building in which the poultry are kept, or where the birds have free access to more than one building on a particular holding, from each group of buildings to which the flock has access. The faeces shall be pooled and a minimum of 2 pooled samples per flock analysed. The number of sites from which separate faeces samples are to be taken in order to make a pooled sample shall be as follows:

Number of birds in the breeding flock //Number of samples of faeces to be taken from the breeding flock

250-349 200

350-449 220

450-799 250

800-999 260

1000 or more 300

b) Boot swab samples, comprising 5 pairs of absorbent boot swabs. The laboratory will handle the boot swabs as 2 composite samples, each one comprising 5 boot swabs. Boot swabs used shall be sufficiently absorptive to soak up moisture. Tubegauze ‘socks’ shall also be acceptable for that purpose. The surface of the boot swab shall be moistened using appropriate diluents (such as 0.8 % sodium chloride, 0.1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority). Furthermore, measures shall be taken to prevent the potential bacterial growth inhibiting effects of the disinfectants used in the foot baths at the entrances to the sheds. The samples shall be taken while walking through the house using a route that produces representative samples for all parts of the poultry house or the respective sector. It shall include littered and slatted areas provided that slats are safe to walk on. All separate pens within a poultry house shall be included in the sampling. On completion of the sampling in the chosen sector, boot swabs must be removed carefully so as not to dislodge adherent material. The boot swabs shall be placed in a bag, flask or other type of sterile container which shall then be sealed and labelled appropriately.

c) For caged flocks, sampling shall consist of naturally mixed faeces from dropping belts, scrapers or deep pits, depending on each holding's dropping collection system. Two samples of at least 150 g each shall be collected to be tested individually. As there are normally several stacks of cages within a house and all must be represented in the sample, the sample shall be taken as described below: -In systems where there are belts or scrapers, these shall be run on the day of the sampling before sampling is carried out in order to collect only fresh faeces. -In systems where there are deflectors beneath cages and scrapers, droppings which have lodged on the scraper after it has been run shall be collected. -In systems where the droppings empty directly into a pit, the droppings shall be collected directly from the pit.

d) In cage houses where a sufficient amount of faeces does not accumulate on scrapers or belt cleaners at the discharge end of belts, four or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area as possible at the discharge end of all accessible belts after they have been run, ensuring each swab is coated on both sides with faecal material from the belts and scrapers or belt cleaners.

e) In multi-tier barn or free range houses in which most of the faecal material is removed from the house by dropping belts, one pair of boot swabs shall be taken by walking around in littered areas in accordance with point (b) and at least 2 moistened fabric swabs shall be taken as hand-held swabs from all accessible dropping belts, as in point (d).

A.2. Sampling in rearing flocks

The following procedure will be adopted in rearing flocks:

a) Day-old chicks:

1. One sample made up of from 10 samples taken of the internal coverings of the cages transporting the chicks taken when they are delivered to the holding. The bases of the cages may be used directly as a sample, which will be sent either whole or in parts to the laboratories responsible for processing samples and may be made up of a single or more than one sample, or

2. Liver, caecum and yolk sac of 60 chicks (these parts of the viscera can be removed and processed as a single sample), or

3. A sample made up of meconium from at least 250 chicks.

b) 4-week-old birds, and birds two weeks before transfer to the laying unit (or the start of the laying phase):

1. A sample of portions of fresh faeces of a minimum weight of one gram each collected at random at a minimum of ten different points in accordance with the following table: Faeces may be pooled for analysis up to a minimum of two pools.

Number of birds kept in one house // Number of portions of faeces to be taken in the house/group of houses on the holding

1-24 (equivalent to the number of birds up to a maximum of 20)

25-29 20

30-39 25

40-49 30

50-59 35

60-89 40

90-199 50

200-499 55

500 or more 60

2. The samples shall comprise 5 pairs of absorbent boot swabs. The laboratory will handle the boot swabs as 2 composite samples, each one comprising 5 boot swabs.

Preparation of the samples in the laboratory (official controls and FBO controls)

a) Boot swabs and fabric swabs

The pair(s) of boot swabs must be unpacked carefully to avoid dislodging adherent faecal material. They must be collated into two samples and submerged in 225 ml buffered peptone water (BPW) that has been pre-warmed to room temperature. If necessary, more peptone water may be added to leave liquid around the sample to permit migration of Salmonella. Shake to ensure complete saturation of the sample and continue to apply the detection method.

In case of collection of fabric swabs in accordance with point 7.A.1(d) and e) of this programme pooling shall occur fully submersing boot/socks and fabric swab in BPW to provide sufficient free liquid around the sample for migration of Salmonella away from the sample and therefore more BPW may be added, if necessary.

Separate preparations must be made of the boot swabs and the fabric swab.

b) Other faeces samples and dust samples: - The faeces samples shall be pooled and thoroughly mixed for analysis into a minimum of two pools and a 25-gram sub-sample shall be collected from each one for the culture. - Add 225 ml buffered peptone water to the 25-g sub-sample and shake gently. - Culturing of the sample shall be continued by using the detection method set out in point C. For preparation of all of these samples, Standard UNE-EN ISO 6887-6, “Specific rules for the preparation of samples taken at the primary production stage”, may also be used as a guide.

Identification of samples and results of analyses (official controls and own checks)

The samples sent must be properly preserved and identified (in accordance with the specimen report accompanying the samples to the laboratory, included in the annexed Sampling Sheet) There are two standard sampling sheets: one for official controls and one for own checks, since it is not necessary to collect as much information for own checks as for official controls. In both cases it must be clearly indicated that the samples are taken within the framework of the PNCS to avoid any confusion with private samples taken by the holding. The sampling sheets are to be completed in their entirety since all the information collected on the forms is required for assessment of the PNCS. One copy or a duplicate of the sampling sheet must

remain on the holding and must be filed with the test report sent by the laboratory so that all the documentation relating to the samples is present on the holding (sampling sheet and test results). This documentation must be available to the official veterinary services when official controls are carried out in the framework of the PNCS. The documentation required may be submitted in hard copy or electronic format.

To ensure suitable traceability of the samples, at least the following information must be recorded in the test reports:

1. Date on which samples were taken.

2. Identification of the flock. (REGA, CAPITAL LETTER IDENTIFYING THE SHED, DATE OF ENTRY OF THE BIRDS INTO THE SHED (format mmyyyy). 3. Poultry population (breeders, layers, broilers, fattening or breeding turkeys) 4. Samples (specimen, number and weight or volume) that arrived at the laboratory and method by which they were mixed for analysis. All reports on tests carried out on samples as part of the PNCS, and the annexed sampling sheets, must include the following text, clearly and easily visible: “THESE SAMPLES FALL UNDER THE SALMONELLA NATIONAL CONTROL PROGRAMMES”.

When a vaccine strain has been detected, the laboratory serotyping report must include the following statement: " The flock shall be considered negative because it has been isolated a vaccine strain"

2.1.4 Specific requirements laid down in Annex II.C of Regulation (EC) No 2160/2003 will be complied with where relevant (i.e. due to the presence of SE or ST (including monophasic ST 1,4,[5],12:i:-), all birds of infected rearing or adult flocks are slaughtered or killed and destroyed, and all eggs are destroyed or heat treated):

Please indicate also if birds are slaughtered or killed and destroyed, and if eggs are destroyed or heat treated. Please specify the options applied.

Yes ☒ No ☐

If no, please explain.

The minimum measures to be adopted when the presence of *S*. Enteritidis, *S*. Typhimurium, including the monophasic variant of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, *S*. Hadar, *S*. Virchow and/or *S*. Infantis is detected in a flock of birds are as follows (control and eradication measures after a positive to one or more of the 5 serotypes):

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection, in accordance with the epidemiological survey attached in the programme. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

2. No live birds may be moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document made out by the competent authority stating at least the number of animals and the necessary information for identifying the holding and the transporter.

3. All birds, including day-old chicks, in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading salmonella. Slaughter must be carried out in accordance with Community legislation on food hygiene. Products obtained from these birds may be placed on the market for human consumption only in compliance with Community legislation on food hygiene in force and with part E of Annex II to Regulation (EC) No 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

4. Non-incubated eggs from the flock must be destroyed. However, such eggs may be used for human consumption if they are treated in a manner that guarantees the destruction of Salmonella in accordance with Community legislation on food hygiene and with the provisions of part D of Annex II to Regulation 2160/2003.

5. Where eggs for hatching from flocks in which one of the five serotypes of Salmonella has been confirmed are still present in a hatchery, they must be destroyed or treated in accordance with Regulation (EC) No 1069/2009.

6. Thorough checking of biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on breeding poultry holdings.

7. Once the birds from the infected flock have been slaughtered or destroyed, efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of Salmonella spp. in the environment.

Verification of cleaning and disinfection should be done according to point 17 of this programme.

8. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

9. The dates of slaughter or destruction of the flock, disinfection, collection of environmental samples and restocking must be notified to the competent authorities. All these processes must be duly recorded for possible consultation by the competent authorities and any depopulation, slaughter or destruction of the flock and restocking must take place under official supervision.

10. Where one of the five types of *Salmonella* is confirmed on heavy breeder holdings, the above-mentioned measures at least shall be adopted and, in addition, the next batch of birds introduced must be pullets vaccinated with authorised vaccines or autovaccines in accordance with the legislation in force, before commencing the laying stage.

11. If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals ++or anybody who can be considered as a risk to determine whether there are any *Salmonella* spp. carriers among them.

If, however, a serotype not concerned by the control programme is identified, the following measures will be taken:

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

2. Thorough checking of biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on breeding hen holdings.

2.1.5 Detection of ***Salmonella hadar, Salmonella infantis*** or ***Salmonella virchow***

Please describe the measures that shall be implemented in a flock (rearing and adult) where *Salmonella hadar, Salmonella infantis or Salmonella virchow* is detected
Exactly the same measures must be taken as when *S*. Enteritidis or *S*. Typhimurium, including the monophasic variant with the antigenic formula 1,4,[5],12:i:-, are detected. These measures are described in Section 2.1.4.

2.1.6 **EU microbiological criteria** in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*

If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g. Measures implemented by the FBO (farm level)
In order to clarify the SNCP of poultry, this text was amended as a part of the Action Plan approved after the recommendation of report ref DSG(SANTE) 2019-6597 of the EU audit to evaluate SNCP carried out in November 2019, stating that the CA should ensure that only broiler and turkey flocks that have been sampled for Salmonella with a known test result can be sent for slaughter. In accordance with Royal Decree 361/2009 on food chain information, the operator of the livestock holding must ensure that in all shipments of animals to the slaughterhouse, full information on the results of all analyses of samples taken that have importance for human health, in the framework of the surveillance and control of Salmonella is sent to the slaughterhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or last analyses, if the samples have been taken in the near future) has been negative or positive to Salmonella spp. and, in this last case, in addition, if it is negative or

positive to *S*. Enteritidis or *S*. Typhimurium, and the information of the result/s of such analysis must be included in the FCI (Food Chain Information) to be considered complete.

If a flock on the holding tests positive for *S*. Enteritidis or *S*. Typhimurium, the operator of the livestock holding must also ensure that no live birds are moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.

Measures implemented by the FBO (slaughterhouse level)

Slaughter at the slaughterhouse shall be carried out in accordance with the provisions of Regulation (EC) No. 853/2004, which lays down specific hygiene rules for food of animal origin, and in particular Section II of Annex III thereof.

When a positive herd is received at the slaughterhouse, it is logistically slaughtered, i.e. the herd is slaughtered last in the daily slaughter order to minimize the possibility of cross-contamination, followed by cleaning and disinfection. This is carried out in line with the provisions of Regulation (EU) 2019/627 with the aim of reducing contamination of other animals or their meat as much as possible. In addition, in accordance with the provisions of Regulation (EC) No. 2073/2005, slaughterhouses shall include in their sampling plans poultry carcasses from flocks whose Salmonella status is unknown or positive for Salmonella Enteritidis or Salmonella Typhimurium.

There is a “Manual for the broiler sector in Spain for compliance with Regulation (EU) No 1086/2011 amending Regulations (EU) No 2160/2003 and (EC) No 2073/2005”, which, although it is voluntary, can provide guidance as to the correct way of handling birds slaughtered in slaughterhouses in relation to Salmonella.

As an example of the possible system of action, we attached (see part IV. Maps) the management diagram of birds sent to a slaughterhouse, recommended in the "GUIDE FOR THE MEAT POULTRY SECTOR IN SPAIN FOR COMPLIANCE WITH REGULATION (EU) No. 1086/2011 AMENDING REGULATIONS (EU) No. 2160/2003 AND (EC) No. 2073/2005", with some additional issues that are carried out voluntarily by the slaughterhouses that apply the guide, such as the immobilization of the carcasses sampled until the results are available.

Guide available through:
https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf

Measures implemented by the CA (farm and slaughterhouse level)

The official veterinarian is responsible for verifying that the correct food chain information is passed on as required pursuant to RD 361/2009: accordingly, he or she must check that the livestock holdings are passing this information to the slaughterhouses in a consistent and effective, valid and reliable manner and ensure that the relevant animal health and food safety information, including that relating to the results of Salmonella testing, is also passed on. Provision is thus made for slaughterhouses to only accept animals for which the relevant information on the holding of origin has been received. As a general rule, the information should

be received at least 24 hours prior to the arrival of the animals. Slaughter in slaughterhouses must take place in accordance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and in particular Section II of Annex III.

Official controls must be carried out in accordance with Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules regarding the performance of official controls on meat production and regarding production and relaying areas for live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627, of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council and Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council. No. 2074/2005 of the Commission as regards official controls.

The provisions of Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs, also apply in relation to the criteria for *Salmonella* in poultry meat. Once positive results for *S*. Enteritidis or *S*. Typhimurium are found in a consignment, the official veterinarian will ensure that targeted sampling and tests using the EN/ISO 6579 methodology or a validated alternative method are carried out, and lastly that the carcasses are withdrawn from the market and destroyed or that the destination previously given for the product is changed.

2.1.7 Laboratory accreditation

Laboratories in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation.

Please provide the list of the laboratories accredited to perform the analytical method for *Salmonella*.

Yes ☒ No ☐

If no, please explain

The Central Veterinary Laboratory in Algete (Madrid) of the Ministry of Agriculture, Fish and Food is the National Reference Laboratory for all serotypes of Salmonella in animals.

Laboratories analysing official samples as part of the programme must be established, recognised or designated by the competent bodies in the Autonomous Communities. These official laboratories must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or must apply quality assurance systems in accordance with that standard. They must also participate in the ring tests organised or co-ordinated by the National Reference Laboratory.

The laboratories participating in the programme for the purposes of carrying out own checks must be recognised by the competent authorities of the Autonomous Communities in which

they are established and must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or apply quality assurance systems in accordance with that standard. Laboratories must also regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory.

The list of participating laboratories must be published, for information purposes, at least on the MAPA website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/listadolaboratoriosatcycoporccaasalmonella_15062022_tcm30-431063.pdf

The competent authorities of the Autonomous Communities shall notify the Ministry of Agriculture, Fish and Food of the laboratories referred to in the previous paragraph or of any modifications to them so that the list may be published at least on the departmental website for information purposes.

Where a laboratory serves at the same time as an Autonomous Community's official laboratory and participates in the own-check programme, it must notify the relevant competent authority or authorities and ensure that the two activities are managed separately, and it is subject to monitoring and periodic inspection by the competent authority to check that these are separate. If it fails to notify the authorities, or cannot guarantee that the activities are kept separate, it cannot operate as an official laboratory.

The results obtained by authorised laboratories for both official monitoring and own checks shall be valid and applicable throughout the country.

Laboratories must reject samples which do not meet the requirements specified in this programme.

2.1.8 Analytical methods

The **analytical methods** used for the detection of the target *Salmonella* serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ ISO 6579-1:2017/Amd 1:2020. "Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp. – AMENDMENT 1: Broader range of incubation temperatures, AMENDMENT to the status of Annex D, and correction of the composition of MSRV and SC".
Serotyping is performed following the Kaufman-White-Le Minor scheme.

Yes ☒ No ☐

If no, please describe the alternative method(s) used.

For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.

Yes ☒ No ☐

If no, please explain. If time limits are exceeded, please indicate what is done.

Alternative methods

Alternative methods may be used instead of the methods referred to above, if validated in accordance with the latest version of EN ISO 16140-2 (for alternative detection methods).

Storage of strains

At least the strains isolated from samples collected by the competent authority shall be stored for possible further characterization and antimicrobial susceptibility testing, as determined by Implementing Decision (EU) 2020/1729 of 17 November 2020 on antimicrobial resistance surveillance and reporting Decision 2013/652/EU of 12 November 2013 on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, using normal culture collection methods, which should ensure the integrity of the strains for at least two years.

Pursuant to that Decision, strains isolated from the own-check samples may also be stored to that end if the competent authority so decides.

To that end, the official control laboratories must send all strains of Salmonella isolated in the framework of the PNCS to the National Reference Laboratory (Algete).

Own-check laboratories must also send the National Reference Laboratory (Algete), on request, any strains obtained in the framework of the PNCS.

The frequency of dispatch of such strains shall be as agreed between the National Reference Laboratory and the laboratories.

2.1.9 Transportation and storage of samples

Samples are transported and stored in accordance with point 3.1.1 of the Annex to Regulation (EU) No 200/2010. In particular, samples examination shall start in the laboratory within 48 hours following receipt and within 96 hours after sampling.

Yes ☒ No ☐

If no, please explain the actions taken in case time limits are exceeded

Samples shall be sent to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection, preferably by express mail or courier. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat (over 25°C) and exposure to sunlight are avoided. At the laboratory samples shall be kept refrigerated until examination, which shall be started within 48 hours of receipt and within 96 hours of sampling.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements. Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured. Structure and organization of the Competent Authorities (from the central CA to the local CAs) Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.
Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders. For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters. The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease. This Subdirectorate is the main responsible for the programme and for the coordination of it, through regular communications and meetings with regional authorities and with NRL and stakeholders. The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures). Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results. Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the “National Veterinary Health Warning System Committee” (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health for zoonoses. Its tasks include the following: a) Coordinating animal health actions across the different administrations.

b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.

c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.

d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an

intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc, and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an aditionnal quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website:
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.8.

2.3.1 Official controls at feed level

Please describe the **official controls at feed level** (including sampling)
Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities. As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of *Salmonella* spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for Salmonella (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for Salmonella, an identification of the serotype must be requested. Only in the case of S. Enteritidis, S. Typhimurium, S. Infantis, S. Virchow and S. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp, the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that

it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of Salmonella and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of Salmonella in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including Salmonella. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding, flock and hatchery levels

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as Salmonella control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of Salmonella. There are "Guides to Good Hygiene Practice for the prevention of zoonotic Salmonella in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Food and the Environment. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also

available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Holders of breeding hen establishments must have in place a code of good hygiene practices in order to meet the objective of this national Salmonella control programme and to ensure that health information is kept up-to-date. They must also keep the following records on holdings:

a) A record of the type and origin of the feed supplied to the animals.

b) A record of the outbreak of diseases that could affect the safety of products of animal origin.

c) An up-to-date record of visits, listing the people and vehicles that have entered the holding.

d) A record of medicinal treatments, containing the information specified under Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products and including the vaccinations referred to in this programme.

e) All the results of analyses and checks to detect Salmonella carried out on the flock concerned, including those carried out in the incubator or breeding shed of origin of the flock, must be kept by the owner of the holding for at least three years and the records of the flock currently in production must, without fail, be kept on the holding.

f) All movements of flocks entering and leaving the holding must be recorded in the holding register. The flock sheet must be kept for at least three years after the flock is slaughtered.

g) There must also be a documentary record of:

i. The protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).

ii. Analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of Salmonella with public health significance.

iii. Rat and insect extermination programmes and implementation records (dates, products used, procedure for verifying the effectiveness of the programme, etc.)

h) Producers of rearing pullets must report on the health status of the breeding flock of origin and on any vaccinations and own checks during the rearing of the pullets; this information must accompany the pullets when they are transferred to the producing holdings.

The owner of the holding must be in possession of all the mandatory health documentation and keep records of all of the necessary data so that the competent authority can regularly check compliance with the health programme referred to in this paragraph as well as the code of good hygiene practices, in particular the records mentioned above (a), b), c), d) and e)).

Without prejudice to Royal Decree 637/2021, the holder must adopt protective livestock rearing measures to control the introduction of or contamination by *Salmonella* spp on the holding. In particular:

a) The design and maintenance of the installations must be suitable for preventing the entry of *Salmonella* spp.;

b) Appropriate measures must be taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease. A rat extermination programme must be carried out either by the holding itself or by authorised establishments.

c) Day-old chicks must be obtained from holdings and hatcheries which have satisfactorily passed inspections to prevent the vertical transmission of the five Salmonella serotypes; the supplier must certify that the said chicks are exempt from the five abovementioned serotypes, and documentary evidence of the favourable outcome of laboratory tests must be made available to the purchaser. Rearing pullets (future layers) must be accompanied when leaving the rearing establishment by a certificate from the supplier stating that own checks have been properly carried out and detailing their results (day-old chicks and birds two weeks before entering the laying stage or unit must have satisfactorily passed the tests for the five Salmonella serotypes). Where appropriate, they shall also be accompanied by a certificate stating that the pullets have been vaccinated in accordance with the programme. These requirements must be met before authorisation is given for the transfer and restocking of the laying shed.

d) Adequate washing, cleaning, disinfection and rat extermination measures must be taken in rearing houses, breeding hen houses and adjoining structures and also with regard to the material and equipment used for productive activity.

e) Tests must be conducted to verify that cleaning and disinfection were carried out correctly. To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm^2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority), shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes (SNCP).

The detection methods used must be the same as for the other samples under the SNCP. The results for the same must be recorded using the MAPA computer application for FBO checks.

The samples must be recorded alongside the samples for the outgoing flock. The sampling sheet for own checks must be used when sending such samples to the laboratory. The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

f) Adequate measures must be taken to prevent the transmission of *Salmonella* spp through drinking water.

g) The appropriate measures must be taken to prevent the presence of *Salmonella* spp in raw materials and feedingstuffs. Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for Salmonella has been carried out and make express provision for such tests in the relevant HACCP system. The checks must include analysis of the corresponding samples, which will be made available to the health managers of the holdings receiving the feed. The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis.

h) Adequate training courses must be given to workers and appropriate health checks must be carried out to detect possible contamination of workers on the holding with any of the five Salmonella serotypes if the bacterium is detected in animals.

i) Suitable health checks must be carried out to detect the possible source or sources of Salmonella contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation.

j) Appropriate vaccination programmes must be carried out where necessary.

k) Appropriate sampling and analyses are carried out to detect *Salmonella* spp.

l) Adequate measures must be taken to ensure the traceability of eggs produced in accordance with the legislation in force.

m) Adequate measures must be adopted if positive cases of salmonellosis involving any of the five Salmonella serotypes occur.

n) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.

More information on biosecurity checks, the official protocol and the procedure in case of shortcomings, is explained in point 2.1.1. and the protocol is available on the website.

b) Routine official **sampling scheme when FBO sampling takes place at the hatchery**: EU minimum requirements are implemented i.e. If the EU target is achieved for more than 2 years, the CA has decided to implement the derogation of point 2.1.2.3 of Annex to Regulation (EC) No 200/2010 and therefore the EU minimum requirement for official sampling is once a year at the hatchery and once a year on the holding during the laying phase.

Yes ☐ No ☒

If no, the EU minimum requirements for official sampling are implemented as follows:

- every 16 weeks at the hatchery
- twice during the laying phase at the holding (within four weeks at the beginning, within eight weeks before the end), and
- at the holding each time samples taken at the hatchery are positive for target serovar

Yes ☐ No ☒

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Samples are not taken at the hatcheries in Spain.

c) Routine official **sampling scheme when FBO sampling takes place at the holding**: EU minimum requirements are implemented i.e.: If the EU target is achieved for more than 2 years, the CA has decided to implement the derogation of point 2.1.2.3 of Annex to Regulation (EC) No 200/2010 and therefore the EU minimum requirement for official sampling is twice during the laying phase at the holding.

Yes ☒ No ☐

If no, the EU minimum requirements for official sampling are implemented as follows:
§ Three times during the laying phase at the holding (within four weeks at the beginning, within eight weeks before the end and a third one in between)

Yes ☒ No ☐

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, please describe, 2) who is taking the official samples

Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by other sufficiently trained authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

A minimum of three separate official checks on all the flocks on all holdings with more than 250 birds must be carried out on three occasions during the production cycle:

• The first within four weeks of the transfer to the laying unit;

• The third towards the end of the laying phase, not earlier than eight weeks before the end of the production cycle;

• The second official analysis must be carried out during the productive period at an appropriate interval from the other two.

In addition, sampling by the competent authority shall take place whenever the competent authority considers it appropriate.

Given that the Community target has been reached at national level for at least two consecutive calendar years in Spain, the competent authority may replace the routine samplings by two samplings on the holding, on any two occasions with sufficient time between each other during the production cycle.

It falls to each Autonomous Community to decide whether or not to make use of this exemption. In Spain, most of the Autonomous Communities have decided to make use of it.

During sampling, all the data necessary to identify the sample and the flock from which it comes will be collected and will comprise at least the data set out in the sampling sheet for official checks.

Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check).

All data and information gathered on holdings on which official sampling has been performed (SEE THE SAMPLING SHEET FOR OFFICIAL CHECKS and the BIOSECURITY SURVEY) and the

laboratory results shall be recorded in a dedicated computer application developed for the national programme for the control of Salmonella.

Official sampling protocol is the same as the protocol described for FBO samples (sampling in adult breeding flocks).

Other official samples

Whenever the competent authority deems it necessary, official samples of animal feed and drinking water and environmental samples may be taken to confirm the effectiveness of cleaning and disinfection measures.

If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anyone who can be considered as a risk, in order to determine whether there are any *Salmonella* spp. carriers among them.

d) If confirmatory samples taken at the holding (after positive results at the hatchery, or suspicion of false positivity on FBO samples taken on the holding) are negative, please describe the measures taken:

☒ Testing for antimicrobials or bacterial growth inhibitors (at least 5 birds per house) and if those substances are detected the flock is considered infected and eradication measures are implemented (annex II.C of Regulation (EC) No 2160/2003):

☐ Other official samples are taken on the breeding flock; if positive, the flock is considered infected and eradication measures are implemented, if negative, all restrictive measures are lifted

☐ Other official samples are taken on the progeny; if positive, the flock is considered infected and eradication measures are implemented, if negative, all restrictive measures are lifted

☐ None of these measures

Describe also if any other measures are implemented

Insert text

e) **Official confirmatory sampling** (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery):

After positive official samples at the holding

☐ Always
☒ Sometimes (criteria apply)
☐ Never

After positive FBO samples at the holding

☐ Always
☒ Sometimes (criteria apply)
☐ Never

When official confirmatory sampling is performed, additional samples are taken for checking the presence of antimicrobials:

☒ Always

☐ Sometimes
☐ Never

Please insert any comments. Describe the criteria used to determine if confirmatory sampling is performed. Indicate also which samples (if any) are taken to check the presence of antimicrobials.

In exceptional cases, and with a view to ruling out false positives or false negatives for samples taken as part of official controls or self-controls, the competent authority may decide to carry out confirmatory analyses according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of Salmonella serotypes subjected to control in poultry farms", available on the MAPA's website:

i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected using fabric swabs of at least 900 cm^2 or replacing the dust samples by 2 extra samples of faeces or boot swabs; however, a sub-sample of 25 grams must be collected of each faecal material and dust sample for analysis; all samples must be analysed separately, or
ii) bacteriological investigation of the caeca and oviducts of 300 birds, or
iii) bacteriological investigation of the shell and the content of 4 000 eggs from each flock, in pools of maximum 40 eggs.

In addition to the set arrangements above, the competent authority will check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

Whenever confirmatory testing is conducted, additional samples shall be collected for the possible testing of antimicrobials or bacterial growth inhibitors, as follows: birds shall be taken at random from within each poultry house of birds on the holding, normally up to five birds per house, unless the competent authority deems it necessary to sample a higher number of birds.

Additionally, samples of feed and water can be taken to determine whether the results of the confirmatory test may have been affected by the use of antimicrobials.

If antimicrobials or bacterial growth inhibitors are detected, the Salmonella infection shall be considered to be confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a justification to the CA with the reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc, the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and Salmonella results, biosecurity measures, not relation with any foodborne outbreak last years, etc).

f) **Number of official confirmatory samples**

1	2	3	4
For routine samples taken at the holding	N of flocks positive to SE/ST	Out of the flock in column 2, N of cases where official confirmatory samples[3] were taken	Out of the N of cases in column 3, N of cases where confirmatory samples were negative
FBO samples[1]	7	4	4
Official samples[2]	4	1	1

(1) Reg 200/2010, point 2.2.2.1 of the Annex
(2) Reg 200/2010, point 2.2.2.2 of the Annex
(3) Reg 200/2010, point 2.2.2.2.c of the Annex

In 2022, 5 confirmatory tests were done in flocks positive to SE/ST (monophasic strains included), all of them with negative results, so the infection was discarded.

f) Antimicrobial control
Article 2 of Regulation (EC) No 1177/2006 (**antimicrobials** shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).
For samples please describe the samples taken, the analytical method used, the result of the tests.

The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the documentary checks, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling. Other sample's specifications shall be made according to the laboratory indications.

The examination shall consist on a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the Salmonella serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Vaccination

☒ Voluntary
☐ Compulsory
☐ Forbidden

The use of *Salmonella* vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.
If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Vaccination shall be carried out in accordance with Article 3 of Regulation (EC) No 1177/2006. Vaccination of breeding hens is not mandatory, but if it is carried out, only vaccines with prior marketing authorisation from the Spanish Medical and Health Products Agency or the European Commission in accordance with Regulation (EC) No 726/2004 may be used.

Where one of the three types of Salmonella (SE, ST, SMT, SI) is confirmed on egg production breeder holdings, the above-mentioned measures at least shall be adopted and, in addition, the next batch of birds introduced must be pullets vaccinated with authorised vaccines or autovaccines in accordance with the legislation in force, before starting the laying stage. Once vaccination has been carried out, at least the following information will be entered in the register of treatment with medicinal products: date of vaccination, name of the vaccine(s) administered, type of vaccine(s) administered, quantity (number of doses and quantity of each dose), name and address of the supplier of the medicinal product and identification of the batch of animals treated. Vaccine use must also be recorded using a computer application.

Most FBOs vaccinate breeder's flocks in Spain. The vaccination strategy is variable, depending on the holding or even the flock. Last years around 3,5 doses per bird were used in breeding birds.

2.3.4 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the shed that hosts the infected flock has been depopulated, an efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by a disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of *Salmonella* spp. in the environment.

After depopulation of an infected flock, the competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

To verify cleaning and disinfection, two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes.

The detection methods used must be the same as for the other samples under the PNCS.

The results for the same must be recorded using the MAPA computer application for self-controls.

The samples must be recorded alongside the samples for the outgoing flock.

The sampling sheet for own checks must be used when sending such samples to the laboratory.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.5 Monitoring of the target Salmonella serovars (*Salmonella enteritidis, Salmonella typhimurium*)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target *Salmonella* serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain
Since 1993, *Salmonella* monitoring and control in Spain has been conducted in accordance with Council Directive 92/117/EEC — repealed by Directive 2009/99/EC — concerning measures for protection against specified zoonoses and specified zoonotic agents in animals

and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. The monitoring and control have focused on S. Enteritidis and S. Typhimurium.

Data on breeding flocks of *Gallus gallus* were monitored and collected throughout 2004 on the basis of instructions given at Community level in order to meet the target for the reduction of prevalence laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council on the control of Salmonella and other specified food-borne zoonotic agents. The data obtained from the study showed prevalence of the five serotypes (SE, ST, SH, SV, SI) in the production phase to be 16.6 %, rising to 20.3 %for Salmonella spp.

The evolution of prevalence of the monitored Salmonella serotypes in flocks of breeding hens of the species *Gallus Gallus* is attached (see part IV: Maps). The most prevalent target serotypes in 2022 were *S*. Enteritidis and *S*. Infantis, followed by *S*. monophasic Typhimurium, *S*. Typhimurium and S. Virchow (a file containing the evolution of prevalence is enclosed):

2.3.6 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks
Legislative measures and provisions concerning the registration of livestock holdings. The requirement to register livestock holdings in Spain stems primarily from Article 39 of Law 8/2003 of 24 April 2003, the Animal Health Act. More specifically, and where poultry farming is concerned, the requirement to register holdings is regulated by the following instruments: Royal Decree 479/2004, of 26 March 2004, establishing and regulating a general register of livestock holdings. Covers all livestock species. Royal Decree 1084/2005 of 16 September 2005 establishing regulations for poultry farming for meat. Applies to holdings where poultry birds are reared or kept for meat, excluding holdings where birds are kept for own consumption, as defined in Article 2.b. Measures and applicable legislation as regards the identification of animals The programme shall cover breeding poultry flocks, since individual animals are not identified. For the purposes of the programme an epidemiological unit shall be considered to be a breeding flock, defined as all poultry of the same health status kept on the same premises or within the same enclosure; in the case of housed poultry, this includes all birds sharing the same airspace, in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of breeding hens shall be identified individually. To identify the flocks on a holding the REGA code will be used, consisting of a capital letter corresponding to the shed (this letter must be written on the entrance door to the shed) and the date of entry of the birds into that shed, in the format mmyyyy. REGA+ SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mmyyyy).

2.3.7 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation

In cases where birds are subjected to compulsory slaughter, the owners of the birds will be entitled to compensation, provided that they have complied with the animal health legislation in force.

The scales for compensation are fixed by the Ministry of Agriculture, Food and the Environment following consultation with the Autonomous Communities. The above scales are public and are included in Royal Decree 823/2010 of 25 June 2010, laying down the scales of compensation for the compulsory slaughter of animals covered by the national control programmes for Salmonella in breeding and laying flocks of *Gallus gallus* and breeding turkey flocks.

The age of the birds for compensation purposes shall be considered to be their age when the competent authority ordered the compulsory slaughter.

2.3.8 System to monitor the implementation of the programme

Please describe
Taking account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all of the results. Lastly, we have a monitoring plan for own checks and inspection of own-check laboratories: In order to verify that own checks are being performed correctly, the competent authority will implement the following “Monitoring Plan for FBO checks and inspection of laboratories testing FBO samples” (document available on the website): The Official Veterinary Services carry out quality controls on own checks on a percentage of holdings, selected each year in accordance with the following ranked risk criteria: • Holdings where results for the serotypes being monitored were negative in own checks and positive in official controls. • Holdings where results for the serotypes being monitored were negative in own checks but for which there was a Public Health notification of a positive result.

• Holdings where results for the serotypes being monitored were negative in own checks but positive results were obtained for the LOD in effectiveness checks.

• At random on holdings where results for the serotypes being monitored were negative in own checks and no official controls were carried out.

This will involve 5% of the holdings in each Autonomous Community. If there are fewer than 20 holdings in a Community, they will be carried out on at least one farm. The control will involve conducting a survey to verify whether the requirements of the programmes are being met. The Autonomous Community may decide to carry out a site inspection of an own-check sampling exercise. In this case, the own-check sampling must take place in the presence of the official veterinarian who, as an observer, will attempt to identify practices that do not correspond to the procedures for sampling set out in detail in the National Programmes and applicable to own checks. Close attention will be paid to critical aspects of those procedures that could presumably affect the results (such as the use of peptone as an enrichment medium for boot swabs, origin, expiry; representativeness of the sample: number of steps taken and surface area covered; where appropriate, dispersion of the collection of aliquots of faeces to generate sufficient representativeness in pools, etc). The manner and location of storage of the sample when delivered to the laboratory must also be checked, as must compliance with the maximum deadlines set for receipt of the samples. It is very important that before any own checks are carried out on holdings, and whenever routine official controls are carried out, the holding information recorded in the own-check application is consulted. During this inspection the competent authority must also ask any questions considered necessary and request the necessary documentation on the performance of own checks. The official veterinarian must note down the results of the control in an inspection report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, will be used by the competent authority to draw up an appraisal report. In the event that any shortcomings are detected, these must be reported to the producer as soon as possible to be corrected immediately for future own checks, without prejudice to any administrative consequences this may have. The competent authority must issue a copy of the report to the party responsible for taking the own-check samples. If the competent authority considers it appropriate, duplicate samples will be taken. One of the samples will be taken by the official veterinarian using his or her own materials. This sample will be retained by the veterinarian and will be sent to an official laboratory together with the sampling sheet. The other sample will be taken by the party responsible for taking the own-check samples, using material provided by that party. It will remain in that party's possession and must be analysed in the same way as any other own-check sample. In those cases where there are significant discrepancies between the results of the official controls and the own checks in the same flock, the competent authority may, if it considers it appropriate, request the strains isolated from the flock in question from the own-check laboratory where they were tested and test them in an official laboratory of the Autonomous Community concerned. Inspections in laboratories will take place in accordance with the document enclosed above. Each Autonomous Community must have inspected all the laboratories in its territory within two years.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: *Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and especificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on	Appropriate awareness and knowledgement of deadlines and requirements of the SNCP.

	the propagation of the disease if implementation of the measures is delayed. (Low risk)	
5	Non-compliance of the EU target for the reduction of the prevalence (Low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Knowledgement of the SNCP requirements in advance.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official

correction of possible data recording errors (fixing of bugs).		databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August-September (year N)	Intermediate follow-up technical report (data of first semester).
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view) Who are the target groups? How will the target groups benefit concretely from the project and what would change for them? Define the short, medium and long-term effects of the project. ***Possible examples:*** *reduction to 1% or less the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for the target Salmonella serovars: S. enteritidis (SE), S. typhimurium (ST)(including the antigenic formula 1,4,[5],12: i:-), S. hadar (SH), S. infantis (SI) and S. virchow (SV).*
The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector. The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agri-food chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-), *S*. Virchow (SV), *S*. Infantis (SI) and *S*. Hadar (SH). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement “funded by the European Union”.

The programme will be available in the MAPA’s website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the *Salmonella* Control Programme.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	**1020**		1020	5
Adult flocks	**1720**	1700	1720	1700
Number of adult flocks where FBO sampling is done at the hatchery		0	0	0
Number of adult flocks where FBO sampling is done at the holding		1700	1720	1700
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: “MAPA "

II. Targets for 2024

Table 2: Targets on laboratory tests on official samples from breeding flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	5000
Serotyping	100
Antimicrobial detection test	50
Test for verification of the efficacy of disinfection	10

Table 3: Targets on official samples from breeding flocks of *Gallus gallus*

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1020	1720
N of flocks in the programme	1020	1720
N of flocks planned to be checked (b)	5	1700
No of flock visits to take official samples (c)	5	2500
N of official samples taken	35	5010
Target serovars (d)	☒ SE+ ST + SH +SI + SV	☒ SE+ ST + SH +SI + SV
	☐ SE+ ST	☐ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	2	4
Possible N of flocks to be depopulated	2	4
Total N of birds to be slaughtered/culled	18000	42000
Total N of eggs to be destroyed	n/a	300000
Total N of eggs to be heat treated	n/a	500000

(a) Including eligible and non-eligible flocks
(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
(c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
(d) *Salmonella enteritidis* and *Salmonella typhimurium* = SE + ST; *Salmonella enteritidis, typhimurium, hadar, infantis, virchow* = SE+ ST + SH +SI + SV

Table 4: Targets on vaccination for breeding flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the *Salmonella* programme	1720
Number of flocks expected to be vaccinated	1600
Number of birds expected to be vaccinated	14000000
Number of doses expected to be administered	42000000

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

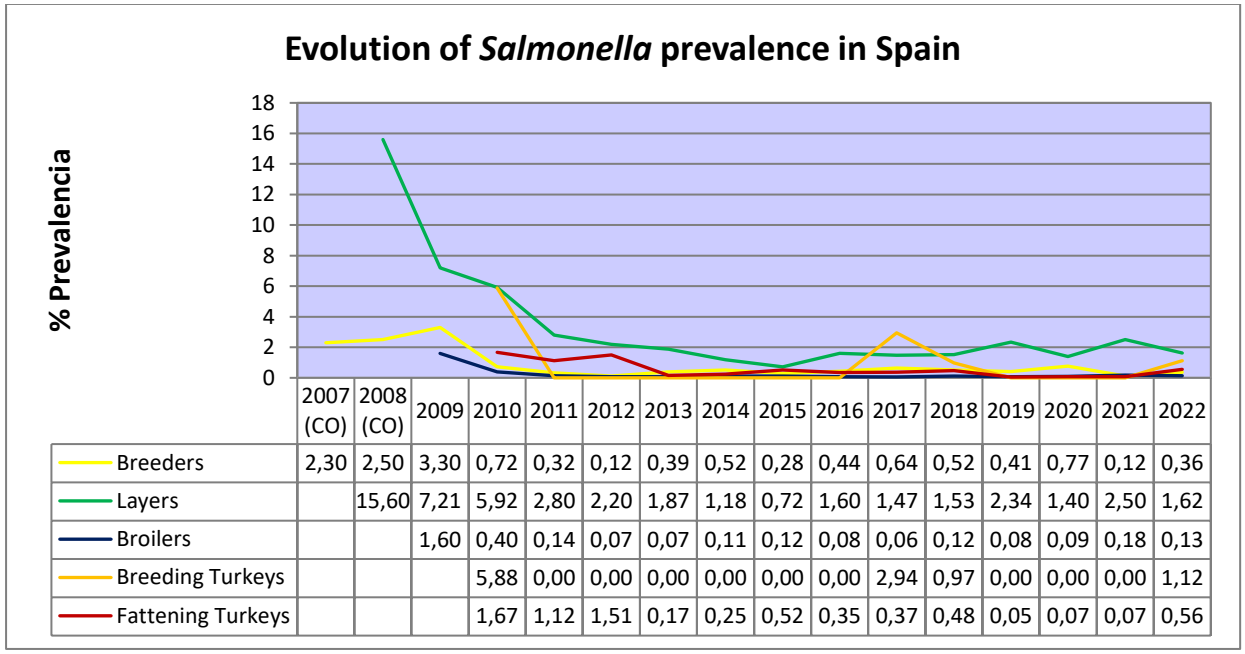
- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010R0200-20190310&qid=1652941483997
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2022)



	2007 (CO)	2008 (CO)	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Breeders	2,30	2,50	3,30	0,72	0,32	0,12	0,39	0,52	0,28	0,44	0,64	0,52	0,41	0,77	0,12	0,36
Layers		15,60	7,21	5,92	2,80	2,20	1,87	1,18	0,72	1,60	1,47	1,53	2,34	1,40	2,50	1,62
Broilers			1,60	0,40	0,14	0,07	0,07	0,11	0,12	0,08	0,06	0,12	0,08	0,09	0,18	0,13
Breeding Turkeys				5,88	0,00	0,00	0,00	0,00	0,00	0,00	2,94	0,97	0,00	0,00	0,00	1,12
Fattening Turkeys				1,67	1,12	1,51	0,17	0,25	0,52	0,35	0,37	0,48	0,05	0,07	0,07	0,56

b. Most prevalent serotypes of *Salmonella* in the different poultry populations (2022)

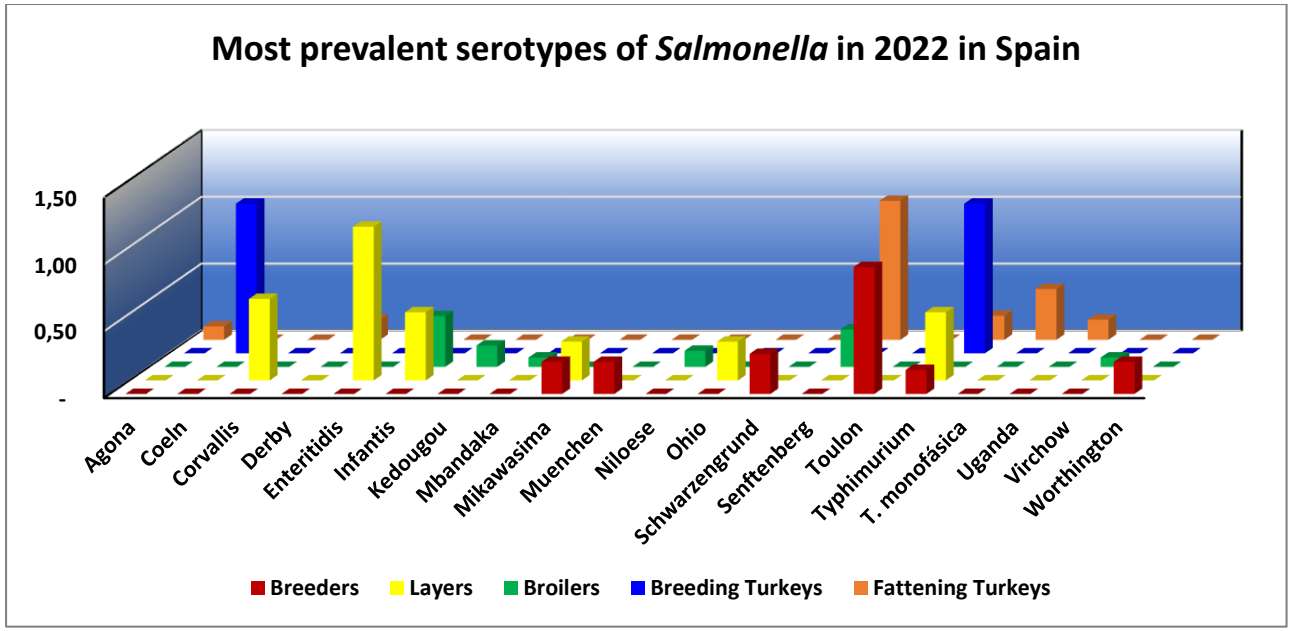

Most prevalent serotypes of *Salmonella* in 2022 in Spain
1,50
1,00
0,50
-
Agona
Coeln
Corvallis
Derby
Enteritidis
Infantis
Kedougou
Mbandaka
Mikawasima
Muenchen
Niloese
Ohio
Schwarzengrund
Senftenberg
Toulon
Typhimurium
T. monofásica
Uganda
Virchow
Worthington
Breeders
Layers
Broilers
Breeding Turkeys
Fattening Turkeys

Diagramme of veterinary services

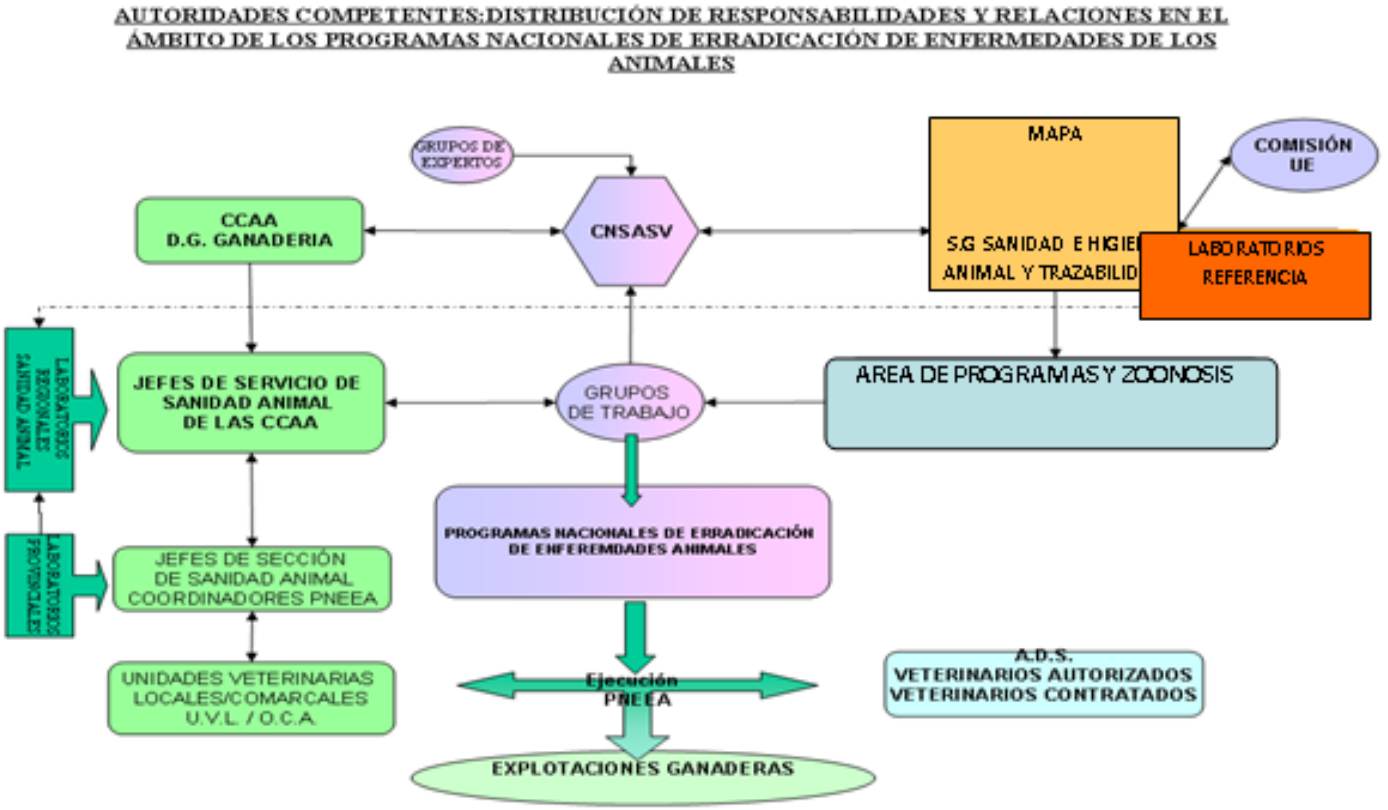
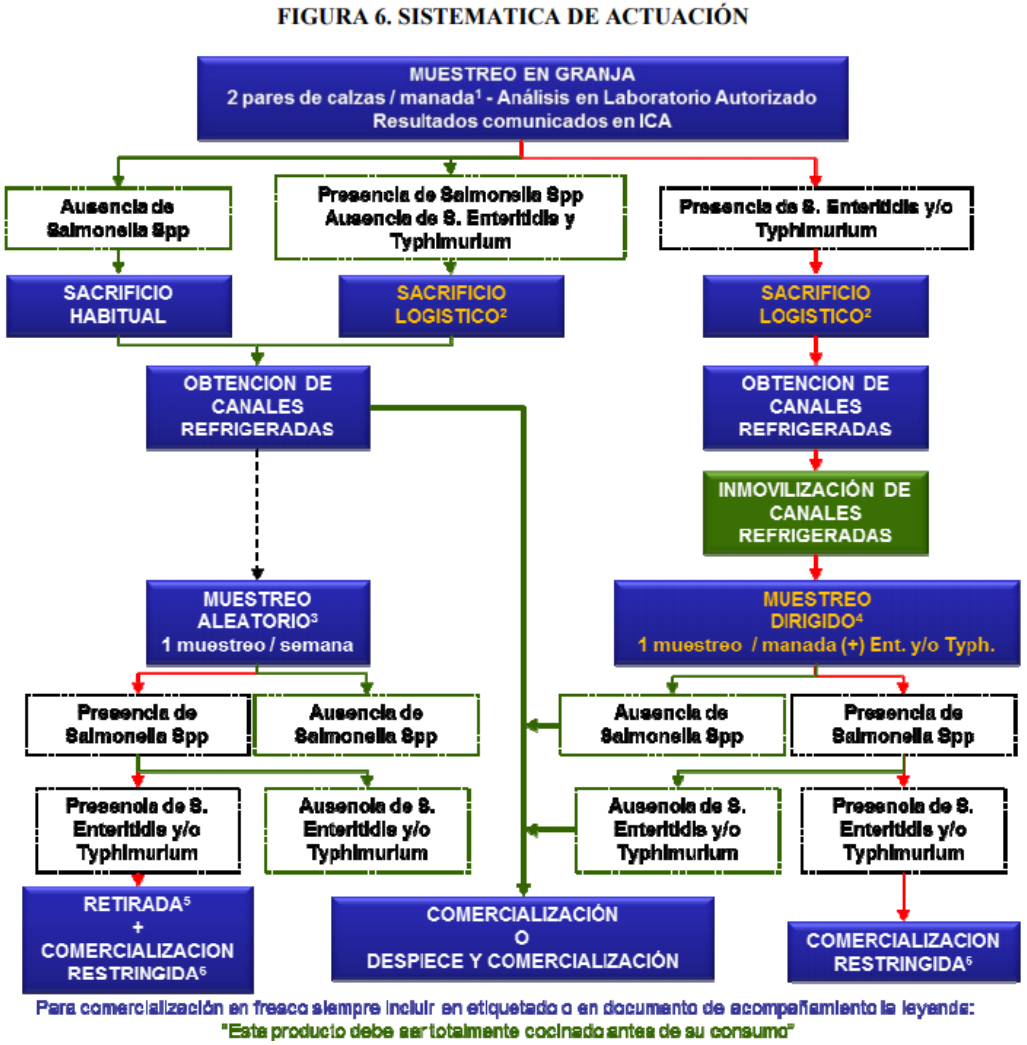


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Zoonotic *Salmonella* Programme
Control programme – Reduction of prevalence of *Salmonella* serotypes in Laying flocks of *Gallus gallus*

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	Spain
Disease	**ZOONOTIC SALMONELLA**
Animal population/Species	**Laying flocks *Gallus gallus***
Implementation Year	**2024**

CONTACT PERSON on Zoonotic *Salmonella* programme :

Name	Soledad Collado
e-mail	Scollado@mapa.es
Job type within the CA	Head of Service of Zoonoses

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Salmonella in Laying flocks *Gallus gallus* Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Regulation (EU) No 517/2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in laying hens of *Gallus gallus*,
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes ☒ **No** ☐

If no, please explain:

(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce the prevalence of *Salmonella enteritidis* (SE) and *Salmonella typhimurium* (ST) (including the serotypes
with the antigenic formula l,4,[5],12:i:-) in adult laying hens of *Gallus gallus* ('Union target') as follows:

☐ An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least 10% where the prevalence in the preceding year was less than 10%

☐ An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least 20% where the prevalence in the preceding year was more than or equal to 10% and less than 20%

☒ A reduction of the maximum percentage equal to 2% or less of positive flocks of adult laying hens

☐ The Member States has less than 50 flocks of adult laying hens: the target is to have not more than one adult flock remaining positive.

The Union target shall be achieved every year based on the monitoring of the previous year.

Definition of positive

A laying flock shall be considered to have produced a positive result for the purposes of determining whether the Community target has been met:

a) when the presence of the relevant Salmonella serotypes, other than vaccine strains, has been detected in one or more samples taken from the flock, even if the relevant Salmonella serotype is only detected in the dust sample;

b) when antimicrobials or bacterial growth inhibitors have been detected in the flock.

A laying flock testing positive shall only be counted once regardless of how often the relevant Salmonella serotypes have been detected in this flock during the production period or whether the sampling was carried out on the initiative of the food business operator or by the competent authority. However, if sampling during the production period is spread over two calendar years, the result for each year shall be reported separately.

In the event that a positive result is detected and the competent authority decided to perform a confirmatory analysis, the final valid result shall be the result of the said confirmatory analysis.

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as Salmonella, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies that had the scientific assessment of EFSA for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence.

Therefore, the project is a continuation of the previous programmes for the control of Salmonella annually presented to the EU from the establishment of the objective of reduction of the prevalence, who was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to rise the level of public health and animal health in the EU, that at the same time enable the rational development of

the farming sector and provides a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme has an harmonised surveillance, the results are comparable between MSs is based in an EU harmonised system, the results are comparable between MSs, and allow the analysis of the spatial and temporal trend at EU level.

It also has an international dimension, as it boostes the confidence not only of the EU Member States and its consumers but also of Third Countries, who can trust in a solid system which ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and economics, giving benefits worldwide

(maximum 500 words)

1.4 Target population and Area of the implementation

The programme covers all flocks of adult laying hens of *Gallus gallus* but does not apply to flocks for private domestic use or leading to the direct supply, by the producer, of small quantities of table eggs to the final consumer or to local retail establishments directly supplying the eggs to the final consumer. For the latter case (direct supply), national rules are adopted ensuring *Salmonella* control in these flocks.

The programme covers also all rearing flocks of future laying hens.

Yes ☒ No ☐

If no, please explain on which flocks:

It will be implemented in all holdings of *Gallus gallus* laying hens (both adult laying and rearing hens). On laying hen holdings where the producer directly supplies small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer, at least one FBO control should be done per year in all the flocks present in the farm at that moment. The competent authorities of the Autonomous Communities shall take any action required to ensure control and monitoring of salmonellosis with public health significance.

This programme will not be implemented at holdings that produce primary products for own consumption (for private domestic use). Holdings to which the programme will apply must be authorised and registered by the competent authorities.

For the purposes of the programme an epidemiological unit shall be considered to be a laying hen flock, defined as all poultry of the same health status kept on the same premises or within the same enclosure; in the case of housed poultry, this includes all birds sharing the same airspace, in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of breeding hens shall be identified individually.

To identify the flocks on a holding the REGA code will be used, consisting of a capital letter corresponding to the shed (this letter must be written on the entrance door to the shed) and

the date of entry of the birds into that shed, in the format mmyyyy. REGA+ SHED (CAPITAL LETTER)+ DATE OF ENTRY OF BIRDS (mmyyyy)

(maximum 500 words)

Fill in **Table 1**) **in the Annex** to this Form.

This programme will be implemented on the whole territory of the Member State

Yes ☒ No ☐

If no, please explain:

(maximum 500 words)

1.5 Notification of detection of target *Salmonella* serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ☒ No ☐

If yes, please describe the procedure briefly.

If no, please explain:

All legal or natural persons, and particularly veterinarians, must notify the competent authorities of any confirmed or suspected cases of *Salmonella*, whether or not they are related, and of action taken under the national programmes for the control of *Salmonella*. Accordingly, all confirmed or suspicious results from samples taken and analysed by operators for purposes other than those of the National Salmonella Control Plans (PNCS) must also be reported as if they were part of the plans.

If *Salmonella* spp. is isolated in samples taken in operators' own checks, the laboratories must serotype so as at least to be able to distinguish between the serotypes subject to monitoring for the purposes of this programme and other serotypes of Salmonella spp. The laboratory itself may undertake serotyping or commission another laboratory that is authorised for the purposes of the PNCS, as described at point 11c of this programme, to do so. If serotyping is positive for the serotypes subject to monitoring or for any other or the presence of these serotypes cannot be ruled out and the initial sample was taken in an own check, the competent authority must be notified as soon as possible, and never later than 24 hours after the laboratory and the owner of the holding receive the results of the analysis.

As soon as the operator becomes aware of the existence of a positive result, he must take the appropriate measures provided in the programme for cases in which the *Salmonella* serotypes

to which the check relates are detected. The competent authority may exceptionally carry out a confirmatory analysis if it considers this appropriate.

All the results of own checks must be recorded using the dedicated computer application used by the authorised laboratories to communicate results, without prejudice to the contents of the previous paragraph.

To ensure suitable traceability of the samples taken during own checks and official monitoring and in order to ensure suitable computer processing of the sampling data for this programme, the sampled flocks shall be identified as specified at point 3 of the programme.

The competent authorities of the livestock service and Public Health will between them ensure due reporting of positive results.

(maximum 500 words)

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of Salmonella cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on S. Enteritidis and S. Typhimurium.

During 2004, the monitoring and data collection of Gallus gallus laying flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents.

Since the beginning of the implementation of *Salmonella* Control Programme in laying hens until nowadays, the prevalence of *Salmonella* has dropped from 15,6% (2008) to <2%, which corroborates the effectiveness of the programme.

The most prevalent salmonellas with importance in public health in 2022 are *S*. Enteritidis in first place, followed by *S*. Typhimurium and *S*. Typhimurium monophasic strain.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of laying flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining biosecurity measures in free-range production systems, that are increasing progressively as a result of consumers' demand. These production systems could make difficult to guarantee a Salmonella-free environment, and control measures should focus on those achievable actions, such as feed control, hygiene practices between flocks, correct training and awareness of all workers, limited external visits, frequent rodent control, keeping clean and without residues the outdoors' facilities, keeping controlled the herbage, thoroughly cleaning and disinfection techniques after a positive result, with adequate verification analysis, by-products and manure management, etc.

Fill in **Table 4** (as appropriate) **in the Annex** to this Form.

1.6. Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.
See reply in the point 1.5 (repeated question).

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the *Salmonella* in Layers *Gallus gallus* situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks. **Yes ☒ No ☐** If yes, please make a short description of the most relevant biosecurity measures applied in order to prevent Salmonella contamination of their flock and please quote the document describing them, if any. Also please specify if biosecurity is part of the salmonella programmes or if there is national legislation in place for the implementation of biosecurity. Specify if there is a national guidance available for the biosecurity measures to be implemented and if this guidance is easily accessible by the FBO's. If no, please describe.
Biosecurity measures are part of the SNCP and there are national rules reinforcing them (Royal Decree 637/2021, establishing basic rules for the management of poultry farms and national Animal Health Law 8/2003, that states general rules related with prevention, control and eradication measures, sector health organisation, authorisation and marketing of animal health and animal feed products, and the fees, inspections and sanctions in case of shortcomings). These rules are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic Salmonella in laying farms and a general

national work guideline for the prevention and control of Salmonella in all poultry populations, published to sum up the legal measures established in the legal provisions.

The guidelines and the information of general biosecurity are public and available at the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Within all these regulations, it is specified that the holder of the poultry farm must take protected husbandry measures to control the entry or contamination by Salmonella spp in the farm, and in particular that:

- the design and maintenance of the farm facilities is adequate.

- appropriate rodent control measures are carried out.

- adequate washing, cleaning and disinfection measures are carried out in the rearing sheds, production sheds, annexed structures and other structures, production facilities, annexed structures, as well as the material and utensils used in production activities.

- adequate measures are adopted to prevent the transmission of Salmonella spp. through drinking water.

- appropriate measures are taken to prevent the presence of Salmonella spp in raw materials and feedstuffs.

Therefore, without prejudice to the provisions of Royal Decree 637/2021, of July 27, establishing the basic rules for the management of poultry farms, the owner of the farm must take the necessary measures to control the entry or contamination by *Salmonella* spp in the farm, as described in the as described in section 14 of the national program.

Biosecurity measures will be checked at least once a year using the guideline protocol for checking biosecurity measures for holdings of laying hens in this programme (see protocol in the programme available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx).

These measures will be checked at the same time as official sampling in the flock takes place. The data gathered in such surveys must be recorded using the computer application in the 'Biosecurity' section.

If, in the course of an inspection, shortcomings in the biosecurity measures are detected, this will be made known to the owner of the holding by means of a report in at least triplicate for the owner of the holding and his legal representative or the person in charge of the animals, setting out all the shortcomings and the deadlines set for them to be remedied.

The official veterinarian shall adopt a proportionate and progressive approach in his work to enforce biosecurity rules and measures.

The competent authority may, if necessary, make use of the measures established in Chapter IV, Title V, of Law 8/2003 on animal health. This is without prejudice to other measures or

penalties which may be adopted in respect of that flock or throughout the holding, depending on the type of shortcoming. The measures to be adopted to prevent health risks depend on the seriousness of the shortcoming and may range from shutting down the holding to the loss of the health authorisation for operating a holding.

The guideline protocol shall be observed in order to check and assess the biosecurity measures at holdings (biosecurity survey included in the programme and available in MAPA's website).

2.1.2 Minimum sampling requirements for food business operators (FBO)

Samples at the initiative of the FBO must be taken and analysed to test for the target *Salmonella* serovars respecting the following minimum sampling requirements:

a. Rearing flocks: day-old chicks, four-week-old birds, two weeks before moving to laying phase or laying unit
b. Adults breeding flocks: every 15 weeks during the laying period

Yes ☒ No ☐

if no, please explain - Indicate also who takes the FBO samples, and, if additional FBO sampling, going beyond the minimum sampling requirements, is performed, please describe what is done

Samples shall be taken in accordance with the minimum requirements laid down in Part B of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Zoonosis / Zoonotic agent Salmonella spp with public health significance (ST and SE)

Flocks of birds producing eggs for human consumption:

1.1. Rearing flocks.

1.2. Adult breeding birds

Stages of production to be covered by sampling

I. Day-old chicks

II. Pullets two weeks before transfer to the laying unit

III. Every 15 weeks during the laying phase from 24 +2 weeks)

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding Salmonella, as reflected in section 14 of the programme.

The owner of the holding shall be responsible for carrying out own checks, including sampling, in the form and under the conditions provided for by this programme. Sampling may also be carried out by qualified staff of the laboratory performing the analyses. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

All the results of the analysis on the samples must be known before the animals leave for the slaughterhouse and suitably notified in accordance with the legislation in force.

The data and information obtained from holdings where own checks are performed (Own-check Sampling Annex) and the laboratory results shall be recorded using the computer application for the National Programme for the Control of Salmonella https://servicio.mapa.gob.es/ The results for those own-check samples and all the information accompanying them have to be recorded on the ATC application within one month of receiving the laboratory result, on the understanding that - barring exceptions - results will be available on average within 10-15 days of the date of sampling. All the data from the sampling annex must be properly filled in because it will not be possible to record the samples on the application if any data are missing.

All the samples and data referring to the flocks sampled (official controls and own checks) that are not recorded on the Ministry's applications will not be valid for the purposes of the PNCS.

Nevertheless, any positive result for Salmonella, which is considered to have public health significance, must be notified as laid down in the PNCS.

2.1.3 Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 517/2011

Yes ☒ No ☐

If no, please explain

A. MINIMUM REQUIREMENTS FOR SAMPLING IN OWN CHECKS

7.1 Rearing flocks

a) Day-old chicks:

1. One sample made up of from 10 samples taken of the internal coverings of the cages transporting the chicks taken when they are delivered to the holding. The bases of the cages may be used directly as a sample, which will be sent either whole or in parts to the laboratories responsible for processing samples and may be made up of a single or more than one sample, or

2. Liver, caecum and yolk sac of 60 chicks (these parts of the viscera can be removed and processed as a single sample), or

3. A sample made up of meconium from at least 250 chicks.

b) pullets two weeks before transfer to the laying unit (or the start of the laying phase):

1. Pooled fresh droppings each weighing at least one gramme, collected at random from at least ten different points of the shed in accordance with the following table. Droppings may be pooled for analysis in a single sample composed as follows:

No of birds kept in a shed/ No of portions of faeces to be taken per shed/group of sheds on holding

1-24	(same number as the number of birds, up to a maximum of 20)
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60.

2. The samples shall consist of two pairs of boot swabs of absorbent material which shall be used for collecting representative samples of faeces in a sector covering at least 100 paces for each pair of swabs. The two pairs of swabs will be sent whole and combined to the laboratories responsible for processing the sample.

In all cases, the boot swabs must be moistened with a diluent of 0.8% sodium chloride and 0.1% peptone in sterile deionised water or sterile water. Furthermore, measures must be taken to avoid the bacterial growth inhibitory effects which the disinfectants in the footbaths at the entrance to sheds may have.

Once moistened, they shall be placed over the boot covers or other normal protective layer and the wearer shall walk through the shed so as to take samples from all its sectors, including littered and slatted areas when slats are safe to walk on. All areas that are separated off within the shed shall be sampled.

7.2 Flocks of adult laying hens/laying phase

It is mandatory to take samples of faeces in all the flocks at the holding every 15 weeks, with the first sample being taken at 24+ 2 weeks.

The criteria for sampling are as follows:

a) In caged flocks, 2 × 150 grams of naturally pooled faeces shall be taken from all belts or scrapers in the house after running the manure removal system; In the case of step cage houses without scrapers or belts, 2 × 150 grammes of mixed fresh faeces must be collected from 60 different points of the pit beneath the cages.

In cage houses where a sufficient amount of faeces does not accumulate on scrapers or belt cleaners at the discharge end of belts, four or more moistened fabric swabs of at least 900 cm2 per swab shall be used to swab as large a surface area as possible at the discharge end of all accessible belts after they have been run, ensuring each swab is coated on both sides with faecal material from the belts and scrapers or belt cleaners.

b) In barn or free-range houses, two pairs of boot swabs or socks shall be taken. Boot swabs used must be sufficiently absorptive to soak up moisture. The surface of the boot swab must be moistened using appropriate diluents. In all cases, the boot swabs must be moistened with a diluent of 0.8% sodium chloride and 0.1% peptone in sterile deionised water or sterile water.

Once moistened, they shall be placed over the boot covers or usual protective layer placed on the boots and the wearer shall walk through the shed taking a route enabling representative samples to be taken from all parts of the shed or the respective sector. That route shall include littered and slatted areas provided that slats are safe to walk on. All separate pens within the same shed shall be included in the sampling. On completion of the sampling in the chosen sector, boot swabs must be removed carefully so as not to dislodge adherent material.

In multi-tier barn or free range houses in which most of the faecal material is removed from the house by dropping belts, one pair of boot swabs shall be taken by walking around in littered areas and at least a second pair of moistened fabric swabs shall be taken from all accessible dropping belts, as in the second paragraph of point (a).

The two samples can be pooled together to form one sample for testing.

B. MINIMUM SAMPLING REQUIREMENTS IN OFFICIAL CHECKS

1. Caged flocks

Sampling shall comprise the taking of three samples (2 + 1) of naturally mixed faeces from dropping belts, scrapers or deep pits, depending on the dropping collection system in use at each holding, according to sampling protocol described in point 7.2.a) of this program.

Further samples may be taken to ensure that sampling is representative, if this is made necessary by the distribution or size of the flock.

A minimum of approximately 150 to 200 grams shall be taken for each sample.

As there are normally several stacks of cages within a house and all must be represented in the sample, the sample shall be taken as described below:

- In systems where there are collection belts or scrapers, these shall be run on the day of the sampling before sampling is carried out so that only fresh droppings are collected.

- In systems where there are deflectors beneath cages and scrapers, droppings which have lodged on the scraper after it has been run shall be collected.

- In systems where faeces fall directly into a deep pit, faeces shall be collected directly from at least 60 different points in the pit.

2. Holdings without cages (other forms of breeding: barn, free range etc.)

Three pairs of boot swabs of absorbent material (2 + 1) shall be used for collecting representative samples of in a sector of least 100 paces for each pair of swabs and all areas of the premises must be included in the sampling.

Samples shall be taken according to sampling protocol described in point 7.2.b) of this program.

Further samples may be taken to ensure that sampling is representative, if this is made necessary by the distribution or size of the flock.

The boot swabs must be moistened with a diluent of 0.8% sodium chloride and 0.1% peptone in sterile distilled water, sterile water or any other diluent approved by the competent authority). Furthermore, measures must be taken to avoid bacterial growth inhibitory effects which the disinfectants in the footbaths at the entrance to sheds may have.

Once moistened, they shall be placed over the boots and the wearer shall walk through the shed so as to take samples from all its sectors, including littered and slatted areas when slats are safe to walk on. All areas that are separated off within the shed shall be sampled.

On completion of sampling, the boot swabs must be removed carefully so as not to dislodge adherent material. The boot swabs shall be placed in a bag, flask or other type of sterile container which shall then be sealed and labelled appropriately.

The competent authority may decide to replace one sample of faeces or one pair of boot swabs with a sample of dust containing at least 100 grams of dust collected at various points throughout the shed. Dust may also be collected from a surface of at least 900 cm2 using one (or more) moistened fabric swabs.

Such a dust sample shall be taken if:

• it is observed that the hygienic and sanitary and/or biosecurity conditions at the farm are inadequate;

• the holding has a history of positive findings;

• own checking has been found to be defective or non-existent.

The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling through a case-by-case evaluation based on epidemiological parameters, namely the biosecurity conditions, size of the flock or other relevant conditions.

Preparation of samples in the laboratory (official control and own checks).

a) Absorbent boot swabs:

The two pairs of boot swabs must be unpacked carefully to avoid dislodging adherent faecal material and combined to form a single sample (4 boot swabs) and must be submerged in 225 ml buffered peptone water (BPW) that has been pre-warmed to room temperature. If necessary, more peptone water may be added so that free liquid remains around the sample to permit Salmonella to migrate.

Swirl to fully saturate the sample and continue with the detection method.

b) Other samples of faeces and dust:

- The two faeces samples shall be combined and uniformly mixed and a 25 g sub-sample shall be collected for culture.

- Add 225 ml tempered buffered peptone water to the 25-g sub-sample and shake gently.

- Culture of the sample shall then be continued using the detection method indicated in this programme.

If sampling is being carried out by the competent authority, the third faeces or boot swab sample (or dust sample if such samples have been taken) must be analysed independently.

UNE-EN ISO 6887-6 'specific rules for the preparation of samples taken at the primary production stage' may also serve as a guide when preparing all these samples.

Identification of samples and results from official- control and own-check analyses.

Samples sent must be properly preserved and identified (in accordance with the model report to accompany the samples to the laboratory in the Sampling Sheet Annex) There are two model sampling sheet annexes, one for official control and the other for own checks given that, in own checks, it is not necessary to collect so much information as in official controls. In both cases it must be clearly visible that the samples are for the purposes of the PNCS, so as to avoid confusion with the holding's own samples.

Those annexes must be completed in their entirety, because all the data collected therein are necessary for evaluating the PNCS.

A copy or duplicate of the sampling annex must be kept on the holding and must be kept together with the test results sent by the laboratory so that all the documentation relating to the samples (sampling annex and test results) is available on the farm. That documentation must be available to the official veterinary services when the official controls are carried out for the purposes of the PNCS. The documentation required may be in hard copy or electronic format.

To ensure suitable traceability of the samples, in the test result reports must record the following at least:

1. Date when samples were taken.

2. Identification of the flock of birds, as described in this programme.

3. Poultry population (breeders, layers, broilers, fattening or breeding turkeys)

4. Samples (specimen, number and weight or volume) received in the laboratory and how mixed for analysis.

All statements of the results of analysis and sampling annexes for the purposes of the PNCS must include the following statement in clear, readily visible form: “THESE SAMPLES FALL UNDER THE SALMONELLA NATIONAL CONTROL PROGRAMMES”

When a vaccine strain has been detected, the laboratory serotyping report must include the following statement: " The flock shall consider negative because it has been isolated a vaccine strain".

2.1.4 Specific requirements laid down in Annex II.D of Regulation (EC) No 2160/2003 will be complied with where relevant.

In particular:

- due to the presence of SE or ST (including monophasic ST 1,4,[5],12:i:-) in the flock, eggs cannot be used for human consumption unless heat treated;

- eggs from these flocks shall be marked and considered as class B eggs

Yes ☒ No ☐

If no, please explain. *Indicate also if prompt depopulation of the infected flocks is compulsory*

1. MEASURES TO BE ADOPTED IN CASE OF POSITIVE RESULT FOR SALMONELLA SPP.

From the moment that Salmonella has been isolated and identified in a flock, eggs can no longer be sold for fresh consumption until it is ruled out that the serotype is one of the target serovars (SE, ST, STM).

With the aim of shortening the deadlines and limit the duration of the restrictions to the minimum possible, the laboratory responsible for isolation and identification will carry out the analysis as soon as possible, issue a first detection report when Salmonella has been isolated and identified, and send it to the Competent Authority (CA) of the corresponding Autonomous Community (CA), as soon as possible, and always within 24 hours from obtaining the result.

At this moment, the SSVVOO (Official Veterinary Services) of animal health will communicate it:

- to the farmer, so that, once the analytical result is known, he/she does not commercialize eggs for fresh consumption, and carries out all the necessary actions to comply with the regulations in force in this respect.

- to the SSVVOO of public health, so that they can supervise the correct withdrawal of the sale of those eggs.

Subsequently, and always as soon as possible, the isolated strain of Salmonella will be serotyped.

Based on the group diagnosis, the laboratory that carries out the serotyping, will issue a first serotyping report, which will state whether target Salmonella serovars (*S*. Enteritidis and *S*.

Typhimurium, including its monophasic variant) are discarded, or if on the contrary, a target serovar (Enteritidis or Typhimurium, including its monophasic variant) cannot be discarded.

If the first option occurs (detected serovars are not EU target serovars), upon receipt of this report by the SSVVOO of livestock, the restrictions imposed will be lifted.

1. If the target serovars are discarded, two situations arise, depending on whether the laboratory is able to identify additional serovars to the target serotypes under control or not:

- Those laboratories that are only able to identify the target serovars under control, will not need to do anything else after the issuance of this first serotyping report (no further reports would be necessary).

- In the event that the laboratories are able to identify additional serovars in addition to the target serovars under control, serotyping will continue until a second serotyping report is issued noting the serovar identification.

2. If the target serovars under control are not discarded, it is necessary to continue with the serotyping procedure until the second serotyping report is issued, and there are also two situations, depending on whether the laboratory is able to identify additional serovars to those target serovars under control or not:

- Those laboratories that are only able to identify the target serovars under control, will issue a second serotyping report indicating that the serovars under control have been discarded, or on the contrary, indicating the target serotype under control that they have identified.

- In the case of laboratories that are able to identify additional serovars to those target serovars under control, they will continue with the serotyping until issuing a second serotyping report, stating the identification of the serovar (which could be a target serovar under control or another).

If necessary, the differentiation of the vaccine strain (with the appropriate differentiation methods according to the vaccine used) or the confirmation of monophasic S. Typhimurium (by a PCR method) will also be carried out.

As mentioned above, in order to correctly carry out the differentiation of vaccine strains, it is necessary for the laboratory to have information on the vaccination status of the herd and the vaccine used in each case.

If after the issuance of this second report, the target serovars under control are discarded, after the receipt of this report by the SSVVOO of livestock, the restrictions imposed will be lifted.

All reports will be issued within 24 hours after obtaining the result, and will be sent to the SSVVOO of livestock of the corresponding autonomous community, within 24 hours after its issuance.

The Central Veterinary Laboratory has sent a technical note to all laboratories participating in the NCCP, describing the procedure to be followed by the laboratories that carry out the detection and serotyping of these strains.

2. MEASURES TO BE ADOPTED IN CASE OF POSITIVE RESULT FOR S. ENTERITIDIS OR S. TYPHIMURIUM (INCLUDING ITS MONOPHASIC STRAINS):

The minimum measures to be adopted when the presence of S. Enteritidis or S. Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, is detected in a flock of birds are as follows:

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection in accordance with the epidemiological enquiry attached to the programme. Where appropriate, official samples of feed and/or water used on the holding or to supply the flock may be taken.

2. No live birds may be moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document made out by the competent authority stating at least the number of animals and the necessary information for identifying the holding and the transporter.

When birds from infected flocks are slaughtered or destroyed, steps must be taken to reduce the risk of spreading zoonoses as far as possible. Slaughtering shall be carried out in accordance with Community legislation on food hygiene.

3. Products obtained from these birds may be placed on the market for human consumption only in compliance with the Community legislation in force on food hygiene and with part E of Annex II to Regulation (EC) No 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

4. A rigorous check on the biosecurity measures applied to all flocks at the holding will be carried out in accordance with the guideline protocol for checking biosecurity measures at holdings with laying hens. The correct performance of self-monitoring for these flocks will also be verified.

5. Eggs originating from flocks with unknown health status, that are suspected of being infected or that are infected with Salmonella serotypes for which a target for reduction has been set or which were identified as the source of infection in a specific human foodborne outbreak, may be used for human consumption only if treated in a manner that guarantees the destruction of all Salmonella serotypes with public health significance in accordance with Union legislation on food hygiene.

a) they shall be considered class B eggs as defined in Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 on marketing standards for eggs;

b) they shall be marked with the indication referred to in Article 10 of Commission Regulation (EC) No 589/2008 which clearly distinguishes them from Class A eggs prior to being placed on the market;

c) access to packaging centres shall be prohibited unless the competent authority is satisfied with the measures to prevent possible cross-contamination of eggs from other flocks.

6. Once the birds from the infected flock have been slaughtered or destroyed, efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of Salmonella spp. in the environment.

Verification of cleaning and disinfection should be done according to point 17 of this programme.

7. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected.

Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

8. The competent authorities shall be informed of the dates of slaughter or destruction of the flock, disinfection, taking of environmental samples and restocking, and all of these processes shall be duly recorded for possible consultation by the competent authorities. Preventive depopulation of the shed in which the positive flock was kept and slaughter or destruction of the animals, and restocking, must all take place under official supervision.

9. All the measures set out above shall be extended to the entire productive cycle of the flock.

10. A routine official control shall be carried out on all the other flocks on the holding.

11. If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anybody who can be considered as a risk, in order to determine whether there are any Salmonella spp. carriers among them.

If, however, a serotype not concerned by the control programme is identified, the following measures will be taken:

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

2. Thorough checking of biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on laying poultry holdings.

2.1.5 EU microbiological criteria in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*

If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g. *Measures implemented by the FBO (farm level)*
In order to clarify the SNCP of poultry, this text was amended as a part of the Action Plan approved after the recommendation of report ref DSG(SANTE) 2019-6597 of the EU audit to evaluate SNCP carried out in November 2019, stating that the CA should ensure that only broiler and turkey flocks that have been sampled for Salmonella with a known test result can be sent for slaughter. In accordance with Royal Decree 361/2009 on food chain information, the operator of the livestock holding must ensure that in all shipments of animals to the slaughterhouse, full information on the results of all analyses of samples taken that have importance for human health, in the framework of the surveillance and control of Salmonella is sent to the slaughterhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or last analyses, if the samples have been taken in the near future) has been negative or positive to Salmonella spp. and, in this last case, in addition, if it is negative or positive to S. Enteritidis or S. Typhimurium, and the information of the result/s of such analysis must be included in the FCI (Food Chain Information) to be considered complete. If a flock on the holding tests positive for S. Enteritidis or S. Typhimurium, the operator of the livestock holding must also ensure that no live birds are moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.
Measures implemented by the FBO (slaughterhouse level)
Slaughter at the slaughterhouse shall be carried out in accordance with the provisions of Regulation (EC) No. 853/2004, which lays down specific hygiene rules for food of animal origin, and in particular Section II of Annex III thereof. When a positive herd is received at the slaughterhouse, it is logistically slaughtered, i.e. the herd is slaughtered last in the daily slaughter order to minimize the possibility of cross-contamination, followed by cleaning and disinfection. This is carried out in line with the provisions of Regulation (EU) 2019/627 with the aim of reducing contamination of other animals or their meat as much as possible. In addition, in accordance with the provisions of Regulation (EC) No. 2073/2005,

slaughterhouses shall include in their sampling plans poultry carcasses from flocks whose Salmonella status is unknown or positive for Salmonella Enteritidis or Salmonella Typhimurium.

There is a “Manual for the broiler sector in Spain for compliance with Regulation (EU) No 1086/2011 amending Regulations (EU) No 2160/2003 and (EC) No 2073/2005”, which, although it is voluntary, can provide guidance as to the correct way of handling birds slaughtered in slaughterhouses in relation to Salmonella.

As an example of the possible system of action, we attached the management diagram of birds sent to a slaughterhouse (see part IV: Maps), recommended in the "GUIDE FOR THE MEAT POULTRY SECTOR IN SPAIN FOR COMPLIANCE WITH REGULATION (EU) No. 1086/2011 AMENDING REGULATIONS (EU) No. 2160/2003 AND (EC) No. 2073/2005", with some additional issues that are carried out voluntarily by the slaughterhouses that apply the guide, such as the immobilization of the carcasses sampled until the results are available.

Guide available through: https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf

Measures implemented by the CA (farm and slaughterhouse level)

The official veterinarian is responsible for verifying that the correct food chain information is passed on as required pursuant to RD 361/2009: accordingly, he or she must check that the livestock holdings are passing this information to the slaughterhouses in a consistent and effective, valid and reliable manner and ensure that the relevant animal health and food safety information, including that relating to the results of Salmonella testing, is also passed on. Provision is thus made for slaughterhouses to only accept animals for which the relevant information on the holding of origin has been received. As a general rule, the information should be received at least 24 hours prior to the arrival of the animals. Slaughter in slaughterhouses must take place in accordance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and in particular Section II of Annex III.

Official controls must be carried out in accordance with Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules regarding the performance of official controls on meat production and regarding production and relaying areas for live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627, of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council and Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council. No. 2074/2005 of the Commission as regards official controls.

The provisions of Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs, also apply in relation to the criteria for Salmonella in poultry meat. Once positive results for S. Enteritidis or S. Typhimurium are found in a consignment, the official veterinarian will ensure that targeted sampling and tests using the EN/ISO 6579 methodology or a validated alternative

method are carried out, and lastly that the carcasses are withdrawn from the market and destroyed or that the destination previously given for the product is changed.

2.1.6 Laboratory accreditation

Laboratories in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation

Yes ☒ No ☐

If no, please explain

The Central Veterinary Laboratory in Algete (Madrid) of the Ministry of Agriculture, Fish and Food is the National Reference Laboratory for all serotypes of Salmonella in animals.

Laboratories analysing official samples as part of the programme must be established, recognised or designated by the competent bodies in the Autonomous Communities. These official laboratories must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or must apply quality assurance systems in accordance with that standard. They must also participate in the ring tests organised or co-ordinated by the National Reference Laboratory.

The laboratories participating in the programme for the purposes of carrying out own checks must be recognised by the competent authorities of the Autonomous Communities in which they are established and must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or apply quality assurance systems in accordance with that standard. Laboratories must also regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory.

The list of participating laboratories must be published, for information purposes, at least on the MAPA website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/listadolaboratoriosatcycoporccaasalmonella_15062022_tcm30-431063.pdf

The competent authorities of the Autonomous Communities shall notify the Ministry of Agriculture, Fish and Food of the laboratories referred to in the previous paragraph or of any modifications to them so that the list may be published at least on the departmental website for information purposes.

Where a laboratory serves at the same time as an Autonomous Community's official laboratory and participates in the own-check programme, it must notify the relevant competent authority or authorities and ensure that the two activities are managed separately, and is subject to monitoring and periodic inspection by the competent authority to check that these are separate. If it fails to notify the authorities, or cannot guarantee that the activities are kept separate, it cannot operate as an official laboratory.

The results obtained by authorised laboratories for both official monitoring and own checks shall be valid and applicable throughout the country. Laboratories must reject samples which do not meet the requirements specified in this programme.

2.1.7 Analytical methods

The **analytical methods** used for the detection of the target *Salmonella* serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ ISO 6579-1:2017/Amd 1:2020. "Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp. – AMENDMENT 1: Broader range of incubation temperatures, AMENDMENT to the status of Annex D, and correction of the composition of MSRV and SC".
Serotyping is performed following the Kaufman-White-Le Minor scheme.

Yes ☒ No ☐

If no, please describe the alternative method(s) used.

For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.

Yes ☒ No ☐

If no, please explain. If time limits are exceeded, please indicate what is done.

Salmonella spp. shall be isolated in accordance with Standard EN/ISO 6579-1, entitled "Microbiology of food and animal feedingstuffs. Horizontal method for the detection of Salmonella spp. in animal faeces and in samples at primary production level" which uses a semi-solid culture medium (modified semi-solid Rappaport -Vassiladis - MSRV) as a single selective enrichment medium. The semi-solid medium should be incubated at 41.5 ± 1 °C for 2x (24±3) hours. At least one isolate from each sample showing a positive reaction shall be typed, in accordance with the Kaufmann-White-Le Minor scheme. Laboratories may type their own Salmonella isolates or send them other laboratories authorised within the PNCS to be typed. The laboratory where typing takes place must issue a report including its results and send it to the laboratory that sent the isolates to be typed. The recording of results in the application and the notification of results as indicated in this programme are the responsibility of the laboratory that isolated the Salmonella. To prevent any delays in obtaining and notifying the results of typing:

• The isolate must be sent to another laboratory for typing no more than 24 hours following isolation.

• Typing must begin in the laboratory no more than 24 hours following receipt of the isolate in the laboratory.

• The issue and dispatch of the results report from the typing laboratory to the laboratory that sent the isolate, or the notification of the results, as appropriate, must take place no more than 24 hours after the results are obtained in the laboratory.

• The recording in the application and the notification of positive results by the isolating laboratory must take place within the deadlines laid down in this programme.

Alternative methods

Alternative methods may be used instead of the methods referred to above, if validated in accordance with the latest version of EN ISO 16140-2 (for alternative detection methods).

Storage of strains

At least strains isolated from samples collected by the Competent Authority shall be stored for possible further characterization and antimicrobial susceptibility testing, as determined by Implementing Decision (EU) 2020/1729 of 17 November 2020 on antimicrobial resistance surveillance and reporting Decision 2013/652/EU of 12 November 2013 on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, using normal culture collection methods, which should ensure the integrity of the strains for at least two years.

Pursuant to that Decision, strains isolated from the own-check samples may also be stored to that end if the competent authority so decides. To that end, the official control laboratories must send all strains of Salmonella isolated in the framework of the PNCS to the National Reference Laboratory (Algete). Own-check laboratories must also send the National Reference Laboratory (Algete), on request, any strains obtained in the framework of the PNCS. The frequency of dispatch of such strains shall be as agreed between the National Reference Laboratory and the laboratories.

2.1.8 Transportation and storage of samples

Samples are transported and stored in accordance with point 3.1. of the Annex to Regulation (EU) No 517/2011. In particular, samples examination shall start in the laboratory within 4 days after sampling.

Yes ☒ No ☐

If no, please explain the actions taken in case time limits are exceeded

Samples shall be sent to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection, preferably by express mail or courier. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat (over 25°C) and exposure to sunlight are avoided. At the laboratory samples shall be kept refrigerated until examination, which shall wherever possible be started within 48 hours of receipt and always within 96 hours of sampling.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements. Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured. Structure and organization of the Competent Authorities (from the central CA to the local CAs) Please provide a short description and reference to a document presenting this description
Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders. For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters. The Subdirectora-te-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease. The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures). Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results. Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the “National Veterinary Health Warning System Committee” (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health, Consumption and Welfare, for zoonoses. Its tasks include the following:

a) Coordinating animal health actions across the different administrations.

b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.

c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.

d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks

located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc, and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an aditionnal quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents available on the website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.8.

2.3.1 Official controls at feed level

Please describe the **official controls at feed level** (including sampling)
Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities. As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The

producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of *Salmonella* spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for Salmonella (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for Salmonella, an identification of the serotype must be requested. Only in the case of S. Enteritidis, S. Typhimurium, S. Infantis, S. Virchow and S. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp, the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of Salmonella and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of Salmonella in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including Salmonella. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding, flock and hatchery levels

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as Salmonella control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of Salmonella. There are guides to Good Hygiene Practices that have been drawn up with the aim of encouraging the use of appropriate hygiene practices on holdings for monitoring hazards in primary production and related activities and are specifically aimed at the prevention and control of Salmonella of public health importance. To this end, model Guidelines to Good Hygiene Practice on Laying Hen Farms have been produced in conjunction with representatives of the laying hen sector (INPROVO - Organización Interprofesional del Huevo y sus Productos, Inter-professional Egg and Egg Products Organisation) and the Ministry of Agriculture, Food and Fish. They are available in printed form for distribution to livestock farmers and the competent authorities, and on the MAPA website: http://www.mapa.es/ or the INPROVO website www.inprovo.com.

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Operators of laying hen holdings must have a code of good hygiene practice in place to achieve the aim of this national Salmonella surveillance and control Programme, and shall ensure that the health information is kept up-to-date. In addition, the following records must be kept at holdings:

a) A record of the type and source of feed supplied to the animals.

b) A record of the outbreak of diseases that could affect the safety of animal by-products.

c) An up-to-date visitors' register, listing the people and vehicles that have entered the holding.

d) A record of medicinal treatments, containing the information specified under Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products, including the vaccinations referred to in this programme.

e) All the results of the Salmonella analyses and controls carried out on a flock, including those carried out in the hatchery or rearing shed of origin of the flock in question, must be kept by the owner of the holding for at least three years and the records of the flock currently in production must, without fail, be kept at the holding.

f) The holding register shall be used to record incoming and outgoing flocks of birds. The flock sheet must be kept for at least two years after the flock is slaughtered.

g) There must also be a documentary record of:

• the protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).

• analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of Salmonella with public health significance.

• the programmes and records of insect and rat extermination operations (dates, products used, procedure to check the effectiveness of the programme, etc.).

h) Producers of rearing pullets must report on the health status of the breeding flock of origin and on any vaccinations and own-checks during the rearing of the pullets; this information must accompany the pullets when they are transferred to the producing holdings.

The owner of the holding must be in possession of all the compulsory health documentation and record all the necessary data so that the competent authority can regularly check compliance with the health programme referred to in this paragraph as well as the code of good hygiene practices, in particular the records mentioned above (a),b),c),d) and e)).

Without prejudice to Royal Decree 637/2021, the holder must adopt protective livestock rearing measures to control the introduction of or contamination by *Salmonella* spp on holdings, and in particular:

a) The design and maintenance of the installations are suitable for preventing the entry of *Salmonella* spp.;

b) Appropriate measures are taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease; It is obligatory for holdings to carry out rat extermination programmes using their own resources or to have authorised undertakings do so.

c) Day-old chicks come from breeding holdings and hatcheries which that have passed the checks set up to prevent the vertical transmission of *S*. Enteritidis and *S*. Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:- and are certified by the supplier as coming from breeding holdings and flocks free of the five serotypes (*S*. Enteritidis, *S*. Typhimurium, *S*. Virchow, *S*. Infantis and *S*. Hadar). Buyers must be provided with the relevant documentation containing the results and dates of the laboratory analyses performed since the most recent official inspection.

During the rearing stage, day-old chicks and pullets two weeks before entering the laying phase must pass the corresponding checks for the two Salmonella serotypes. In the laying phase, the birds must always be accompanied by a certificate from the supplier to prove that the above checks have been carried out and passed. Where appropriate, they shall also be accompanied by a certificate attesting that the chicks have been vaccinated as laid down in the programme, and these requirements must be met before transfer and restocking of the laying shed.

d) Adequate washing, cleaning, disinfection and rodent control measures must be taken in rearing houses, laying hen houses and adjoining structures and also with regard to the material and utensils used for productive activities;

e) Analyses are carried out to check that cleaning and disinfection have been carried out properly.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipments, watering equipments, belts, pilars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes.

The detection methods used must be the same as for the other samples under the PNCS. The results for the same must be recorded using the MAPA computer application for own checks.

The samples must be recorded alongside the samples for the outgoing flock. The sampling sheet for own checks must be used when sending such samples to the laboratory. The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

If there is a positive result (we detect Salmonella spp.), cleaning and disinfection should be repeated.

f) The appropriate measures are taken to prevent the transmission of *Salmonella* spp by drinking water.

g) Relevant measures are taken to prevent the presence of *Salmonella* spp in raw materials and feedingstuffs. Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for *Salmonella* has been carried out and make express provision for such tests in the relevant HACCP system. The checks must include analysis of the corresponding samples, which will be made available to the health managers of the holdings receiving the feed. The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis;

h) Suitable training courses are given to the workers and owners of holdings, as appropriate.

i) Suitable health checks must be carried out to detect the possible source or sources of Salmonella contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation.

j) Appropriate vaccination programmes must be carried out where necessary.

k) Appropriate sampling and analyses are carried out to detect *Salmonella* spp.;

l) Adequate measures must be taken to ensure the traceability of eggs produced in accordance with the legislation in force.

m) The appropriate measures are taken in the event of positive cases of salmonellosis caused by any of the Salmonella serotypes concerned by the programme.

n) Appropriate measures are taken to ensure correct management of animal by-products not intended for human consumption.

b) Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:

■ in one flock per year per holding comprising at least 1,000 birds;
■ at the age of 24 +/- 2 weeks in laying flocks housed in buildings where the relevant *Salmonella* was detected in the preceding flock;
■ in any case of suspicion of *Salmonella* infection when investigating foodborne outbreaks in accordance with Article 8 of Directive 2003/99/EC or any cases where the competent authority considers it appropriate, using the sampling protocol laid down in point 4(b) of Part D to Annex II to Regulation (EC) No 2160/2003;
■ in all other laying flocks on the holding in case Salmonella Enteritidis or *Salmonella* t*yphimurium* is detected in one laying flock on the holding;
■ in cases where the competent authority considers it appropriate.

Yes ☒ No ☐

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by other sufficiently trained authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

Official monitoring of at least one flock of adult laying hens per holding per year shall be carried out at all holdings with over 1 000 birds. If possible, samples will be taken at the end of the production period, within the nine weeks before the birds are slaughtered. Sampling carried out by the competent authority as an official monitoring activity may replace sampling carried out on the initiative of the operator (own checks).

Sampling by the competent authority shall also take place at least:

a) At the age of 24 + 2 weeks in laying flocks housed in sheds where Salmonella has been detected in the preceding flock.

b) In any case of suspected infection by S. Enteritidis or S. Typhimurium, including monophasic strains of Salmonella typhimurium with the antigenic formula 1,4,[5],12:i:-, as a result of the epidemiological investigation of a food-borne outbreak under Article 8 of Directive 2003/99/EC of the European Parliament and of the Council or in any case where the competent authority considers it to be appropriate. In such cases, samples will be taken with the confirmation sampling protocol.

c) In all the other flocks at the holding in the event that any of the serotypes covered by the programme have been detected in one of the flocks at the holding.

d) In any case where the competent authority considers it appropriate.

During sampling all the data necessary to identify the sample and the flock from which it comes, and at least those set out on the sampling sheet annex, shall be collected.

The data and information obtained from holdings where official sampling is performed (sampling sheet and biosecurity surveys) and the laboratory results shall be recorded in the application of the National programme for monitoring Salmonella in laying hens.

Checks to detect antimicrobial veterinary medicinal products

In the case of sampling referred to in (b), (c) and (d), the competent authority shall satisfy itself by conducting further checks, namely by laboratory tests and/or documentary checks as appropriate to ensure that the results of examinations for Salmonella in birds are not affected by the use of antimicrobials in the flocks.

Where the presence of the Salmonella serotypes monitored under the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected the flock shall be considered infected for the purpose of the Union target.

Other official samples

Where considered appropriate, official samples of feed and water may be taken as well as environmental samples to check the effectiveness of cleaning and disinfection, including at other stages of the food chain as considered appropriate by the competent authorities.

c) Official confirmatory sampling (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery):

After positive official samples at the holding

☐ Always
☒ Sometimes (criteria apply)
☐ Never

After positive FBO samples at the holding

☐ Always
☒ Sometimes (criteria apply)
☐ Never

When official confirmatory sampling is performed, additional samples are taken for checking the presence of antimicrobials:

☒ Always
☐ Sometimes
☐ Never

Please insert any comments. Describe the criteria used to determine if confirmatory sampling is performed. Indicate also which samples (if any) are taken to check the presence of antimicrobials.

In exceptional cases, and with a view to ruling out false positives or false negatives for samples taken as part of official controls or own checks, the competent authority may decide to carry out confirmatory analyses, according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of Salmonella serotypes subjected to control in poultry farms", available on the MAPA's website:

i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected from a surface of at least 900 cm2, or 5 faeces samples or 5 pairs of boot swabs and two additional faeces or boot swab samples may be collected; however, a sub-sample of 25 grams must be collected of each faecal material and dust sample for analysis; all samples must be analysed separately, or ii) bacteriological investigation of the caeca and oviducts of 300 birds,

or iii) bacteriological investigation of the shell and the content of 4 000 eggs from each flock, in pools of maximum 40 eggs.

In addition to the set arrangements above, the competent authority will check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

Whenever confirmatory testing is conducted, additional samples can be collected for the possible testing of antimicrobials or bacterial growth inhibitors as follows: birds shall be taken at random from within each poultry house of birds on the holding, normally up to five birds per house, unless the competent authority deems it necessary to sample a higher number of birds.

Additionally, samples of feed and water can be taken to determine whether the results of the confirmatory test may have been affected by the use of antimicrobials.

If antimicrobials or bacterial growth inhibitors are detected, the Salmonella infection shall be considered to be confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a justification to the CA with the reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc, the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and Salmonella results, biosecurity measures, not relation with any foodborne outbreak last years, etc).

d) Number of official confirmatory samples

1	2	3	4
For routine samples taken at the holding	N of flocks positive to SE/ST	Out of the flock in column 2, N of cases where official confirmatory samples[3] were taken	Out of the N of cases in column 3, N of cases where confirmatory samples were negative

FBO samples[1]	24	2	1
Official samples[2]	34	5	2

(1) Reg 517/2011, point 2.2.1 of the Annex
(2) Reg 517/2011, point 2.2.2 of the Annex
(3) Reg 2160/2003, point II.D.4 of the Annex

What happened to the flocks counted under 4 (re checked for the presence of Salmonella? Checked for the presence of antimicrobials?

Insert text

In 2022, 7 flocks were sampled for confirmatory tests after positive results to SE/ST (monophasic strain included).

In 3 cases the confirmatory tests were negative and the following actions were varied. In some cases the birds were decided to be slaughtered and no more correlative routine sampling of the FBO and Official samples were taken. In other cases the restrictions were lifted and the sampling followed until the end of the productive life.

The premises were cleaned, disinfected and disinsected and before entering new birds it was made the sampling for verification of cleaning and disinfection, with negative results.

Flocks with negative results in the confirmatory tests are sampled to detect the use of antimicrobial products and in all cases results were negative.

e) Antimicrobial control

Article 2 of Regulation (EC) No 1177/2006 (**antimicrobials** shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).
For samples please describe the samples taken, the analytical method used, the result of the tests.

The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the Salmonella serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Vaccination

☐ Voluntary
☒ Compulsory
☐ Forbidden

The use of *Salmonella* vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.

Yes ☒ No ☐

If no, please explain. If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Laying hens shall be vaccinated pursuant to Regulation (EC) No 1177/2006.

All laying hens shall be subject to mandatory vaccination programmes against Salmonella enteritidis, to reduce shedding and the contamination of eggs, at least during the rearing phase. The only exceptions will be holdings that the competent authority deems to have adequate biosecurity measures and to have fully implemented a plan for monitoring and control of Salmonella and that have demonstrated its effectiveness by having tested negative for S. Enteritidis and S. Typhimurium, including monophasic strains of Salmonella typhimurium with the antigenic formula 1,4,[5],12:i:-, for at least the past twelve months (in own checks) and as long as the most recent official monitoring has likewise produced negative results for S. Enteritidis and S. Typhimurium, including monophasic strains of Salmonella typhimurium with the antigenic formula 1,4,[5],12:i:-.

However, the said vaccination will be compulsory in all laying-hen holdings engaging in intra-Community trade of eggs for human consumption.

Only vaccines with prior marketing authorisation from the Spanish Medical and Health Products Agency or the European Commission in accordance with Regulation (EC) No 726/2004 may be used for vaccinating flocks. Attenuated vaccines, for which there is no suitable way of bacteriologically distinguishing between vaccine strains and field strains, may not be used for the purposes of this control programme.

Live vaccines may not be used for laying hens during the laying phase unless they have demonstrated their safety and have been authorised for this purpose in accordance with Directive 2001/82/EC of the European Parliament and of the Council as amended by Directive 2004/28/EC or by the Spanish Medical and Health Products Agency.

Once vaccination has been carried out, at least the following information will be entered in the register of treatment with medicinal products: date of vaccination, name of the vaccine(s) administered, type of vaccine(s) administered, quantity (number of doses), name and address of the supplier of the medicinal product and identification of the batch of animals treated.

The owner of every rearing farm must certify the vaccination of every lot of chicks for the laying holding of destination, stating the type of vaccine used and the vaccination dates.

2.3.4 Efficacy of disinfection

Please describe the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...)

Once the shed housing the infected flock has been depopulated, an efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of Salmonella spp. in the environment.

The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipments, watering equipments, belts, pilars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes.

The detection methods used must be the same as for the other samples under the PNCS.

The results for the same must be recorded using the MAPA computer application for own checks.

The samples must be recorded alongside the samples for the outgoing flock.

The sampling sheet for own checks must be used when sending such samples to the laboratory.

If there is a positive result (we detect Salmonella spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected.

Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.5 Monitoring of the target Salmonella serovars (*Salmonella enteritidis, Salmonella typhimurium*)

Give a short summary of the outcome of the **monitoring of the target *Salmonella* serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain)
Monitoring and control of *Salmonella* in Spain has been carried out since 1993 in accordance with Council Directive 92/117/EEC concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning, repealed by Directive 2003/99/EC. During the period from October 2004 to September 2005, a reference study was carried out on the prevalence of Salmonella in flocks of Gallus gallus laying hens at Community level; the data were monitored and collected in flocks of Gallus gallus laying hens in accordance with the guidelines laid down at Community level by Commission Decision 2004/665/EC of 22 September 2004. The data obtained by holding according to the study showed the prevalence of serotypes Enteritidis and Typhimurium to be 51.5 % and 73.2 % for Salmonella spp. The development of the prevalence of Salmonella in flocks of Gallus gallus laying hens was as follows, S. Enteritidis being the most prevalent target serotype (see attached document layers prevalence). The most prevalent target serotypes in 2022 were *S*. Enteritidis, followed by S. TRyphimurium and *S.* Typhimurium monofasic strain.

2.3.6 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks
Legislative measures and provisions concerning the registration of livestock farms. The obligation to register livestock farms in Spain derives primarily from Article 39 of Law 8/2003 of 24 April 2003 on animal health.

More specifically, in poultry farming, the obligation to register poultry farms is regulated as follows:

Royal Decree 479/2004 of 26 March 2004 establishing and regulating a general register of livestock holdings. This refers to all livestock species.

They are to be identified by means of a code / with a registration number and classed in one of the following groups:

- egg-producing farms
- farms for breeding or rearing production poultry for producing eggs.

Legislative measures and provisions concerning flock identification:

For the purposes of the programme, an epidemiological unit shall be considered to be a flock of laying poultry, defined as all poultry reared for the production of eggs with the same health status kept on the same premises or within the same enclosure and constituting a single population in epidemiological terms; in the case of housed poultry, this includes all birds sharing the same airspace, in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

Flocks of laying hens must have an individual identification. Flocks shall be identified within a holding by means of a capital letter corresponding to the shed (the letter must be written on the door to the shed) and the date on which those birds entered the shed (mmyyyy).

To avoid errors, the date on which the birds entered the shed must be taken from the flock sheet or from the holding records containing the flock data. REGA+ SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mmyyyy)

2.3.7 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation
In specific cases, the competent authority may order the compulsory slaughter of birds testing positive for the *Salmonella* serotypes subject to monitoring. In those cases, slaughter must be undertaken in accordance with Articles 20 and 21 of Law 8/2003 on Animal Health. In cases where the competent authority orders compulsory slaughter, the owners of the birds will be entitled to compensation, provided that they have complied with the animal health legislation in force. The scales for compensation are fixed by the Ministry of Agriculture, Food and the Environment following consultation with the Autonomous Communities. The above scales are public and are included in Royal Decree 823/2010 of 25 June 2010, laying down the scales of compensation for the compulsory slaughter of animals covered by the national control programmes for Salmonella in breeding and laying flocks of *Gallus gallus* and breeding turkey flocks. The age of the birds for compensation purposes shall be considered to be their age when the competent authority ordered the compulsory slaughter.

2.3.8 System to monitor the implementation of the programme

Please describe
Taking into account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all of the results. Lastly, we have a monitoring plan for own checks and inspection of own-check laboratories: In order to verify that own checks are being performed correctly, the competent authority will implement the following Monitoring Plan for own checks and inspection of own-check laboratories (available in the website): The Official Veterinary Services will carry out quality control on the own checks of a percentage of holdings selected every year according to the following hierarchy of risk criteria: • holdings with own checks yielding negative results for the serotypes subject to monitoring and positive official control results. • holdings with own checks yielding negative results for the serotypes subject to monitoring regarding which any positive results are reported for public health purposes. • holdings with own checks yielding negative results for the serotypes subject to monitoring and analysis of the check on positive LODs. • random checks among holdings with own checks yielding negative results for the serotypes subject to monitoring and subject to not official checks. These shall be carried out on 10% of the holdings in every Autonomous Community. In any Autonomous Community with fewer than 10 holding checks shall be conducted on at least one farm. The control shall consist of an on-site inspection of the taking of samples for own checks and conduct of an investigation to check compliance with the requirements of the programmes.

In this case, the own-check sample shall be taken in the presence of the official veterinarian, who, as an observer, shall try to identify practices that are inconsistent with the sampling procedures set out in detail in the applicable national programmes for own checks. Critical aspects of these must be checked which presumably may influence the results (e.g. the use of peptone for enrichment on swabs, origin and expiry dates; sample representativeness: number of swabs and surface investigated; where appropriate, dispersal of the taking of the aliquots of droppings to make pools, etc. sufficiently representative). How and where samples are kept before being sent to the laboratory must also be investigated, as must compliance with the deadlines for their being received in the laboratory.

It is very important that, before own checks are carried out on holdings and whenever routine official checks are carried out, the information on the holdings recorded on the own checks application is consulted. During this inspection, the competent authority shall also put such questions as it deems appropriate and ask to see the necessary documentation concerning the conduct of own checks.

The official veterinarian must note down the results of the control in an inspection report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, will be used by the competent authority to draw up an appraisal report. Any anomalies detected shall be brought to the producer's attention without delay so that they may be remedied immediately for the purposes of subsequent own checks, regardless of any administrative effects arising from any particular case. The competent authority shall supply the individual responsible for taking own-check samples with a copy of the report.

Duplicate samples shall be taken if the competent authority sees fit. The official veterinarian shall take one of the samples using his own material and shall keep it in his possession. He shall send it to an official laboratory along with the sampling sheet. The other sample shall be taken by the individual responsible for taking own-check samples, using his own material. He shall retain that in his own possession, and it must be analysed in the same way as any other own check.

In those cases in which there are substantial discrepancies between the results of official controls and own checks for the same flock, the competent authority may, should it see fit, ask the own-check laboratory that analysed the strains isolated from that flock to supply them for analysis in an official laboratory in the Autonomous Community concerned.

Laboratory inspections shall be carried out in accordance with the document inserted above. Every Autonomous Community must have inspected all the laboratories on its territory within two years.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

***Note:** Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and especificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed.	Appropriate awareness and knowledgement of deadlines and requirements of the SNCP.

	(Low risk)	
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated egg or egg-products. Impact on public health, on food safety, on farmer's production (Medium risk)	Rigorous accomplishment of the control programme. Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and restrictive measures and improve animal health in order to avoid new cases.

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Knowledgement of the SNCP requirements in advance.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results.	Not fixed (must be done periodically or when considered, all	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for

Review and identification of possible data recording errors (fixing of bugs).	along the year N)	the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August-September (year N)	Intermediate follow-up technical report (data of first semester).
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view) Who are the target groups? How will the target groups benefit concretely from the project and what would change for them? Define the short, medium and long-term effects of the project. ***Possible examples:*** *reduction to 1% or less the maximum percentage of laying flocks of Gallus gallus remaining positive for the target Salmonella serovars: S. enteritidis (SE), S. typhimurium (ST)(including the antigenic formula 1,4,[5],12: i:-), S. hadar (SH), S. infantis (SI) and S. virchow (SV).*
The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agri-food chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 2% or less the maximum percentage of adult laying flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the *Salmonella* Control Programme.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Flocks subject to the programme

	Total number of flocks of layers in the MS	Number of flocks covered by the programme	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling will take place
Rearing flocks	**1460**		1460	10
Adult flocks	**3115**	3115	3115	1200
Number of holdings with more than 1,000 laying hens				1200
Number of flocks in these holdings				3200
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: “MAPA "

II. Targets for 2024

Table 2: Targets on laboratory tests on official samples from laying hens flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	2450
Serotyping	250
Antimicrobial detection test	30
Test for verification of the efficacy of disinfection	50

Table 3: Targets on official samples from laying hens flocks of *Gallus gallus*

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1460	3115
N of flocks in the programme	1460	3115
N of flocks planned to be checked (b)	10	1200
No of flock visits to take official samples (c)	10	1200
N of official samples taken	50	3650
Target serovars (d)	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
	X ☐ SE+ ST	X ☐ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	2	50
Possible N of flocks to be depopulated	2	45
Total N of birds to be slaughtered/culled	4000	1000000
Total N of eggs to be destroyed	n/a	60000
Total N of eggs to be heat treated	N/a	15000000

(a) Including eligible and non-eligible flocks
(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
(c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
(d) *Salmonella enteritidis* and *Salmonella typhimurium* = SE + ST; *Salmonella enteritidis, typhimurium, hadar, infantis, virchow* = SE+ ST + SH +SI + SV

Table 4: Targets on vaccination for laying hens flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the *Salmonella* programme	3115
Number of flocks expected to be vaccinated	3115
Number of birds expected to be vaccinated	70000000
Number of doses expected to be administered	210000000

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

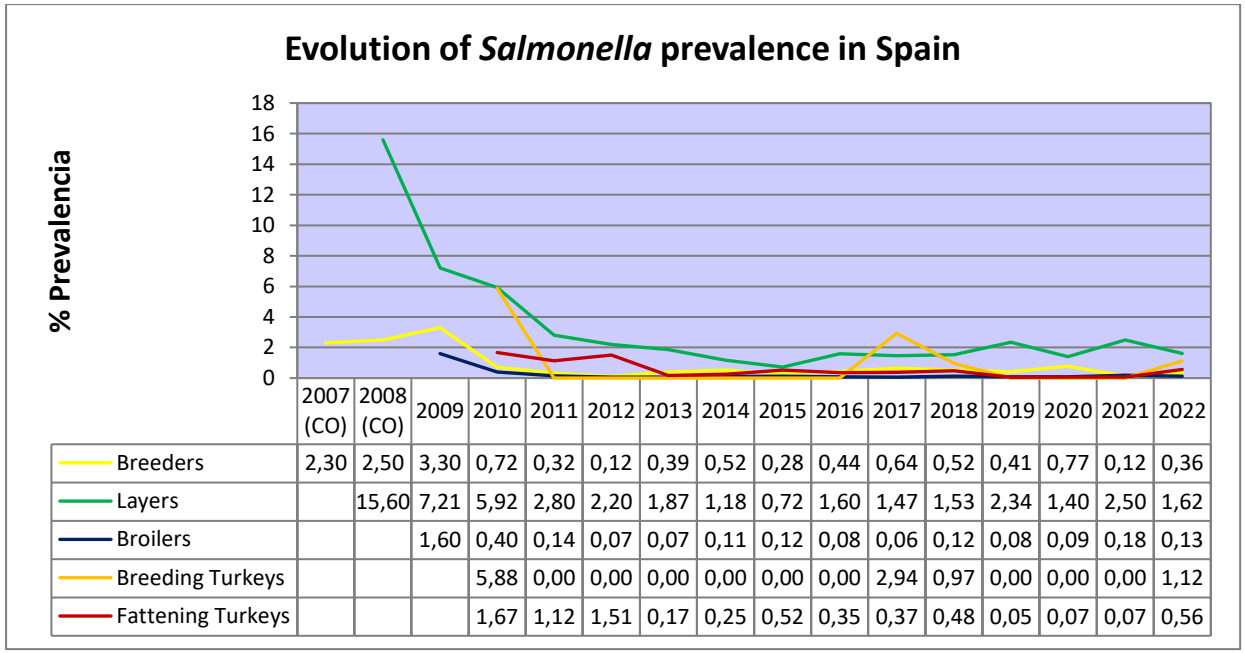
- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0517-20190310&qid=1652941558459
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2022)



	2007 (CO)	2008 (CO)	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Breeders	2,30	2,50	3,30	0,72	0,32	0,12	0,39	0,52	0,28	0,44	0,64	0,52	0,41	0,77	0,12	0,36
Layers		15,60	7,21	5,92	2,80	2,20	1,87	1,18	0,72	1,60	1,47	1,53	2,34	1,40	2,50	1,62
Broilers			1,60	0,40	0,14	0,07	0,07	0,11	0,12	0,08	0,06	0,12	0,08	0,09	0,18	0,13
Breeding Turkeys				5,88	0,00	0,00	0,00	0,00	0,00	0,00	2,94	0,97	0,00	0,00	0,00	1,12
Fattening Turkeys				1,67	1,12	1,51	0,17	0,25	0,52	0,35	0,37	0,48	0,05	0,07	0,07	0,56

b. Most prevalent serotypes of *Salmonella* in the different poultry populations (2022)

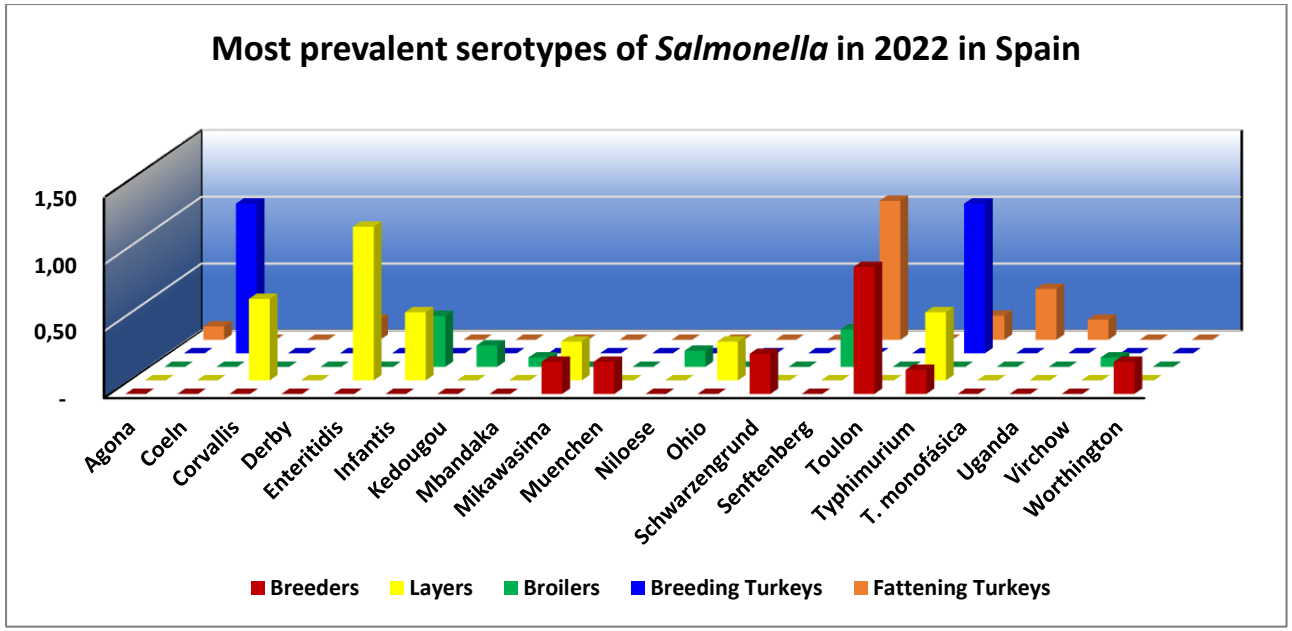
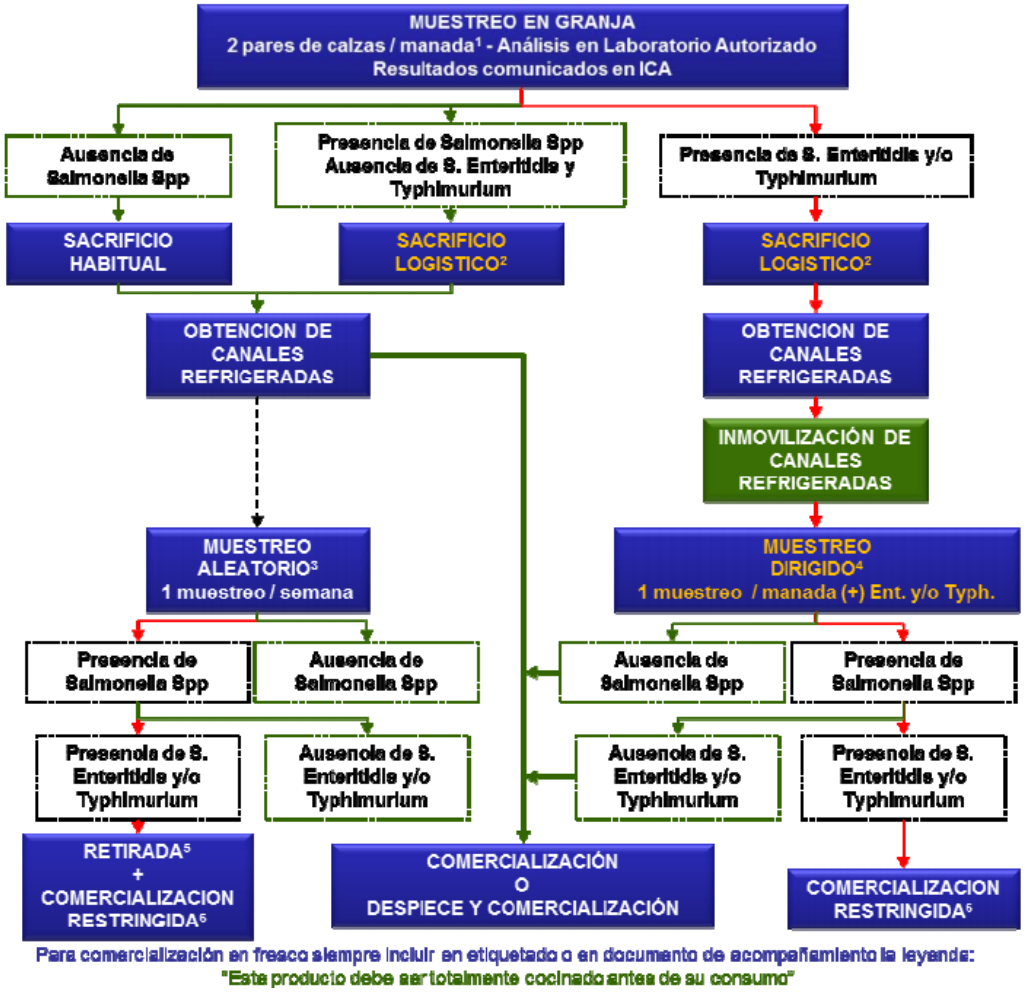


Diagramme of veterinary services

Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):

FIGURA 6. SISTEMATICA DE ACTUACIÓN



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Zoonotic *Salmonella* Programme
Control programme – Reduction of prevalence of *Salmonella* serotypes in Broiler flocks of *Gallus gallus*

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	Spain
Disease	**ZOONOTIC SALMONELLA**
Animal population/Species	**Broiler flocks *Gallus gallus***
Implementation Year	**2024**

CONTACT PERSON on Zoonotic *Salmonella* programme :

Name	Soledad Collado
e-mail	scollado@mapa.es
Job type within the CA	Head of Service of Zoonoses

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Salmonella in Broiler flocks *Gallus gallus* Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Regulation (EU) No 200/2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers,
broilers- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes ☒ No ☐

If no, please explain:

(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce the maximum annual percentage of flocks of *broilers* remaining positive to *Salmonella enteritidis* (SE) and *Salmonella typhimurium* (ST) (including the serotypes with the antigenic formula 1,4,[5],12:i:-)('Union target') to 1% or less.

Yes ☒ No ☐

If no, please explain:

The aim of this programme is to reduce *Salmonella* Enteriditis and *Salmonella* Typhimurium, including the monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, the maximum percentage of broiler flocks which test positive for these serotypes to 1% or less.

A flock of broilers shall be considered positive for the purpose of verifying the achievement of the Community target where: a) the presence of *Salmonella* Enteriditis and/or *Salmonella* Typhimurium (other than vaccine strains) was detected in the flock; or b) antimicrobials or bacterial growth inhibitors have been detected.

Positive flocks of broilers will be counted only once per round, irrespective of the number of sampling and only be reported in the year of the first positive sampling.

If *Salmonella* spp. is detected, the samples must be serotyped. If either of the mentioned serotypes are detected in the samples, appropriate measures will be taken in accordance with Regulation 2160/2003 and explained in point 2.1.4.

(maximum 500 words)

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as Salmonella, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies that had the scientific assessment of EFSA for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence.

Therefore, the project is a continuation of the previous programmes for the control of Salmonella annually presented to the EU from the establishment of the objective of reduction of the prevalence, who was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to rise the level of public health and animal health in the EU, that at the same time enable the rational development of the farming sector and provides a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme has an harmonised surveillance, the results are comparable between MSs is based in an EU harmonised system, the results are comparable between MSs, and allow the analysis of the spatial and temporal trend at EU level.

It also has an international dimension, as it boostes the confidence not only of the EU Member States and its consumers but also of Third Countries, who can trust in a solid system which ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and economics, giving benefits worldwide.

1.4 Target population and Area of the implementation

This programme will be implemented on all broiler flocks of *Gallus gallus*

Yes ☒ No ☐

If no, please explain on which flocks:

It will be applied to all holdings of broilers of the species *Gallus gallus* intended for commercial slaughter. On broiler holdings involved in the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer; at least one FBO control should be done per year in all the flocks present in the farm at that moment.

The competent authorities of the Autonomous Communities will take the necessary action to guarantee the control and monitoring of salmonellosis which is important in terms of public health. This programme will not be implemented on holdings which produce primary products for own consumption (for private domestic use). Holdings to which the programme applies must be authorised and registered by the competent authorities.

For the purposes of the programme, 'epidemiological unit' will mean the flock of birds, defined as all birds reared for meat production with the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit. in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003. Flocks of broilers will have an individual identification. To identify the flocks on a holding, the REGA code will be used: a capital letter corresponding to the shed (this letter must be written on the shed door) and the date of entry of the birds in the format mm/yyyy. REGA+ NAVE (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mm/yyyy).

Fill in **Table 1**) **in the Annex** to this Form.

This programme will be implemented on the whole territory of the Member State

Yes ☒ No ☐

If no, please explain:

(maximum 500 words)

1.5 Notification of detection of target *Salmonella* serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority (CA) by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ☒ No ☐

If yes, please describe the procedure briefly.

If no, please explain:

All legal or natural persons, and particularly veterinarians, must notify the competent authorities of any confirmed or suspected cases of salmonella, regardless or whether or not they are connected to measures under the salmonella national control programmes (SNCP). Therefore, all the confirmed results or suspected cases in samples taken and analysed by operators outside the framework of the SNCPs must also be communicated in the same way as those which come under the SNCPs.

When Salmonella spp. is isolated in samples taken in controls by the operator, the laboratories must carry out serotyping to be able to distinguish between those serotypes controlled under this programme and other serotypes of Salmonella spp. Serotyping may be done by the laboratory itself or another laboratory may be commissioned which is authorised under the SNCP, as described in point 10 of this programme. If the serotyping shows positive for the serotypes subject to control or any other serotype, or if the presence of such serotypes cannot be ruled out and the initial sample was taken in an own check, the competent authority must be informed as soon as possible and at the latest within 24 hours of the analyses results becoming available at least to the laboratory and the owner of the holding.

As soon as the operator becomes aware of the existence of a positive result, he must take the appropriate measures provided in the programme for cases in which the Salmonella serotypes to which the check relates are detected.

All the results of own checks must be recorded using the dedicated computer application used by the authorised laboratories to communicate results, without prejudice to the contents of the previous paragraph.

To ensure suitable traceability of the samples taken during own checks and official monitoring and in order to ensure suitable computer processing of the sampling data for this programme, the sampled flocks will be identified as specified in point 3 of the programme.

The competent authority of the livestock and public health service will keep both appropriately informed of the positive results.

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on S. Enteritidis and S. Typhimurium.

During 2004, the monitoring and data collection of Gallus gallus broiler flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents.

Since the beginning of the implementation of the *Salmonella* Control Programme in broilers until nowadays, the prevalence of Salmonella has dropped from 1,6% (2009) to 0,13% (2022), which corroborates the effectiveness of the programme.

The most prevalent salmonellas with importance in public health in 2022 are *S*. Typhimurium in first place, *S*. Typhimurium monophasic strain and *S*. Enteritidis.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of broiler flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining biosecurity measures in free-range production systems, that are increasing progressively as a result of consumers' demand. These production systems could make difficult to guarantee a Salmonella-free environment, and control measures should focus on those achievable actions, such as feed control, hygiene practices between flocks, correct training and awareness of all workers, limited external visits, frequent rodent control, keeping clean and without residues the outdoors' facilities, keeping controlled the herbage, thoroughly cleaning and disinfection techniques after a positive result, with adequate verification analysis, by-products and manure management, etc.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the *Salmonella* in Broilers *Gallus gallus* situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks. **Yes ☒ No ☐** If yes, please make a short description of the most relevant biosecurity measures applied in order to prevent *Salmonella* contamination of their flock and please quote the document describing them, if any. Also please specify if biosecurity is part of the S*almonella* programmes or if there is national legislation in place for the implementation of biosecurity. Specify if there is a national guidance available for the biosecurity measures to be implemented and if this guidance is easily accessible by the FBO's. If no, please describe.
Biosecurity measures are part of the SNCP and there are national rules reinforcing them (Royal Decree 637/2021, establishing basic rules for the management of poultry farms and national Animal Health Law 8/2003, that states general rules related with prevention, control and eradication measures, sector health organisation, authorisation and marketing of animal health and animal feed products, and the fees, inspections and sanctions in case of shortcomings). These rules are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic Salmonella in broiler farms and a general national work guideline for the prevention and control of Salmonella in all poultry populations, published to sum up the legal measures established in the legal provisions. The guidelines and the information of general biosecurity are public and available at the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/ https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx Within all these regulations, it is specified that the holder of the poultry farm must take protected husbandry measures to control the entry or contamination by Salmonella spp in the farm, and in particular that: - the design and maintenance of the farm facilities is adequate. - appropriate rodent control measures are carried out.

- adequate washing, cleaning and disinfection measures are carried out in the rearing sheds, production sheds, annexed structures and other structures, production facilities, annexed structures, as well as the material and utensils used in production activities.

- adequate measures are adopted to prevent the transmission of Salmonella spp. through drinking water.

- appropriate measures are taken to prevent the presence of Salmonella spp in raw materials and feedstuffs.

Therefore, without prejudice to the provisions of Royal Decree 637/2021, of July 27, establishing the basic rules for the management of poultry farms, the owner of the farm must take the necessary measures to control the entry or contamination by *Salmonella* spp in the farm, as described in the as described in section 14 of the national program.

Biosecurity measures will be checked at least once a year using the guideline protocol for checking biosecurity measures for holdings of broilers Gallus gallus (see protocol in the programme available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx).

These measures will be checked at least at the same time as official sampling in the flock takes place. The data gathered in such surveys must be recorded using the computer application in the 'Biosecurity' section.

If, in the course of an inspection, shortcomings in the biosecurity measures are detected, this will be made known to the owner of the holding by means of a report in at least triplicate for the owner of the holding and his legal representative or the person in charge of the animals, setting out all the shortcomings and the deadlines set for them to be remedied.

The official veterinarian shall adopt a proportionate and progressive approach in his work to enforce biosecurity rules and measures.

The competent authority may, if necessary, make use of the measures established in Chapter IV, Title V, of Law 8/2003 on animal health. This is without prejudice to other measures or penalties which may be adopted in respect of that flock or throughout the holding, depending on the type of shortcoming. The measures to be adopted to prevent health risks depend on the seriousness of the shortcoming and may range from shutting down the holding to the loss of the health authorisation for operating a holding.

The guideline protocol shall be observed in order to check and assess the biosecurity measures at holdings for broilers (Broiler biosecurity survey).

2.1.2 Minimum sampling requirements for food business operators

Samples at the initiative of the FBO must be taken and analysed to test for the target *Salmonella* serovars respecting the following minimum sampling requirements:

All flocks of broilers within three weeks before slaughter

Yes ☒ No ☐

If no, please explain. Indicate also who takes the FBO samples.

All broiler flocks on all the holdings covered by this programme will be sampled as part of a programme of own checks carried out on the producer's initiative. All the results of the sample analyses must be known before the animals leave for the slaughterhouse and suitably notified in accordance with the legislation in force. Samples shall be taken in accordance with the following minimum requirements:

- Zoonoses / Zoonotic agent *Salmonella* with public health significance (ST and SE).

- Broiler flocks intended for human consumption.

- Production phases which must cover sampling: Chicks in the 3 weeks prior to slaughter.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding Salmonella, as reflected in section 14 of the national program.

Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding, or may be carried out by qualified staff of the laboratory performing the analyses. The veterinarian responsible for the holding shall verify that the sampling protocol is being observed in accordance with the conditions set in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

In those herds in which a thinning or partial depopulation is to be carried out, a self-control must be carried out in the 3 weeks prior to the animals' departure to the slaughterhouse. In the case that a previous self-control has already been carried out in that herd but the time elapsed is longer than 3 weeks, the self-control must be repeated.

Recording of results in the Ministry's own-check computer application

The data and information collected on holdings where own checks are performed (Annex OWN CHECK sampling), and the laboratory results will be recorded in the computer application of the Salmonella National Control Programme https://servicio.mapa.gob.es/. The results of the own-check samples must be recorded in the own-check application, together with the required accompanying data, within one month of the laboratory analysis result being obtained; the results must be obtained within 15 days of the sampling, on average, except in exceptional circumstances. All the data in the sampling annex must be duly completed because if any information is missing, the samples cannot be entered in the application. All the samples and information relating to sampled flocks which are not entered in the Ministry's applications (official control and own check) will not be valid in the context of the SNCP. However, where there is a positive test result for Salmonella, given its significance for public health, it must be notified as specified in the SNCP.

The CA accepts to derogate from this sampling rule and instead of this the FBOs shall sample at least one flock of broilers per round on holdings with more than one flock where:
(i) an all in / all out system is used in all flocks of the holding;
(ii) the same management applies to all flocks;
(iii) feed and water supply is common to all flocks;

(iv) during at least the last six rounds, tests for *Salmonella* spp. according to the sampling scheme set out in the first subparagraph in all flocks on the holding and samples of all flocks of at least one round were carried out by the competent authority;
(v) all results from the testing according to the first subparagraph and point (b) for SE or ST were negative.

Yes ☒ No ☐

If yes, please indicate how many holdings and flocks are concerned

Since the introduction of the SNCPs for broiler chickens in Spain, this exception has been applied to only one holding. It may be applied for the years covered by this programme, but until the programme is implemented each year, we do not know whether the sector will request this and therefore whether the CA will authorise it and it will be applied.

The CA accepts to derogate from the general sampling rule and authorises FBO sampling in the last six weeks prior to the date of slaughter in case the broilers are either kept more than 81 days or fall under organic broiler production according to Commission Regulation (EC) No 889/2008.
Yes ☒ No ☐

If yes, please indicate how many holdings and flocks are concerned.

Even if it is applied, we cannot specify the number of holdings and flocks until the programme has been completed.

During 2022, less than 100 holdings were authorised for this derogation.

2.1.3 Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 200/2012

Yes ☒ No ☐

If no, please explain

The competent authority or the food business operator will ensure that samples are taken by persons trained for that purpose. At least two pairs of boot swabs will be taken for sampling.

Boot swabs are put on the boots and the sample is taken by walking around in the poultry house. Furthermore, measures must be taken to prevent any effects on the inhibition of bacterial growth caused by disinfectants in the footbaths at the entrances to the sheds. All swabs will be grouped together and considered to be one sample.

Before putting on the boot swabs, their surface will be moistened by: a) the application of maximum recovery diluents (MRD: 0.8 % sodium chloride, 0.1 % peptone in sterile deionised water); b) the application of sterile water; c) the application of any other diluents approved by the national reference laboratory referred to in Article 11(3) of Regulation (EC) No 2160/2003; or d) being autoclaved in a container together with diluents. The way to moisten

boot swabs shall be to pour the liquid inside before putting them on or to shake them in a container of diluent. It shall be ensured that all sections in a house are represented in the sampling in a proportionate way.

Each pair of boot swabs must cover about 50 % of the area of the house. On completion of sampling, the swabs shall be carefully removed from the boots so as not to dislodge adherent material. Boot swabs may be inverted to retain material. They shall be placed in a bag or pot and labelled.

The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling on a case-by-case evaluation of epidemiological parameters, such as biosafety conditions, the distribution or size of the flock.

For free range flocks of broilers, samples will only be collected in the area inside the house. In flocks with less than 100 broilers, where it is not possible to use boot swabs as access to the sheds is not possible, they may be replaced by hand drag swabs, where the boot swabs are worn over gloved hands and rubbed over surfaces contaminated with fresh faeces, or if not feasible, by other sampling techniques for faeces fit for the intended purpose.

Where the presence of *Salmonella* Enteritidis and *Salmonella* Typhimurium is not detected but antimicrobials or bacterial growth inhibitory effect are detected, the flock will be considered to be an infected flock of broilers for the purpose of the Union target referred to in Article 1(2). Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check).

Methods used in the examination of the samples in the framework of the programme.

A. Preparation of the samples in the laboratory

a) Absorbent boot swabs - The sample (consisting of two pairs of boot swabs) must be unpacked carefully to avoid dislodging faecal material and placed in 225 ml buffered peptone water (BPW) which has been pre-warmed to room temperature. Where necessary, more peptone water will be added so that free liquid is left around the sample to allow for the migration of *Salmonella*. - The sample will be swirled to fully saturate it and culture shall be continued by using the detection method described. To prepare these samples, standard UNE-EN ISO 6887-6 'Specific rules for the preparation of samples taken in the primary production stage' can also be taken as a guide.

B. Identification of the samples and results of the analyses

The sample must be correctly preserved and identified for dispatch. It will be accompanied by a series of data in accordance with the model sampling annex. There are two sampling annex models: one for the official control and another for own checks, because own checks do not require as much information to be collected as the official control. In both cases, it must be clearly visible that the samples come within the scope of the SNCP, to avoid any confusion with private samples on the holding. These annexes must be fully completed because all the data collected in them are necessary for the assessment of the SNCPs. A copy or duplicate of the sampling annex must stay on the holding, and be kept together with the results sheet sent by the laboratory, so that the farm has all the documentation on samples (sampling annex and results sheet). These documents must be available to the official veterinary services when they perform official controls in the framework of the SNCPs. The required documents may

be in paper or electronic format. To ensure suitable traceability of the samples, the reports of the analyses results, at least the following information must be recorded:

1. Date on which the samples were taken.

2. Identification of the flock. As described in point 3 of this programme.

3. Poultry population (breeding, laying, broiler, turkeys for fattening or breeding)

4. Samples (specimen, number and weight or volume) which arrived at the laboratory and manner in which they were combined for analysis.

The following sentence must appear in a clear and visible manner in all the results sheets for the sample analyses under the SNCPs, and also in sampling annexes. “THESE SAMPLES FALL UNDER THE SALMONELLA NATIONAL CONTROL PROGRAMMES”

When a vaccine strain has been detected, the laboratory serotyping report must include the following statement: " The flock shall be considered negative because it has been isolated a vaccine strain"

2.1.4 **EU microbiological criteria** in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*

If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g. Measures implemented by the FBO (farm level)
If *Salmonella* spp. is detected in samples taken in the farm, the samples must be serotyped. If either of the mentioned serotypes are detected in the samples, appropriate measures will be taken in accordance with Regulation 2160/2003: 1. In all positive broiler flocks, an in-depth epidemiological investigation will be carried out to attempt to identify the cause and detect the source of infection. 2. A rigorous check of the biosafety measures of the flocks in the holding will be performed. 3. No live birds may be moved into or of this site unless prior authorisation has been obtained to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document. 4. Products obtained from these birds may be placed on the market for human consumption only in compliance with Community legislation on food hygiene and with part E of Annex II to Regulation 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation 1069/2009 laying down health rules concerning animal by-products not intended for human consumption. 5. Once the birds have been removed, the holding will be cleaned efficiently followed by disinfection, insect removal and rat extermination. A suitable time after disinfection is complete, environmental samples will be taken to check the effectiveness of cleaning and disinfection. 6. The premises will not be restocked for 12 days after cleaning and disinfection. However, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

7. The competent authorities will be informed of the dates of departure of the birds in the flock, disinfection, taking of environmental samples and restocking, and all these processes shall be duly recorded for possible consultation by the competent authorities. Preventive depopulation of the shed in which the positive flock was kept (and, where appropriate, slaughter or destruction of the animals), and restocking, must all take place under official supervision.
8. If necessary, results may be requested of laboratory analyses of the worker(s) to determine whether there are any *Salmonella* spp. carriers among them.

If a serotype not concerned by the control programme is identified, the following measures will be taken: an in-depth epidemiological investigation will be carried out and thorough checks on the biosafety measures for all flocks on the holding.

In order to clarify the SNCP of poultry, this text was amended as a part of the Action Plan approved after the recommendation of report ref DSG(SANTE) 2019-6597 of the EU audit to evaluate SNCP carried out in November 2019, stating that the CA should ensure that only broiler and turkey flocks that have been sampled for Salmonella with a known test result can be sent for slaughter.

In accordance with Royal Decree 361/2009 on food chain information, the operator of the livestock holding must ensure that in all shipments of animals to the slaughterhouse, full information on the results of all analyses of samples taken that have importance for human health, in the framework of the surveillance and control of Salmonella is sent to the slaughterhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or last analyses, if the samples have been taken in the near future) has been negative or positive to Salmonella spp. and, in this last case, in addition, if it is negative or positive to *S*. Enteritidis or *S*. Typhimurium, and the information of the result/s of such analysis must be included in the FCI (Food Chain Information) to be considered complete.

If a flock on the holding tests positive for *S*. Enteritidis or *S*. Typhimurium, the operator of the livestock holding must also ensure that no live birds are moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.

Measures implemented by the FBO (slaughterhouse level)

Slaughter at the slaughterhouse shall be carried out in accordance with the provisions of Regulation (EC) No. 853/2004, which lays down specific hygiene rules for food of animal origin, and in particular Section II of Annex III thereof.

There is a “Manual for the broiler sector in Spain for compliance with Regulation (EU) No 1086/2011 amending Regulations (EU) No 2160/2003 and (EC) No 2073/2005”, which, although it is voluntary, can provide guidance as to the correct way of handling birds slaughtered in slaughterhouses in relation to Salmonella.

As an example of the possible system of action, we attached the management diagram of birds sent to a slaughterhouse (see part IV: Maps), recommended in the "GUIDE FOR THE MEAT POULTRY SECTOR IN SPAIN FOR COMPLIANCE WITH REGULATION (EU) No. 1086/2011

AMENDING REGULATIONS (EU) No. 2160/2003 AND (EC) No. 2073/2005", with some additional issues that are carried out voluntarily by the slaughterhouses that apply the guide, such as the immobilization of the carcasses sampled until the results are available.

Guide available through: https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf:

Measures implemented by the CA (farm and slaughterhouse level)

The official veterinarian is responsible for verifying that the correct food chain information is passed on as required pursuant to RD 361/2009: accordingly, he or she must check that the livestock holdings are passing this information to the slaughterhouses in a consistent and effective, valid and reliable manner and ensure that the relevant animal health and food safety information, including that relating to the results of Salmonella testing, is also passed on. Provision is thus made for slaughterhouses to only accept animals for which the relevant information on the holding of origin has been received. As a general rule, the information should be received at least 24 hours prior to the arrival of the animals. Slaughter in slaughterhouses must take place in accordance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and in particular Section II of Annex III.

Official controls must be carried out in accordance with Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules regarding the performance of official controls on meat production and regarding production and relaying areas for live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627, of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council and Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council. No. 2074/2005 of the Commission as regards official controls.

The provisions of Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs, also apply in relation to the criteria for Salmonella in poultry meat. Once positive results for S. Enteritidis or S. Typhimurium are found in a consignment, the official veterinarian will ensure that targeted sampling and tests using the EN/ISO 6579 methodology or a validated alternative method are carried out, and lastly that the carcasses are withdrawn from the market and destroyed or that the destination previously given for the product is changed.

2.1.5 Laboratory accreditation

Laboratories in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation.

Please provide the list of the laboratories accredited to perform the analytical method for *Salmonella*.

Yes ☒ No ☐

If no, please explain

The Central Veterinary Laboratory in Algete (Madrid) of the Ministry of Agriculture, Fish and Food is the National Reference Laboratory for all serotypes of *Salmonella* in animals. Laboratories analysing official samples as part of the programme must be established, recognised or designated by the competent bodies in the Autonomous Communities. These official laboratories must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or must apply quality assurance systems in accordance with that standard. They must also participate in the ring tests organised or co-ordinated by the National Reference Laboratory. The laboratories participating in the programme for the purposes of carrying out own checks must be recognised by the competent authorities of the Autonomous Communities in which they are established and must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or apply quality assurance systems in accordance with that standard. Laboratories must also regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory The list of participating laboratories must be published, for information purposes, at least on the MAPA website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/listadolaboratoriosatcycoporccaasalmonella_15062022_tcm30-431063.pdf

The competent authorities of the Autonomous Communities shall notify the Ministry of Agriculture, Fish and Food of the laboratories referred to in the previous paragraph or of any modifications to them so that the list may be published at least on the departmental website for information purposes. Where a laboratory serves at the same time as an Autonomous Community's official laboratory and participates in the own-check programme, it must notify the relevant competent authority or authorities and ensure that the two activities are managed separately, and it is subject to monitoring and periodic inspection by the competent authority to check that these are separate. If it fails to notify the authorities, or cannot guarantee that the activities are kept separate, it cannot operate as an official laboratory. The results obtained by authorised laboratories for both official monitoring and own checks shall be valid and applicable throughout the country. Laboratories must reject samples which do not meet the requirements specified in this programme.

2.1.6 Analytical methods

The **analytical methods** used for the detection of the target *Salmonella* serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ ISO 6579-1:2017/Amd 1:2020. "Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of Salmonella spp. –

AMENDMENT 1: Broader range of incubation temperatures, AMENDMENT to the status of Annex D, and correction of the composition of MSRV and SC".
Serotyping is performed following the Kaufman-White-Le Minor scheme.

Yes ☒ No ☐

If no, please describe the alternative method(s) used.

For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.

Yes ☒ No ☐

If no, please explain. If time limits are exceeded, please indicate what is done.

Salmonella spp. shall be isolated in accordance with Standard EN/ISO 6579-.1 Horizontal method for the detection of *Salmonella* spp. in animal faeces and in samples at primary production level" which uses a semi-solid culture medium (modified semi-solid Rappaport - Vassiladis - MSRV) as a single selective enrichment medium. The semi-solid medium should be incubated at 41.5 ± 1 °C for 2x (24±3) hours. At least one isolate from each sample showing a positive reaction shall be typed, in accordance with the Kaufmann-White-Le Minor scheme. Laboratories may type their own Salmonella isolates or send them other laboratories authorised within the PNCS to be typed. The laboratory where typing takes place must issue a report including its results and send it to the laboratory that sent the isolates to be typed. The recording of results in the application and the notification of results as indicated in this programme are the responsibility of the laboratory that isolated the Salmonella. To prevent any delays in obtaining and notifying the results of typing:

• The isolate must be sent to another laboratory for typing no more than 24 hours following isolation.

• Typing must begin in the laboratory no more than 24 hours following receipt of the isolate in the laboratory.

• The issue and dispatch of the results report from the typing laboratory to the laboratory that sent the isolate, or the notification of the results, as appropriate, must take place no more than 24 hours after the results are obtained in the laboratory.

• The recording in the application and the notification of positive results by the isolating laboratory must take place within the deadlines laid down in this programme.

Alternative methods

Alternative methods may be used instead of the methods referred to above, if validated in accordance with the latest version of EN ISO 16140-2 (for alternative detection methods).

Storage of strains

At least the strains isolated from samples collected by the competent authority shall be stored for possible further characterization and antimicrobial susceptibility testing, as determined by Implementing Decision (EU) 2020/1729 of 17 November 2020 on antimicrobial resistance surveillance and reporting Decision 2013/652/EU of 12 November 2013 on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, using normal culture collection methods, which should ensure the integrity of the strains for at least two years.

Pursuant to that Decision, strains isolated from the own-check samples may also be stored to that end if the competent authority so decides.

To that end, the official control laboratories must send all strains of Salmonella isolated in the framework of the PNCS to the National Reference Laboratory (Algete).

Own-check laboratories must also send the National Reference Laboratory (Algete), on request, any strains obtained in the framework of the PNCS.

The frequency of dispatch of such strains shall be as agreed between the National Reference Laboratory and the laboratories.

2.1.7 Transportation and storage of samples

Samples are transported and stored in accordance with point 2.2.4 and 3.1 of the Annex to Regulation (EU) No 200/2012. In particular samples examination at the laboratory shall start within 48 hours following receipt and within 4 days after sampling.

Yes ☒ No ☐

If no, please explain the actions taken in case time limits are exceeded

The samples will be transported and stored in accordance with points 2.2.4 and 3.1 of the Annex to Regulation (EU) No 200/2012. Samples shall be sent to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection, preferably by express mail or courier. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat (over 25°C) and exposure to sunlight are avoided. At the laboratory, samples shall be kept refrigerated until examination, which shall be started where possible within 48 hours of receipt and always within 96 hours of sampling.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the “National Veterinary Health Warning System Committee” (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health. Its tasks include the following:

a) Coordinating animal health actions across the different administrations.

b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.

c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.

d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc, and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an aditionnal quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents available on the website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.8.

2.3.1 Official controls at feed level

Please describe the **official controls at feed level** (including sampling)
Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities. As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of *Salmonella* spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for Salmonella (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for Salmonella, an identification of the serotype must be requested. Only in the case of S. Enteritidis, S. Typhimurium, S. Infantis, S. Virchow and S. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp, the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that

it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of Salmonella and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of Salmonella in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including Salmonella. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding, flock and hatchery levels

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as Salmonella control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of Salmonella- There are guides to Good Hygiene Practice Guides that have been developed with a view to encouraging the use of appropriate hygiene practices on farms to control dangers in primary production and related activities, with special emphasis on the prevention and control of *Salmonella* of significance to public health. To this end, a model Guide to Good Hygiene Practices for the control and prevention of zoonotic *Salmonella* on

broiler holdings has been drawn up with representatives from the broiler sector (PROPOLLO - an inter-professional organisation for poultry farming in Spain) and the Ministry of Agriculture, Fish and Food, copies of which have been published for distribution among livestock farmers and the competent authorities. It has also been posted on the MAPA website.

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

The owners of broiler farms must have an established code of good hygiene practices in order to meet the objective of this *Salmonella* National Control Programme and guarantee that health information is recorded. The following records must also be kept on farms:

a) A record of the type and source of feed supplied to the animals.

b) A record of the outbreak of diseases that could affect the safety of animal by-products.

c) An up-to-date visitors' register listing the people and vehicles that have entered the holding.

d) A record of treatments with medicinal products, containing the information specified in Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products.

e) All the results of the *Salmonella* analyses and controls performed on the holding during the production stage. The results of the analyses of any samples taken in the incubator relating to that flock must also be kept. All these records shall be kept by the holder for at least three years. Those relating to the last 12 months shall be kept on the holding itself.

f) The holding register shall be used to record incoming and outgoing flocks of birds. The flock sheet must be kept for at least three years after depopulation.

g) There must also be a documentary record of:

1. The protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).
2. Analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of *Salmonella* with public health significance. 3. The programmes and records of insect and rat extermination operations (dates, products used, procedure to check the effectiveness of the programme, etc.).

h) The producer of breeding chickens must provide information on the health status of the flock of origin and on the vaccinations and own checks performed on the rearing of the chickens; this information must accompany the chickens when they are transferred to the producing holdings.

The holder shall have all the mandatory health documentation and record all the necessary details to enable the competent authority to perform ongoing checks on compliance with the holding health programme and the code of good hygiene practice, and in particular the records mentioned above under a), b), c), d), e), f) and g).

All holdings included in the programme shall be placed under the veterinary supervision of both the official veterinary services and of the authorised or competent veterinarians responsible for the holding, as laid down in Law No 8/2003 on animal health.

Without prejudice to Royal Decree 637/2021, the holder must adopt protective livestock rearing measures to control the introduction or prevent the dissemination of *Salmonella* spp on the holding. In particular:

a) The design and maintenance of the installations must be suitable for preventing the entry of *Salmonella* spp.

b) Appropriate measures must be taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease. A rodent control programme must be carried out either by the holding itself or by authorised establishments.

c) Day-old chicks come from breeding holdings and hatcheries that have passed the checks set up to prevent vertical transmission of *S*. Enteritidis and *S*. Typhimurium, including the monophasic strains of *Salmonella* typhimurium with the antigenic formula 1,4,[5],12:i:-, and are certified by the supplier as originating in breeding holdings free of the five serotypes (*S*. Enteritidis, *S*. Typhimurium, including the monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, *S*. Virchow, *S*. Infantis and *S*. Hadar), and documentation including the results and dates of the laboratory analyses (own checks and official sampling) performed since the last official sampling at the source holding must be made available to the purchaser.

d) Appropriate washing, cleaning, disinfection and rat extermination measures are taken in the production sheds and ancillary structures and on the materials and tools used in the production activities.

e) Analyses are performed to check that sufficient cleaning and disinfection has been carried out. To verify cleaning and disinfection one or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the Salmonella National Control Plans.

The detection methods used must be the same as for the other SNCP samples. The results must be entered in the own check computer application of the MAPA.

these samples will be recorded as samples from the outgoing flock.

The own check sampling Annex will be used for dispatch to the laboratory.

The competent authorities will check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

f) Adequate measures are taken to prevent the transmission of *Salmonella* through drinking water.

g) The appropriate measures must be taken to prevent the presence of *Salmonella* spp in raw materials and feedingstuffs. Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for *Salmonella* has been carried out and make express provision for such tests in the relevant HACCP system. The checks must include analysis of the corresponding samples, which will be made available to the health managers of the holdings receiving the feed. The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis.

h) Suitable training courses for operators and, if necessary, for the owners of the holding will be carried out.

i) Suitable health checks must be carried out to detect the possible source or sources of Salmonella contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation.

j) Appropriate sampling and analyses are carried out to detect *Salmonella* spp.

k) Adequate measures must be adopted if positive cases of salmonellosis involving either of the two serotypes of Salmonella covered by the programme occur.

l) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.

Hygiene in transporting animals to and from farms Article 49 of Law 8/2003 on Animal Health establishes that all vehicles or means of transport used to transport production animals must be cleaned of solid residues, washed and disinfected with authorised products after the animals have been unloaded in the closest cleaning and disinfection centre authorised for such purposes. This centre will send a receipt for the work carried out which must accompany the transport. In the case of transport and unloading at the slaughterhouse, the vehicle must leave the slaughterhouse empty, clean and disinfected. In addition to these requirements, Royal Decree 1559/2005 sets out the basic conditions to be met by the cleaning and disinfection centres for vehicles used for road transport in the livestock sector.

b) Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:

- in one flock of broilers per year on 10% of holding comprising at least 5,000 birds

Yes ☒ No ☐

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by sufficiently trained and authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

Each year on 10% of holdings with more than 5 000 birds at least one flock on each holding will be checked. In the ACs with 10 holdings or fewer, the official control will be carried out on at least one holding. The risk criteria for selecting this 10% of holdings include the following:

a) Holding characteristics:

- type of production
- size of holding (population sections)
- provincial poultry density (measured here by number of holdings)

b) Background of the holdings:

- changes in the results obtained in previous years on the holdings from which samples were taken.
- prioritise holdings on which no information is available.

c) Non-compliances:

- prioritise establishing a major risk of those farms where unrectified non-compliances have been detected in the biosafety surveys and in surveys where positive results were obtained.

Sampling shall take place within the last three weeks before the birds are sent for slaughter. Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check). Whenever it is considered necessary, official samples of animal feed and drinking water and environmental samples may be taken to confirm the effectiveness of cleaning and disinfection measures. Other types of samples may also be taken as and when the competent authorities deem it necessary. The competent authority can decide to increase the number of samples to ensure the representativeness of sampling, depending on epidemiological parameters such as biosafety conditions, distribution or flock size.

c) Official confirmatory sampling (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery):

After positive official samples at the holding

☐ Always
☐ Sometimes (criteria apply)
☒ Never

After positive FBO samples at the holding

☐ Always
☐ Sometimes (criteria apply)
☒ Never

When official confirmatory sampling is performed, additional samples are taken for checking the presence of antimicrobials:

☐ Always
☐ Sometimes
☒ Never

Please insert any comments. Describe the criteria used to determine if confirmatory sampling is performed. Indicate also which samples (if any) are taken to check the presence of antimicrobials.

Confirmatory analyses are not carried out for broilers.
d) Article 2 of Regulation (EC) No 1177/2006 **(antimicrobials** shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision. For samples please describe the samples taken, the analytical method used, the result of the tests.
The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used. In addition to the sampling provided for, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling. The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials. Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary. Where the presence of the Salmonella serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target. These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary. If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).
Once the birds have been removed, the holding will be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks will be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples will be taken to check the effectiveness of the cleaning and disinfection and to make sure that *Salmonella* is no longer present in the environment.

The competent authorities will check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and, where appropriate, will authorise restocking with new animals.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes.

The detection methods used must be the same as for the other samples under the PNCS.

The results for the same must be recorded using the MAPA computer application for own checks.

The samples must be recorded alongside the samples for the outgoing flock.

The sampling sheet for own checks must be used when sending such samples to the laboratory.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (*S. enteritidis, S. typhimurium*)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target *Salmonella* serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain

Monitoring and control of *Salmonella* in Spain has been carried out since 1993 in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and

products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning.

During the period from October 2005 to September 2006, a reference study was carried out on the prevalence of *Salmonella* in flocks of broilers of the *Gallus gallus* species at Community level; the analysis and sampling of the selected chicken flocks was carried out in accordance with the guidelines laid down at Community level by Commission Decision 2005/636/EC.

The data obtained in the study showed the prevalence of serotypes Enteritidis and Typhimurium in broiler flocks to be 28.2% and 41.2% for *Salmonella* spp.

The development of prevalence of Salmonella subject to controls in flocks of *Gallus gallus* broilers was as shown below, with *S*. Typhimurium, followed by *S*. monophasic Typhimurium and *S*. Enteritidis, the more prevalent serotypes under control.

2.3.5 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks
Measures and applicable legislation as regard as the registration of holdings: Legislative measures and provisions concerning the registration of livestock farms. The obligation to register livestock farms in Spain derives primarily from Article 39 of Law 8/2003 of 24 April 2003 on animal health. More specifically, in poultry farming, the obligation to register poultry farms is regulated as follows: Holdings of broiler chickens will be entered in the General Register of Livestock Holdings (REGA, Royal Decree 479/2004) with a code/register number, irrespective of their size, and will be classified as: • meat production farms. All holdings, except those excluded in Article 1 of Royal Decree 637/2021, must comply with the provisions stablished in this regulation on the organisation of poultry rearing, concerning the minimum conditions to be met by poultry holdings with regard to buildings and installations, hygiene and health conditions, location, poultry identification, holding register, holding record book, the duties of the holder of the establishment and the minimum welfare conditions to be observed for poultry. For the purposes of the programme, 'epidemiological unit' will mean the flock of birds, defined as all birds reared for meat production with the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit. in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003. To identify flocks within a holding, the REGA code will be used: a capital letter corresponding to the shed and the date of entry of the birds in the format mm/yyyy, as specified in point 3 of this programme.

2.3.6 System to monitor the implementation of the programme

Please describe

Taking into account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all of the results.

Lastly, we have a monitoring plan for own checks and the inspection of own check laboratories: In order to verify that the own checks are being carried out correctly, the competent authority may carry out the following monitoring plan for own checks and the inspection of own check laboratories (available in MAPA website). The official veterinary services will run a quality control on the own checks on a percentage of holdings, selected annually in accordance with the following hierarchised risk criteria:

• Holdings where own checks show negative results for the serotypes subject to control and official controls show positive results.

• Holdings where own check show negative results for the serotypes subject to control and on which there is a public health communication concerning positive results.

• Holdings where own checks show negative results for the serotypes subject to control and positive results in the analysis of the LOD (limit of detection) effectiveness check.

• On a random basis, between holdings with own checks with negative results for the serotypes subject to control and with no official checks. When this inspection is carried out, the control will involve performing a survey to check compliance with the specifications in the programmes and an in situ inspection of sampling for own checks. In this case, own check sampling will be in the presence of the official veterinarian who will try, in an observer capacity, to identify practices which do not correspond to the procedures detailed for samples in the national programmes which are applicable for both official and own checks.

Critical aspects of these checks which may impact the results must be verified (e.g. use of enrichment peptone in stockings, origin, expiry date; representativeness of the sample: no steps and surface area in question; where appropriate, dispersion of the taking of aliquots of faeces to generate sufficient representativeness in the pools, etc.). It must also be checked how and where the sample is kept when it is submitted to the laboratory, as well as compliance with the established deadlines for receipt.

In this inspection, the competent authority will also raise the questions it considers appropriate and will request the necessary documentation in relation to the performance of own checks. The official veterinarian will set out in the control results in an inspection report.

From this information and from what can be gathered from monitoring the sample until its arrival at the laboratory, an assessment report will be drafted by the competent authority.

Any anomalies detected will be communicated as soon as possible to the producer for immediate correction for application in successive own checks, irrespective of the administrative effects which can be deduced from that case in particular. The CA will leave a copy of the report for the person responsible for performing the own check sampling. Where considered appropriate by the competent authority, samples will be taken in duplicate. One of the samples will be taken by an official veterinarian using his/her own material, and will remain in his/her possession. This sample will be sent to an official laboratory together with the sampling sheet. The other sample will be taken by the person responsible for own check sampling, using material provided by that person. It will remain in his/her possession, and must be analysed in the same way as any other own check. In cases of significant discrepancies between the official control results and the own checks on the same flock; the competent authority may request, where it considers appropriate, the isolated strains from the flock in question, from the own check laboratory which analysed them, to perform an analysis of them in an official laboratory of its Autonomous Community.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

***Note:** Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.

2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and especificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledgement of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated poultry meat. Impact on public	Rigorous accomplishment of the control programme and of the next stages of the agri-

	health, on food safety, on farmer's production. (Medium risk)	food chain (hygiene process, slaughtering process). Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and corrective actions established in the SNCP (in case the cause of contamination was at farm level).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Knowledgement of the SNCP requirements in advance.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August-September (year N)	Intermediate follow-up technical report (data of first semester).

Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view) Who are the target groups? How will the target groups benefit concretely from the project and what would change for them? Define the short, medium and long-term effects of the project. ***Possible examples:*** reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).
The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector. The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agri-food chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin. The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation. The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment. The expected effects of the programme are: - Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level

of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.

- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of broiler flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement “funded by the European Union”.

The programme will be available in the MAPA’s website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the *Salmonella* Control Programme.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Flocks subject to the programme

	Number of holdings
Total number of holdings with broilers in the MS	4650
Total number of houses in these holdings	40000
Number of holdings with more than 5 000 broilers	4500

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: “MAPA "

II. Targets for 2024

Table 2: Targets on laboratory tests on official samples from broiler flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	525
Serotyping	180
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	25

Table 3: Targets on official samples from broiler flocks of *Gallus gallus*

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	15	40000
N of flocks in the programme	15	40000
N of flocks planned to be checked (b)	5	480
No of flock visits to take official samples (c)	5	500
N of official samples taken	5	510
Target serovars (d)	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
	☒ SE+ ST	☒ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	0	45

(a) Including eligible and non-eligible flocks
(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
(c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
(d) *Salmonella enteritidis* and *Salmonella typhimurium* = SE + ST*Salmonella enteritidis, typhimurium, hadar, infantis, virchow* = SE+ ST + SH +SI + SV

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

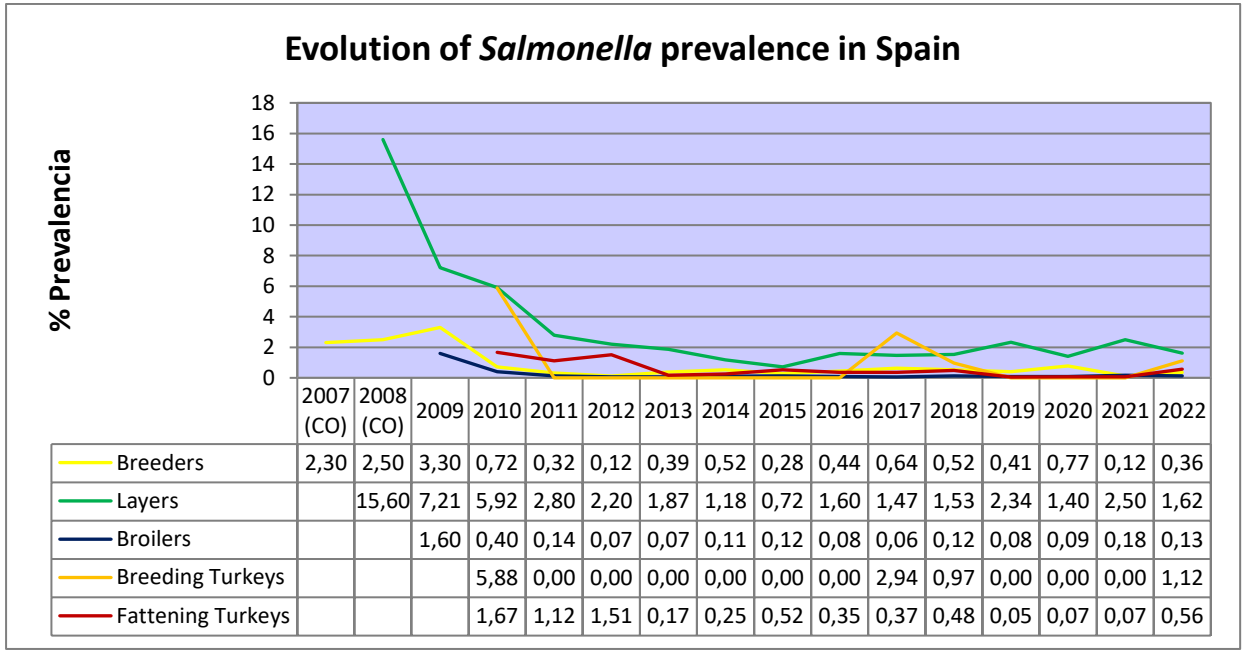
- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of Salmonella enteritidis and Salmonella typhimurium in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0200-20190310&qid=1652941636751
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2022)



	2007 (CO)	2008 (CO)	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Breeders	2,30	2,50	3,30	0,72	0,32	0,12	0,39	0,52	0,28	0,44	0,64	0,52	0,41	0,77	0,12	0,36
Layers		15,60	7,21	5,92	2,80	2,20	1,87	1,18	0,72	1,60	1,47	1,53	2,34	1,40	2,50	1,62
Broilers			1,60	0,40	0,14	0,07	0,07	0,11	0,12	0,08	0,06	0,12	0,08	0,09	0,18	0,13
Breeding Turkeys				5,88	0,00	0,00	0,00	0,00	0,00	0,00	2,94	0,97	0,00	0,00	0,00	1,12
Fattening Turkeys				1,67	1,12	1,51	0,17	0,25	0,52	0,35	0,37	0,48	0,05	0,07	0,07	0,56

b. Most prevalent serotypes of *Salmonella* in the different poultry populations (2022)

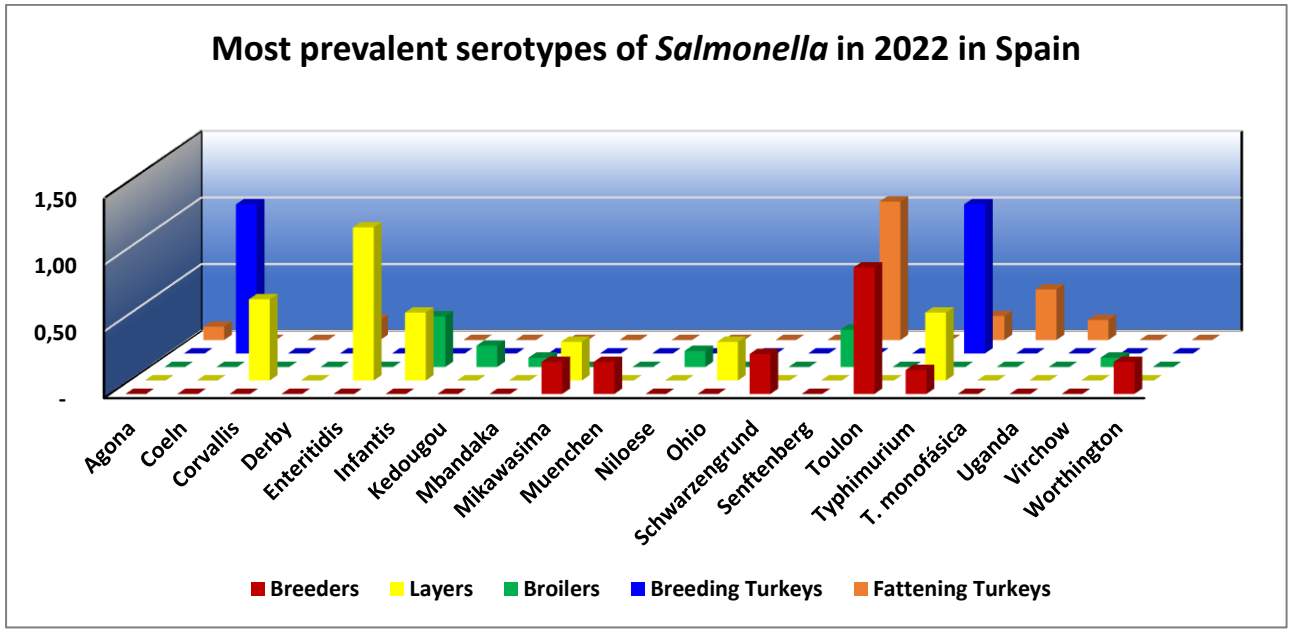


Diagramme of veterinary services

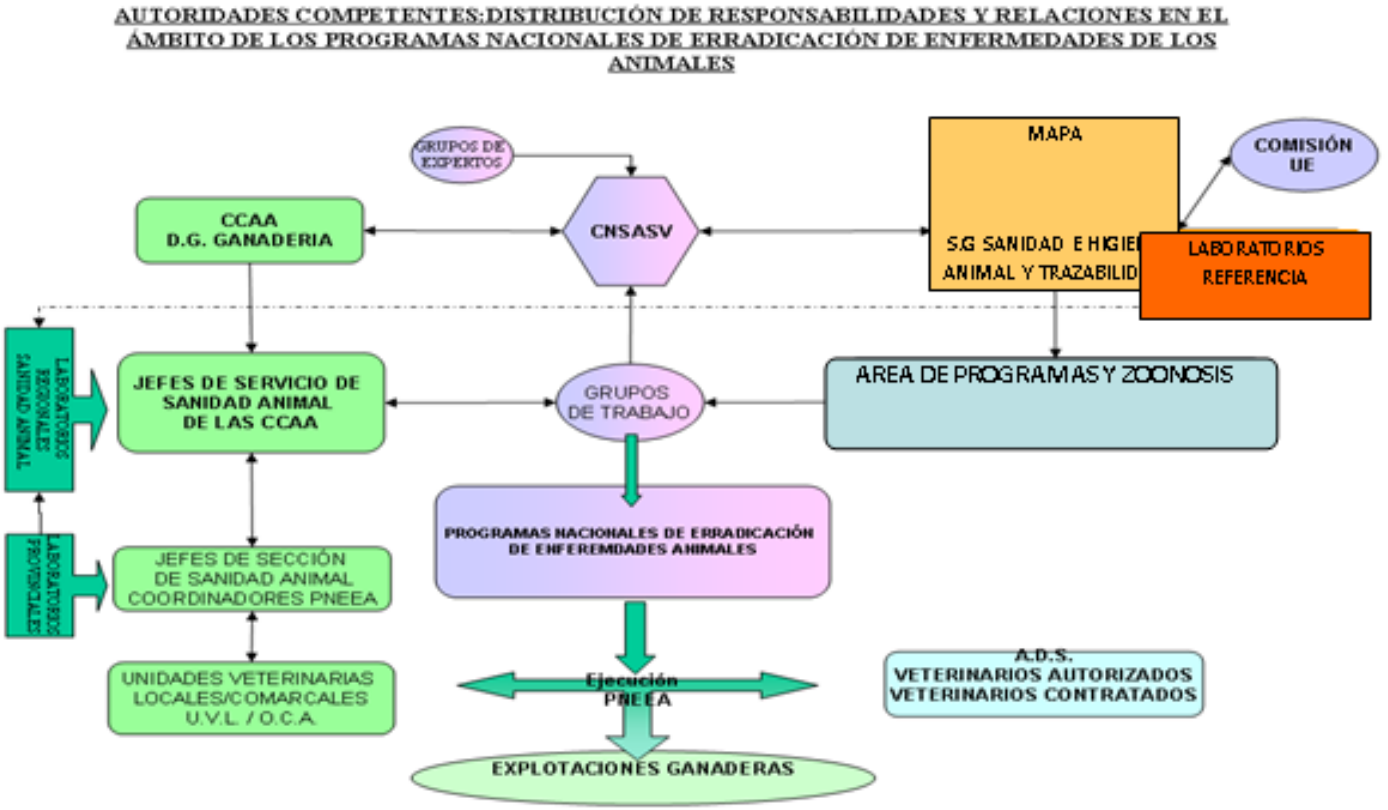
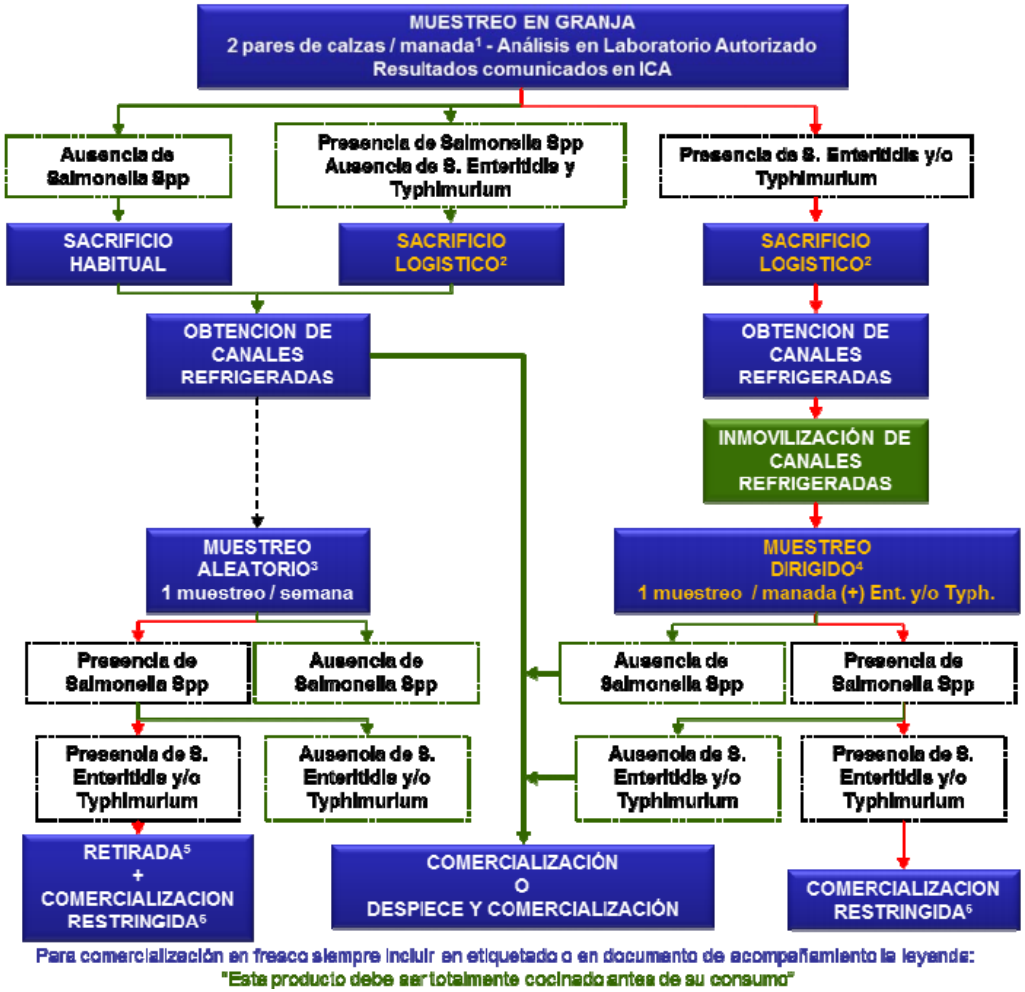


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):

FIGURA 6. SISTEMATICA DE ACTUACIÓN



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Zoonotic *Salmonella* Programme
Control programme – Reduction of prevalence of *Salmonella* serotypes in Breeding flocks of Turkeys

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	Spain
Disease	**ZOONOTIC SALMONELLA**
Animal population/Species	**Breeding flocks Turkeys**
Implementation Year	**2024**

CONTACT PERSON on Zoonotic *Salmonella* programme :

Name	Soledad Collado
e-mail	scollado@mapa.es
Job type within the CA	Head of Service of Zoonoses

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Salmonella in Breeding flocks Turkeys Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council,
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes ☒ No ☐

If no, please explain:

(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of flocks of breeding turkeys remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Yes ☒ No ☐

If no, please explain:

The answer is yes, but S. Hadar, S. Infantis and S. Virchow are not target serovars.

The National Programme takes account of the specifications set out in Commission Regulation 1190/2012 implementing Regulation 2160/2003 with regard to the Community objective of reducing the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in turkeys. Accordingly, the target will be the reduction of the maximum percentage of positive adult breeding turkey flocks to *Salmonella* Enteritidis and Salmonella Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

Given that there are currently fewer than 100 breeding turkey flocks in Spain, the Community target could be no more than one adult breeding turkey flock continuing to test positive.

For the purposes of verifying the attainment of the Community objective, a flock of turkeys shall be considered positive when:

a) the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:- (therefore different from the vaccine strains) has been detected in the flock, or
b) when antimicrobials or bacterial growth inhibitors have been detected in the flock.

Positive flocks of turkeys shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

If either of the two mentioned serotypes is detected or Salmonella spp is detected, the appropriate measures are explained in point 2.1.4.

For MS with less than 100 flocks of breeding turkeys, the Union target shall be that annually no more than one flock of adult fattening turkeys may remain positive.

Yes ☒ No ☐

If no, please explain:

Spain has less than 100 adult breeding flocks (89 in 2022).

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?
The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as Salmonella, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies that had the scientific assessment of EFSA for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence. Therefore, the project is a continuation of the previous programmes for the control of Salmonella annually presented to the EU from the establishment of the objective of reduction of the prevalence, who was progressively amended until reaching a fixed target. The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to rise the level of public health and animal health in the EU, that at the same time enable the rational development of the farming sector and provides a safer EU trade of poultry and poultry products in the EU single market. Furthermore, as the programme has an harmonised surveillance, the results are comparable between MSs is based in an EU harmonised system, the results are comparable between MSs, and allow the analysis of the spatial and temporal trend at EU level. It also has an international dimension, as it boostes the confidence not only of the EU Member States and its consumers but also of Third Countries, who can trust in a solid system which ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and economics, giving benefits worldwide.

1.4 Target population and Area of the implementation

This programme will be implemented on all breeding flocks of turkeys
Yes ☒ No ☐ If no, please explain on which flocks: It shall apply on all holdings where turkeys are reared for breeding in accordance with point 1 of the Annex to Commission Regulation (EU) No 1190/2012. In breeding turkey holdings from which the producer directly supplies small quantities of primary products to the final consumer or to a local retail establishment directly supplying primary products to the final consumer; at least 1 FBO control shall carry out in all flocks in the farm at that moment. The competent authorities of the Autonomous Communities shall take the necessary steps to ensure control and monitoring of salmonellosis of importance for public health.

This programme shall not apply to holdings that produce primary products intended for self-consumption (for private domestic use). Holdings to which the programme applies must be authorised and registered by the competent authorities. For the purposes of the programme, an epidemiological unit shall be considered to be a flock of turkeys, defined as all poultry reared for the production of meat or eggs with the same health status kept on the same premises or within the same enclosure and constituting a single population in epidemiological terms; in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of turkeys shall have an individual identification. To identify the flocks on a holding a capital letter corresponding to the shed shall be used (this letter must be written on the door to the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

Fill in **Table 1**) **in the Annex** to this Form.

This programme will be implemented on the whole territory of the Member State

Yes ☒ No ☐

If no, please explain:

(maximum 500 words)

1.5 Notification of detection of target *Salmonella* serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ☒ No ☐

If yes, please describe the procedure briefly.

If no, please explain:

All individuals or companies, and particularly veterinary officers, must notify the competent authorities of any confirmed or suspected cases of *Salmonella*, whether or not these are related to the action performed within the framework of the national salmonella control programmes. Therefore, all confirmed or suspected results of samples taken and analysed by operators outside the framework of the *Salmonella* National Control Programme (SNCP) must be reported as if they had taken place under the SNCP.

If *Salmonella* spp is isolated in samples taken in checks by the operator, the laboratories shall serotype them, in order to be able to at least distinguish between the serotypes subject to this programme's tests and other serotypes of *Salmonella* spp. Serotyping may be performed by the laboratory itself or could be outsourced to another laboratory, authorised under the

SNCPs, as described in point 10 of this programme. If the serotyping shows positive for one of the serotypes subject to checks, or any other serotype, or if the presence of any serotype cannot be ruled out, and the initial sample was taken in an own check, it shall be reported to the competent authority as soon as possible, and never later than 24 hours after the laboratory or the farm operator receives the results of the analysis.

As soon as the operator becomes aware of the existence of a positive result, he shall be responsible for taking the appropriate measures, as set out in this programme for cases where the Salmonella serotypes concerned by the programme are detected. The competent authority may carry out a confirmatory analysis in exceptional cases and if considered appropriate.

It is mandatory to record all the results of own checks using the computer application developed to this end for the authorised laboratories to communicate the results, the provisions of the preceding paragraph notwithstanding.

To ensure suitable traceability of the samples taken during own checks and official monitoring and, in order to ensure suitable computer processing of the sampling data for this programme, the sampled flocks shall be identified as specified in point 3 of the programme.

The competent authority of the livestock service and Public Health shall, between them, ensure that there is sufficient information about the positive results.

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of Salmonella cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on S. Enteritidis and S. Typhimurium.

During 2006, the monitoring and data collection of flocks of turkeys was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents.

Since the beginning of the implementation of the *Salmonella* Control Programme in breeding turkeys until nowadays, the prevalence of *Salmonella* has dropped from 5,88% (2010) to 1,12% (2022), which corroborates the effectiveness of the programme. Despite overtaking the 1% of control object *Salmonella* prevalence, there was only 1 positive flock. Thus, as the number of flocks is less than 100, the reduction objective has been fulfilled.

The most prevalent *Salmonella* with importance in public health in breeding turkeys in 2022 is *S*. monophasic Typhimurium.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of breeding flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining an extremely high level of biosecurity measures before and after a positive result (as the introduction of birds and incubated eggs Salmonella-free, introduction of feed, keeping strict hygiene practices between flocks, correct training and awareness of all workers, limiting external visits, frequent rodent control, thoroughly cleaning and disinfection techniques and adequate verification analysis, adequate facilities maintenance, by-products and manure management, etc).

Furthermore, the mandatory slaughtering and destruction of the birds and eggs in case of a positive target serotype, with the consequent compensation of the costs, could suppose a technical and financial problem both for the farmer and for the CA, depending on the number and the age of the birds.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the *Salmonella* in Breeders Turkeys situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.
Yes ☒ No ☐

If yes, please make a short description of the most relevant biosecurity measures applied in order to prevent *Salmonella* contamination of their flock and please quote the document describing them, if any. Also please specify if biosecurity is part of the salmonella programmes or if there is national legislation in place for the implementation of biosecurity.

Specify if there is a national guidance available for the biosecurity measures to be implemented and if this guidance is easily accessible by the FBO's.

If no, please describe.

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (Royal Decree 637/2021, establishing basic rules for the management of poultry farms and national Animal Health Law 8/2003, that states general rules related with prevention, control and eradication measures, sector health organisation, authorisation and marketing of animal health and animal feed products, and the fees, inspections and sanctions in case of

shortcomings). These rules are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic Salmonella in broiler farms and a general national work guideline for the prevention and control of Salmonella in all poultry populations, published to sum up the legal measures established in the legal provisions.

The guidelines and the information of general biosecurity are public and available at the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Within all these regulations, it is specified that the holder of the poultry farm must take protected husbandry measures to control the entry or contamination by Salmonella spp in the farm, and in particular that:

- the design and maintenance of the farm facilities is adequate.

- appropriate rodent control measures are carried out.

- adequate washing, cleaning and disinfection measures are carried out in the rearing sheds, production sheds, annexed structures and other structures, production facilities, annexed structures, as well as the material and utensils used in production activities.

- adequate measures are adopted to prevent the transmission of Salmonella spp. through drinking water.

- appropriate measures are taken to prevent the presence of Salmonella spp in raw materials and feedstuffs.

Therefore, without prejudice to the provisions of Royal Decree 637/2021, of July 27, establishing the basic rules for the management of poultry farms, the owner of the farm must take the necessary measures to control the entry or contamination by *Salmonella* spp in the farm, as described in the as described in section 14 of the national program.

Biosecurity measures will be checked at least once a year using the guideline protocol for checking biosecurity measures for holdings of breeding turkeys (see protocol in the programme available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx).

These measures will be checked at the same time as official sampling in the flock takes place. The data gathered in such surveys must be recorded using the computer application in the 'Biosecurity' section.

If, in the course of an inspection, shortcomings in the biosecurity measures are detected, this will be made known to the owner of the holding by means of a report in at least triplicate for the owner of the holding and his legal representative or the person in charge of the animals, setting out all the shortcomings and the deadlines set for them to be remedied.

The official veterinarian shall adopt a proportionate and progressive approach in his work to enforce biosecurity rules and measures.

The competent authority may, if necessary, make use of the measures established in Chapter IV, Title V, of Law 8/2003 on animal health. This is without prejudice to other measures or penalties which may be adopted in respect of that flock or throughout the holding, depending on the type of shortcoming. The measures to be adopted to prevent health risks depend on the seriousness of the shortcoming and may range from shutting down the holding to the loss of the health authorisation for operating a holding.

The guideline protocol shall be observed in order to check and assess the biosecurity measures at holdings (biosecurity survey included in the programme and available in the MAPA website).

2.1.2 Minimum sampling requirements for food business operators

The EU minimum requirements for FBO sampling are as follows:

☐ Rearing flocks: at day-old, at four weeks of age, two weeks before moving to laying phase or laying unit
☐ Adult flocks: Every third week during the laying period at the holding or at the hatchery (only at the holding for flocks producing hatching eggs intended for trade within the union). The last sampling session takes place withing three weeks before slaughter.
Yes ☒ No ☐

Indicate also who takes the FBO samples

Insert text

Samples shall be taken in accordance with the following minimum requirements:

Flocks of breeding turkeys

Stages of production to be covered by sampling

1.1 Rearing flocks. I. One-day old turkeys.

II. 4-week old turkeys.

III. 2 weeks before moving to the laying unit or phase.

1.2. Adult flocks. I. Every 3 weeks during the laying period.

II. Turkeys during the 3 weeks prior to departure to the slaughterhouse.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding Salmonella, as reflected in section 14 of this program.

The results of the analysis on the samples must be known before the animals leave for the slaughterhouse. Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding or may be carried out by qualified staff of the laboratory performing the analyses. The veterinarian responsible for the holding shall ensure that the sampling protocol is in accordance with the conditions

laid down in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

Recording results in the Ministry's own-check application:

The data and information collected in the holdings where the own checks are performed (ANNEX FOR OWN-CHECK SAMPLES), as well as the laboratory results shall be recorded in the computer application of the National programme for monitoring Salmonella https://servicio.mapa.gob.es/

The results of the own-check samples must be recorded in the own-check application, together with the required accompanying data, within one month of the laboratory analysis result being obtained; the results must be obtained within 15 days of the sampling, on average, except in exceptional circumstances. The sampling annex must be filled in appropriately because it will not be possible to record the samples in the application if any data are missing.

All the samples and data referring to the samples flocks that are not recorded in the applications of the ministry (official control and own check) shall not be validity for the SNCP. However, any positive results for Salmonella, which is considered to have public health significance, should be notified as determined by the SNCP.

If the EU target is achieved for more than 2 consecutive calendar years in the whole member state, the CA has accepted to implement the derogation of point 2.1.(a)(iv) of Annex to Regulation (EU) No 1190/2012 and therefore the EU minimum requirements for FBO sampling frequency at the holding on adult flocks is every four weeks. However, the CA may decide to keep or revert to a three-week testing interval in the case of detection of the presence of the relevant *Salmonella* serotypes in a breeding flock on the holding and/or in any other case deemed appropriate by the CA.

Yes ☐ No ☒

If no please explain. Indicate also 1) if additional FBO sampling going beyond EU minimum requirements is performed (to be described) 2) who is taking the official samples

Despite the EU target has been reached last years, the Spanish programme does not allow the derogation to extend the sampling frequency on holding to every four weeks. The sampling of adult flocks shall be done every 3 weeks in all circumstances.

The protocol is explained on the previous point.

2.1.3 Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 1190/2012

Yes ☒ No ☐

If no, please explain

1.Rearing flocks:

The following procedure shall be adopted in rearing flocks:

a) Day-old birds:

1. One sample made up of from 10 samples taken from the internal coverings of the cages transporting the chicks when they are delivered to the holding. The bases of the cages may be used directly as a sample, which shall be sent either whole or in parts to the laboratories responsible for processing samples and may be made up of a single or more than one sample, or
2. Liver, caecum and yolk sac of 60 chicks (parts of the viscera may be removed and processed as a single sample), or
3. A sample made up of meconium from at least 250 chicks.

b) Four-week old birds and two weeks before transfer to the laying unit (or the start of the laying phase):

1. A mixture of fresh faeces, each weighing at least one gram, collected at random from at least 10 different points in the house in accordance with the following chart. The faeces may be mixed for analysis, creating a minimum of two composite samples:

Number of birds kept in one house /// Number of portions of faeces that must be taken in one house/ group of houses at the holding

1-24	(number equal to the number of birds up to a maximum of 20)
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60

2. Or use a damp chamois located at the end of the dropping belt so that at least five metres of it can be sampled when it is in operation. Samples shall be taken from at least 10 different points of the belts and all these may be pooled for analysis up to a minimum of two pools.

2. Flocks of adult breeding turkeys

Sampling shall involve obtaining sufficient faecal samples to detect 1% of infected birds in the flock with a 95% confidence limit.

To that effect, the samples shall comprise one of the following:

a) Pooled faeces obtained from individual samples of fresh faeces weighing not less than 1 g, taken at random from various parts of the building in which the poultry are kept, or where the

birds have free access to more than one building on a particular holding, from each group of buildings to which the flock has access. The faeces shall be pooled and a minimum of 2 pooled samples per flock analysed.

The number of individual samples necessary to obtain the mixture is obtained from the following table:

Number of birds in the flock /// Number of individual faeces samples to be taken in the building

250 – 349: 200

350 – 449: 220

450 – 799: 250

800 – 999: 260

1000 or more: 300

b) Boot swabs and/or dust samples.

I. The samples shall consist of: 5 five pairs of boot swabs, with each pair representing 20% of the area of the shed. Measures must be taken to avoid the inhibiting effects of the development of bacteria that could be produced by the disinfectants used in the footbaths at the entrances to the buildings housing the poultry. The swabs may be pooled for analysis into a minimum of two pools of five boot swabs each or

II. at least one pair of boot swabs representing the whole area of the shed and an additional dust sample collected from multiple places throughout the shed from surfaces with visible presence of dust.

c) For caged flocks, sampling shall consist of naturally mixed faeces from dropping belts, scrapers or deep pits, depending on each holding's dropping collection system.

Two samples of at least 150 g each shall be collected to be tested individually.

As there are normally several stacks of cages within a house and all must be represented in the sample, the sample shall be taken as described below:

- In systems where there are collection belts or scrapers, these shall be run on the day of the sampling before sampling is carried out so that only fresh droppings are collected.

- In systems where there are deflectors beneath cages and scrapers, droppings which have lodged on the scraper after it has been run shall be collected.

- In systems where faeces fall directly into a deep pit, faeces shall be collected directly from the pit.

<u>Specific instructions for certain types of holdings</u>

• For free range flocks of turkeys, samples shall only be collected in the area inside the shed.

• In flocks with fewer than 100 turkeys, where it is not possible to use boot swabs as access to the sheds, they may be replaced by hand drag swabs, where the boot swabs or socks are worn over gloved hands and rubbed over surfaces contaminated with fresh faeces, or if not feasible, by other sampling techniques for faeces fit for the intended purpose.

Preparation of laboratory samples (CO and ATC)

a) Absorbent boot swabs:

-The pair(s) of boot swabs should be carefully unpacked to avoid dislodging adherent faecal material Then placed in 225 ml of buffered peptone water (BPW) pre-warmed to room temperature. If necessary, more peptone water could be added so that there is free liquid around the sample to allow the migration of Salmonella.

- Swirl to fully saturate the sample and continue with the detection method.

b) Other samples of faeces and dust:

- The two faeces samples shall be pooled and thoroughly mixed and a 25 g subsample shall be collected for culture.

- Add 225 ml buffered peptone water to the 25-g sub-sample and shake gently

- The culture of the sample shall be continued by using the detection method described in this programme.

The dust sample shall preferably be analysed separately. However, for fattening flocks, the competent authority may decide to allow it to be pooled with the pair of boot/sock swabs for analysis.

UNE-EN ISO 6887-6 on 'Specific rules for the preparation of samples taken at the primary production stage' may also serve as a guide when preparing all these samples.

Identification of the samples and results of the analyses

The samples sent must be properly preserved and identified (in accordance with the specimen report drawn up to accompany the samples to the laboratory: Sampling Sheet). There are two sampling annex models, one for official controls and another for own checks because it is not necessary to collect as much information for own checks as for official controls. In both cases it must be clearly visible that the samples are part of the SNCP so as to avoid confusion with the holding's private samples.

These annexes must be completely filled in since all the data collected is needed for SNCP assessment.

A copy or duplicate of the sampling annex must be kept at the holding, alongside the results sheet sent by the laboratory, in order to ensure that all of the documents relating to the samples (sampling annex and results sheet) are at the farm. These documents must be available to the official veterinary services when they perform the official controls under the SNCP. The documents required may be presented in either paper or digital format. In order to

ensure adequate traceability of the samples, the following information, at least, must be recorded in the analysis results reports:

1. Date on which the samples were taken.
2. Identification of the flock. REGA CODE, THE CAPITAL LETTER IDENTIFYING THE SHED, DATE ON WHICH THOSE BIRDS ENTERED THE SHED (mm/yyyy).
3. Poultry population (breeding birds, laying birds, broilers, fattening turkeys and turkey breeders)
4. Samples (specimen, number and weight or volume) that have arrived at the laboratory and the way that they have been pooled for analysis.

The following sentence must appear in clear and easily visible lettering on all results sheets of sample analyses performed under the SNCP, as well as in the sampling annexes: "THESE SAMPLES FALL UNDER THE SALMONELLA NATIONAL CONTROL PROGRAMMES"

2.1.4 Specific requirements laid down in Annex II.C of Regulation (EC) No 2160/2003 will be complied with where relevant (i.e. due to the presence of SE or ST (including monophasic ST 1,4,[5],12:i:-), all birds of infected rearing or adult flocks are slaughtered or killed and destroyed, and all eggs are destroyed or heat treated):

Please indicate also if birds are slaughtered or killed and destroyed, and if eggs are destroyed or heat treated. Please specify the options applied.

Yes ☒ No ☐

If no, please explain.

If either of the two serotypes (*S*. Enteritidis or *S*. Typhimurium, including strains with the antigenic formula 1,4,[5],12:i:-) is detected in any of the samples taken from fattening or breeding turkey flocks, the appropriate measures shall be taken and shall involve at least the following:

1. In all turkey flocks in which a positive result was obtained, an in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection, in accordance with the epidemiological survey attached to the programme. If it is considered necessary, an official sample may be taken of the feed and/or water being used on the holding or given to that flock.

2. A thorough check of the biosecurity measures for all the flocks in the holding shall be carried out in accordance with the guideline protocol for verifying biosecurity measures on turkey holdings, and it shall be verified that own checks on such flocks are being carried out correctly on these flocks.

3. No movements of live turkeys to or from the area shall be permitted unless prior authorisation has been obtained for them to leave the holding for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.

4. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and part E of Annex II to Regulation

(EC) No 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

5. Furthermore, with regard to breeding turkeys, non-incubated eggs from the flock must be destroyed. However, such eggs may be used for human consumption if they are treated in a manner that guarantees the elimination of Salmonella in accordance with Community legislation on food hygiene and in compliance with the provisions of part D of Annex II to Regulation (EC) No 2160/2003.

Where eggs for hatching from flocks in which a *Salmonella* serotype is present are still present in a hatchery, they must be destroyed or treated in accordance with Regulation (EC) No 1069/2009 of the European Parliament and the Council.

6. Once the birds have been removed, the holding shall be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection and to make sure that Salmonella is no longer present in the environment. The competent authorities shall check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and, if appropriate, shall authorise restocking with new animals.

For the cleaning and disinfection procedure to be considered valid, measures explained in point 17 of this programme shall be performed.

7. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected.

However, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

8. The competent authorities shall be informed of the dates of departure of the birds in the flock, disinfection, taking of environmental samples and restocking, and all these processes shall be duly recorded for possible consultation by the competent authorities. Depopulation of the shed in which the positive flock was kept (and, when appropriate, slaughter or destruction of the animals) and restocking must all take place under official supervision.

9. If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anybody who can be considered as a risk in order to determine whether there are any Salmonella spp. carriers among them.

If, however, a serotype not concerned by the control programme is identified, the following measures shall be taken:

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

2. Thorough checks on the biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on turkey holdings.

2.1.5 **EU microbiological criteria** in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*

If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g.
Measures implemented by the FBO (farm level)

In accordance with Royal Decree 361/2009 on food chain information, the operator of the livestock holding must ensure that in all shipments of animals to the slaughterhouse, full information on the results of all analyses of samples taken that have importance for human health, in the framework of the surveillance and control of *Salmonella* is sent to the slaughterhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or last analyses, if the samples have been taken in the near future) has been negative or positive to Salmonella spp. and, in this last case, in addition, if it is negative or positive to S. Enteritidis or S. Typhimurium, and the information of the result/s of such analysis must be included in the FCI (Food Chain Information) to be considered complete.

If a flock on the holding tests positive for *S*. Enteritidis or *S*. Typhimurium, the operator of the livestock holding must also ensure that no live birds are moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.

Measures implemented by the FBO (slaughterhouse level)

Slaughter at the slaughterhouse shall be carried out in accordance with the provisions of Regulation (EC) No. 853/2004, which lays down specific hygiene rules for food of animal origin, and in particular Section II of Annex III thereof.

When a positive herd is received at the slaughterhouse, it is logistically slaughtered, i.e. the herd is slaughtered last in the daily slaughter order to minimize the possibility of cross-contamination, followed by cleaning and disinfection. This is carried out in line with the provisions of Regulation (EU) 2019/627 with the aim of reducing contamination of other animals or their meat as much as possible. In addition, in accordance with the provisions of Regulation (EC) No. 2073/2005, slaughterhouses shall include in their sampling plans poultry carcasses from flocks whose Salmonella status is unknown or positive for Salmonella Enteritidis or Salmonella Typhimurium.

There is a “Manual for the broiler sector in Spain for compliance with Regulation (EU) No 1086/2011 amending Regulations (EU) No 2160/2003 and (EC) No 2073/2005”, which, although it is voluntary, can provide guidance as to the correct way of handling birds slaughtered in slaughterhouses in relation to Salmonella.

As an example of the possible system of action, we attached (see part IV. Maps) the management diagram of birds sent to a slaughterhouse, recommended in the "GUIDE FOR THE MEAT POULTRY SECTOR IN SPAIN FOR COMPLIANCE WITH REGULATION (EU) No. 1086/2011 AMENDING REGULATIONS (EU) No. 2160/2003 AND (EC) No. 2073/2005", with some additional issues that are carried out voluntarily by the slaughterhouses that apply the guide, such as the immobilization of the carcasses sampled until the results are available.

Guide available through: https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf

Measures implemented by the CA (farm and slaughterhouse level)

The official veterinarian is responsible for verifying that the correct food chain information is passed on as required pursuant to RD 361/2009: accordingly, he or she must check that the livestock holdings are passing this information to the slaughterhouses in a consistent and effective, valid and reliable manner and ensure that the relevant animal health and food safety information, including that relating to the results of Salmonella testing, is also passed on. Provision is thus made for slaughterhouses to only accept animals for which the relevant information on the holding of origin has been received. As a general rule, the information should be received at least 24 hours prior to the arrival of the animals. Slaughter in slaughterhouses must take place in accordance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and in particular Section II of Annex III.

Official controls must be carried out in accordance with Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules regarding the performance of official controls on meat production and regarding production and relaying areas for live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627, of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council and Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council. No. 2074/2005 of the Commission as regards official controls.

The provisions of Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs, also apply in relation to the criteria for *Salmonella* in poultry meat. Once positive results for *S*. Enteritidis or *S*. Typhimurium are found in a consignment, the official veterinarian will ensure that targeted sampling and tests using the EN/ISO 6579 methodology or a validated alternative method are carried out, and lastly that the carcasses are withdrawn from the market and destroyed or that the destination previously given for the product is changed.

2.1.6 Laboratory accreditation

Laboratories in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation.

Please provide the list of the laboratories accredited to perform the analytical method for *Salmonella*.

Yes ☒ No ☐

If no, please explain

The Central Veterinary Laboratory in Algete (Madrid) of the Ministry of Agriculture, Fish and Food is the National Reference Laboratory for all serotypes of *Salmonella* in animals.

Laboratories analysing official samples as part of the programme must be established, recognised or designated by the competent bodies in the Autonomous Communities. These official laboratories must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or must apply quality assurance systems in accordance with that standard. They must also participate in the ring tests organised or co-ordinated by the National Reference Laboratory. The laboratories participating in the programme for the purposes of carrying out own checks must be recognised by the competent authorities of the Autonomous Communities in which they are established and must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or apply quality assurance systems in accordance with that standard. Laboratories must also regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory.

The list of participating laboratories must be published, for information purposes, at least on the MAPA website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/listadolaboratoriosatcycoporccaasalmonella_15062022_tcm30-431063.pdf

The competent authorities of the Autonomous Communities shall notify the Ministry of Agriculture, Fish and Food of the laboratories referred to in the previous paragraph or of any modifications to them so that the list may be published at least on the departmental website for information purposes. Where a laboratory serves at the same time as an Autonomous Community's official laboratory and participates in the own-check programme, it must notify the relevant competent authority or authorities and ensure that the two activities are managed separately, and it is subject to monitoring and periodic inspection by the competent authority to check that these are separate. If it fails to notify the authorities, or cannot guarantee that the activities are kept separate, it cannot operate as an official laboratory. The results obtained by authorised laboratories for both official monitoring and own checks shall

be valid and applicable throughout the country. Laboratories must reject samples which do not meet the requirements specified in this programme.

2.1.7 Analytical methods

The **analytical methods** used for the detection of the target *Salmonella* serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ ISO 6579-1:2017/Amd 1:2020. "Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of Salmonella spp. – AMENDMENT 1: Broader range of incubation temperatures, AMENDMENT to the status of Annex D, and correction of the composition of MSRV and SC".
Serotyping is performed following the Kaufman-White-Le Minor scheme.

Yes ☒ No ☐

If no, please describe the alternative method(s) used.

For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.

Yes ☒ No ☐

If no, please explain. If time limits are exceeded, please indicate what is done.

Salmonella spp. shall be isolated in accordance with Standard EN/ISO 6579-1. Horizontal method for the detection of *Salmonella* spp. in animal faeces and in samples at primary production level" which uses a semi-solid culture medium (modified semi-solid Rappaport - Vassiladis - MSRV) as a single selective enrichment medium. The semi-solid medium should be incubated at 41.5 ± 1 °C for 2x (24±3) hours. At least one isolate from each sample showing a positive reaction shall be typed, in accordance with the Kaufmann-White-Le Minor scheme. Laboratories may type their own Salmonella isolates or send them other laboratories authorised within the PNCS to be typed. The laboratory where typing takes place must issue a report including its results and send it to the laboratory that sent the isolates to be typed. The recording of results in the application and the notification of results as indicated in this programme are the responsibility of the laboratory that isolated the Salmonella. To prevent any delays in obtaining and notifying the results of typing:

• The isolate must be sent to another laboratory for typing no more than 24 hours following isolation.

• Typing must begin in the laboratory no more than 24 hours following receipt of the isolate in the laboratory.

• The issue and dispatch of the results report from the typing laboratory to the laboratory that sent the isolate, or the notification of the results, as appropriate, must take place no more than 24 hours after the results are obtained in the laboratory.

• The recording in the application and the notification of positive results by the isolating laboratory must take place within the deadlines laid down in this programme.

Alternative methods

Alternative methods may be used instead of the methods referred to above, if validated in accordance with the latest version of EN ISO 16140-2 (for alternative detection methods).

Storage of strains

At least the strains isolated from samples collected by the competent authority shall be stored for possible further characterization and antimicrobial susceptibility testing, as determined by Implementing Decision (EU) 2020/1729 of 17 November 2020 on antimicrobial resistance surveillance and reporting Decision 2013/652/EU of 12 November 2013 on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, using normal culture collection methods, which should ensure the integrity of the strains for at least two years.

Pursuant to that Decision, strains isolated from the own-check samples may also be stored to that end if the competent authority so decides.

To that end, the official control laboratories must send all strains of *Salmonella* isolated in the framework of the PNCS to the National Reference Laboratory (Algete).

Own-check laboratories must also send the National Reference Laboratory (Algete), on request, any strains obtained in the framework of the PNCS.

The frequency of dispatch of such strains shall be as agreed between the National Reference Laboratory and the laboratories.

Alternative methods may be used instead of the methods referred to above, if validated in accordance with EN ISO 16140-2 (for alternative detection methods).

2.1.8 Transportation and storage of samples

Samples are transported and stored in accordance with point 2.2.4 and 3.1 of the Annex to Regulation (EU) No 1190/2012. In particular, samples examination shall start in the laboratory within 48 hours following receipt and within 96 hours after sampling.
Yes ☒ No ☐

If no, please explain the actions taken in case time limits are exceeded

Samples shall be packed to ensure identification and safety of contents up to their arrival at the laboratory, using sterile, hermetically sealed containers. Samples shall be sent to the laboratories.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease. This Subdirectorate is the main responsible for the programme and for the coordination of it, through regular communications and meetings with regional authorities and with NRL and stakeholders.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the “National Veterinary Health Warning System Committee” (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health for zoonoses. Its tasks include the following:

a) Coordinating animal health actions across the different administrations.

b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.

c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.

d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an

intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc, and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an aditionnal quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website:
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.8.

2.3.1 Official controls at feed level

Please describe the **official controls at feed level** (including sampling)
Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities. As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of *Salmonella* spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of

cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for Salmonella (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for Salmonella, an identification of the serotype must be requested. Only in the case of S.

Enteritidis, S. Typhimurium, S. Infantis, S. Virchow and S. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp, the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of Salmonella and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of Salmonella in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including Salmonella. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding and flock

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as Salmonella control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of Salmonella. There are “Guides to Good Hygiene Practice for the prevention

of zoonotic Salmonella in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Food and the Environment. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Turkey holding operators shall have a code of good hygiene practice adapted from that applying to breeding turkeys holdings to achieve the aim of this national Salmonella surveillance and control programme, and shall ensure that the health information is kept up-to-date. The following records must be kept at holdings:

a) A record of the type and source of feed supplied to the animals.

b) A record of the outbreak of diseases that could affect the safety of animal by-products.

c) An up-to-date visitors' register listing the people and vehicles that have entered the holding.

d) A record of medicinal treatments, containing the information specified under Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products.

e) All the results of the *Salmonella* analyses and controls performed on the holding during the production stage. The results of the analyses of any samples taken in the incubator relating to that flock must also be kept. All these records shall be kept by the holder for at least three years. Those relating to the last 12 months shall be kept on the holding itself.

f) All movements of flocks entering and leaving the holding must be recorded in the holding register. The flock sheet must be kept for at least three years after the flock is slaughtered.

g) There must also be a documentary record of:

1. The protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).
2. Analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of Salmonella with public health significance.
3. The programmes and records of insect and rat extermination operations (dates, products used, procedure to check the effectiveness of the programme, etc.).

h) Producers of rearing chickens must report on the health status of the breeding flock of origin and on any vaccinations and own checks during the rearing of the chickens; this information must accompany the chickens when they are transferred to the producing holdings.

The holder shall have all the mandatory health documentation and record all the necessary details to enable the competent authority to perform ongoing checks on compliance with the holding health programme and the code of good hygiene practice, and in particular the records mentioned above under a), b), c), d), e), f) and g).

All holdings included in the programme shall be placed under the veterinary supervision of both the official veterinary services and of the authorised or competent veterinarians responsible for the holding, as laid down in Law No 8/2003 on animal health.

Without prejudice to Royal Decree No 637/2021, the owner of the holding must adopt protective livestock rearing measures to control the introduction of or contamination by Salmonella spp on the holding. In particular:

a) The design and maintenance of the installations must be suitable for preventing the entry of *Salmonella* spp.;

b) Appropriate measures must be taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease. A rat extermination programme must be carried out either by the holding itself or by authorised establishments;

c) Day-old poults are obtained from breeding turkey holdings and hatcheries which have satisfactorily passed inspections to prevent the vertical transmission of *S*. enteritidis and *S*. typhimurium, including its single-phase variant, the supplier must certify that the said chicks come from holdings free from the said serotypes, and documentation including the results and dates of the laboratory analyses (own checks and official sampling) performed since the last official sampling at the source holding must be made available to the purchaser;

d) Appropriate washing, cleaning, disinfection and rat extermination measures are taken in the production sheds and ancillary structures and on the materials and tools used in the production activities;

e) Tests are carried out to ensure that the cleaning and disinfection operations were performed appropriately.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in laboratories authorised under the national Salmonella monitoring and control programmes.

The detection methods used must be the same as those used for all other SNCP samples.

The results must be recorded in the computerised own-check application of MAPA. These samples shall be recorded within the samples of the outgoing flock. The Annex for own-check samples shall be used to send the samples to the laboratory.

The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, shall authorise installations to be occupied by new animals.

f) Adequate measures must be taken to prevent the transmission of *Salmonella* spp through drinking water.

g) The appropriate measures must be taken to prevent the presence of *Salmonella* spp in raw materials and feedingstuffs.

Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for Salmonella has been carried out and make express provision for such tests in the relevant HACCP system.

The checks must include analysis of the corresponding samples, which shall be made available to the health managers of the holdings receiving the feed.

The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis;

h) Suitable training courses for operators and, if necessary, for the owners of the holding shall be carried out;

i) Suitable health checks must be carried out to detect the possible source or sources of Salmonella contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation;

j) Appropriate sampling and analyses are carried out to detect *Salmonella* spp.;

k) Appropriate measures are taken in the event of positive cases of salmonellosis caused by either of the two *Salmonella* serotypes;

l) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.

b) Routine official **sampling scheme when FBO sampling takes place at the hatchery**: EU minimum requirements are implemented i.e. official sampling are performed:

- once a year, all flocks with at least 250 adult breeding turkeys between 30 and 45 weeks of age and in all holdings with elite, great grand-parents and grand-parent breeding turkeys; the competent authority may decide that this sampling may also take place at the hatchery; and
- all flocks on holdings in case of detection of *Salmonella enteritidis* or *Salmonella typhimurium* from samples taken at the hatchery (FBO or official samples), to investigate the origin of infection;

Yes ☒ No ☐

If no please explain. Indicate also : 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples must be taken by the qualified or authorised veterinarian or in some cases by sufficiently trained authorised personnel under veterinary supervision. The sample collection sheet shall identify the person performing the sample and his/her job position. The official sampling shall cover at least:

1. Breeding turkeys

• Once a year, all flocks on holdings with at least 250 adult breeding turkeys between 30 and 45 weeks of age and all holdings with elite, great-grandparent and grandparent breeding turkeys.

• All flocks on holdings where *Salmonella* Enteritidis or *Salmonella* Typhimurium, including monophasic *Salmonella* Typhimurium strains with the antigenic formula 1,4,[5],12:i:-, are detected in samples taken at the hatchery by the producer or as part of official controls, to investigate the source of infection.

Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check). If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals in order to determine whether there are any *Salmonella* spp. carriers among them.

Other official samples Whenever the competent authorities consider it necessary, official samples of animal feed and drinking water and environmental samples may be taken to confirm the effectiveness of cleaning and disinfection measures. Other types of samples may also be taken.

The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling on a case-by-case evaluation of epidemiological parameters, such as biosecurity conditions, the distribution or size of the flock.

c) If confirmatory samples taken at the holding (after positive results at the hatchery, or suspicion of false positivity on FBO samples taken on the holding) are negative, please describe the measures taken:

☒ Testing for antimicrobials or bacterial growth inhibitors (at least 5 birds per house) and if those substances are detected the flock is considered infected and eradication measures are implemented (annex II.C of Regulation (EC) No 2160/2003):

☐ Other official samples are taken on the breeding flock; if positive, the flock is considered infected and eradication measures are implemented, if negative, all restrictive measures are lifted

☐ Other official samples are taken on the progeny; if positive, the flock is considered infected and eradication measures are implemented, if negative, all restrictive measures are lifted

☐ None of these measures

Describe also if any other measures are implemented

In exceptional cases, and with a view to ruling out false positives or false negatives, the competent authority may decide to carry out confirmatory analyses on breeding turkeys, according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of Salmonella serotypes subjected to control in poultry farms" (available on the website):

i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected using fabric swabs of at least 900 cm^2 or replacing the dust samples by 2 extra samples of faeces or boot swabs; however, a 25 g sub-sample must be taken for analysis from each sample of faecal material or dust; all samples must be analysed separately, or

ii) bacteriological investigation of the caeca and oviducts of 300 birds, or

iii) bacteriological investigation of the shell and content of 4 000 eggs from each flock in pools of maximum 40 eggs.

In addition to the sampling provided for above, the competent authority shall check that there has been no use of antimicrobials which may affect the results of the sampling analyses.

Whenever there is a confirmatory result, samples of feed and water shall be taken to check whether the use of antimicrobials has affected the said result.

In addition to the arrangements referred to above, the sampling may include a sample of birds taken at random from each house at a holding, normally up to five birds per house unless the competent authority deems it necessary to take a larger sample.

In addition to the set arrangements above, the competent authority will check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

Whenever confirmatory testing is conducted, additional samples can be collected for the possible testing of antimicrobials or bacterial growth inhibitors as follows: birds shall be taken at random from within each poultry house of birds on the holding, normally up to five birds per house, unless the competent authority deems it necessary to sample a higher number of birds.

Additionally, samples of feed and water can be taken to determine whether the results of the confirmatory test may have been affected by the use of antimicrobials.

If antimicrobials or bacterial growth inhibitors are detected, *Salmonella* infection shall be considered confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a justification to the CA with the reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc, the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and Salmonella results, biosecurity measures, not relation with any foodborne outbreak last years, etc).

d) Antimicrobial control
Article 2 of Regulation (EC) No 1177/2006 (**antimicrobials** shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).
For samples please describe the samples taken, the analytical method used, the result of the tests.

The checks made by the competent authorities (laboratory tests or documentary decks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling. Sample specifications shall be made according to the laboratory indications.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the *Salmonella* serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Vaccination

☒ Voluntary
☐ Compulsory
☐ Forbidden

The use of *Salmonella* vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.
If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Vaccinations are performed in accordance with Article 3 of Commission Regulation (EC) No 1177/2006. Vaccination is not obligatory, but if it is performed, only vaccines with prior marketing authorisation from the Spanish Medical and Health Products Agency or the European Commission in accordance with Regulation (EC) No 726/2004 may be used. Once vaccination has been carried out, at least the following information shall be entered in the register of treatment with medicinal products: date of vaccination, name of the vaccine(s) administered, type of vaccine(s) administered, quantity (number of doses and quantity of each dose), name and address of the supplier of the medicinal product and identification of the batch of animals treated, and vaccine use shall be registered by means of a computerised application.

2.3.4 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).
Once the shed housing the infected flock has been depopulated, efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of *Salmonella* spp. in the environment. The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals. To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect). Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV). These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes. The detection methods used must be the same as for the other samples under the PNCS. The results for the same must be recorded using the MAPA computer application for own checks. The samples must be recorded alongside the samples for the outgoing flock. The sampling sheet for own checks must be used when sending such samples to the laboratory. If there is a positive result (we detect Salmonella spp.), cleaning and disinfection should be repeated. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.5 Monitoring of the target Salmonella serovars (*Salmonella enteritidis, Salmonella typhimurium*)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target *Salmonella* serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain
Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonosis and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning. A reference study was made of prevalence at Community level of *Salmonella* in turkey flocks of the species Meleagris gallopavo between October 2006 and September 2007. Analyses were made and samples taken from selected flocks of turkeys in accordance with Community guidelines as laid down in Commission Decision 2005/662/EC. According to information obtained from the study, prevalence of *S*. Enteritidis and *S*. Typhimurium serotypes in breeding turkey flocks was 0% and 2.8% in turkeys for fattening, rising to 5.3% in breeding turkeys and 56.3% in turkeys for fattening for *Salmonella* spp. The evolution of the prevalence of the types of *Salmonella* covered by checks on breeding turkey flocks is shown in the attached graphic (see part IV. Maps).

2.3.6 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks
The obligation to register livestock holdings in Spain derives, firstly, from Article 39 of Law No 8/2003 of 24 April 2003 on Animal Health More specifically, and in terms of poultry keeping, the obligation to register poultry-keeping holdings is regulated by the following legislation: Royal Decree No 479/2004 of 26 March 2004 setting up and regulating the general register of livestock holdings. This applies to all livestock species. They must be registered with a registration code/number and be classed in one of the following groups: • Meat-producing farms, and • Breeding farms. Royal Decree 2021/637 of July 27, regulating the basic rules of management of poultry Farms. Applicable to holding that breed or keep poultry for both egg and meat production, excluding own-consumption holdings, as set out in Article 1. Legislative measures and provisions concerning identification of the flocks: The programme shall cover breeding turkey flocks, since individual animals are not identified. Poultry flocks shall be defined in accordance with Regulation (EC) No 2160/2003 of the European Parliament and of the Council. For the purposes of the programme, an epidemiological unit shall be considered to be a flock of turkeys, defined as all poultry reared for the production of meat or eggs with the same

health status kept on the same premises or within the same enclosure and constituting a single population in epidemiological terms; in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of turkeys shall have an individual identification. To identify the flocks on a holding a capital letter corresponding to the shed shall be used (this letter must be written on the door to the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

REGA+SHED (CAPITAL LETTER) + ENTRY DATE OF THE BIRDS (mm/yyyy)

2.3.7 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation
In certain cases, the competent authority can order the compulsory slaughter of breeding turkeys that tested positive for the Salmonella serotypes covered by the checks. In these cases, the animals must be slaughtered in accordance with the provisions of Articles 20 and 21 of Law No 8/2003 on Animal Health. In cases where the competent authority orders the compulsory slaughter of birds, the owners of the birds shall be entitled to compensation, provided that they have complied with the animal health legislation in force. The scales for compensation are fixed by the Ministry of Agriculture, Food and the Environment following consultation with the Autonomous Communities. The above scales are public and are included in Royal Decree 823/2010 of 25 June 2010, laying down the scales of compensation for the compulsory slaughter of animals covered by the national control programmes for Salmonella in breeding and laying flocks of *Gallus gallus* and breeding turkey flocks. The age of the birds for compensation purposes shall be considered to be their age when the competent authority ordered the compulsory slaughter.

2.3.8 System to monitor the implementation of the programme

Please describe
Taking account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA), is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official

controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Finally, a plan to control own checks and inspect own-check laboratories is in place.

With a view to ascertaining that the own checks are being performed correctly, the competent authority may carry out the following plan to control own checks and inspect own-check laboratories (available on the website):

The official veterinary services shall perform a quality control of the own checks in a certain percentage of holdings, selected annually on the basis of the following prioritised risk criteria: Holdings in which own checks have shown negative results for the serotypes covered by the checks and official controls have shown positive results. Holdings in which own checks have shown negative results for the serotypes covered by the checks and in which there has been some Public Health communication regarding positive results. Holdings with negative results for own checks relating to the serotypes covered by the checks and positive LOD effectiveness control analysis.

Holdings in which own checks have shown negative results for the serotypes covered by the checks and in which there are no official controls, chosen at random.

The checks performed during the inspection shall consist of a series of questions to ascertain whether the stipulations of the programme are being fulfilled and an on-site inspection of the own-check sampling.

In this case, the own-check sampling shall be performed in the presence of an official veterinarian who, as an observer, shall try to identify practices that are not in line with the sampling procedures that are set out in the National Programmes and applicable to both CO and AUT. They must check critical aspects of these that can presumably have an impact on the results (e.g. use of enriched peptone water in boot swabs, origin, expiry, representativeness of the sample, number of steps and surface area used, where relevant, dispersion of the aliquots of faeces in order to generate sufficient representativeness in the pools, etc.). How and where the samples are kept before being sent to the laboratory must also be investigated, as must compliance with the deadlines for their being received in the laboratory.

During this inspection, the competent authority shall ask any questions it deems relevant and request the necessary documents regarding implementation of the own checks.

The official veterinarian must note down the results of the control in an inspection report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, shall be used by the competent authority to draw up an appraisal report. If any anomalies are detected, they shall be reported to the producer as quickly as possible so that they may be corrected immediately for use in successive own checks, irrespective of the administrative effects that could arise in this case in particular. The competent authority shall give a copy of the report to the person responsible for the own-check sampling.

If the competent authority considers it appropriate, duplicate samples shall be taken. One of the samples shall be taken by the official veterinarian, using his own materials, and shall

remain in his possession. This sample shall be sent to an official laboratory, together with the sampling sheet. The other sample shall be taken by the person in charge of own-check sampling and shall be taken using materials provided by this person. It shall remain in his possession and must be analysed like any other own check.

Whenever there are large discrepancies between the official control results and the own-check results on the same flock, the competent authority may request, if it deems it necessary, the isolated strains of the said flock from the own-check laboratory that analysed them in order to perform an analysis of them in an official laboratory in its Autonomous Community.

The inspections in the laboratories shall take place in accordance with the document attached above. Within two years, each Autonomous Community must have inspected all the laboratories in its territory.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: *Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate	Appropriate training on sampling protocol and requirements of the SNCP.

	sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and especificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledgement of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Knowledgement of the SNCP requirements in advance.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August-September (year N)	Intermediate follow-up technical report (data of first semester).
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view) Who are the target groups? How will the target groups benefit concretely from the project and what would change for them? Define the short, medium and long-term effects of the project. ***Possible examples:*** reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).
The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector. The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agri-food chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin. The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation. The main target group who must implement the programme is the farming sector of breeding turkeys, but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment. The expected effects of the programme are: - Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions. - Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures. - Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.). Describe how the visibility of EU funding will be ensured.
The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences. The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU. It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food. Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme. All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement “funded by the European Union”. The programme will be available in the MAPA’s website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue? Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?
The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed. Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities

(NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the *Salmonella* Control Programme.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	**80**		80	2
Adult flocks	**100**	100	100	100
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: " MAPA"

II. Targets for 2024

Table 2: Targets on laboratory tests on official samples from breeding flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	235
Serotyping	10
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	10

Table 3: Targets on official samples from breeding flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	80	100
N of flocks in the programme	80	100
N of flocks planned to be checked (b)	2	100
No of flock visits to take official samples (c)	2	110
N of official samples taken	14	234
Target serovars (d)	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
	☒ SE+ ST	☒ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	1	1
Possible N of flocks to be depopulated	1	1
Total N of birds to be slaughtered/culled	10000	1500
Total N of eggs to be destroyed	n/a	500
Total N of eggs to be heat treated	n/a	10000

(a) Including eligible and non-eligible flocks
(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
(c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
(d) *Salmonella enteritidis* and *Salmonella typhimurium* = SE + ST*Salmonella enteritidis, typhimurium, hadar, infantis, virchow* = SE+ ST + SH +SI + SV

Table 4: Targets on vaccination for breeding flocks of Turkeys

Type of test (description)	Target on vaccination
Number of flocks in the *Salmonella* programme	70
Number of flocks expected to be vaccinated	70
Number of birds expected to be vaccinated	200000
Number of doses expected to be administered	600000

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of Salmonella Enteritidis and Salmonella Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R1190-20190310&qid=1652941712941

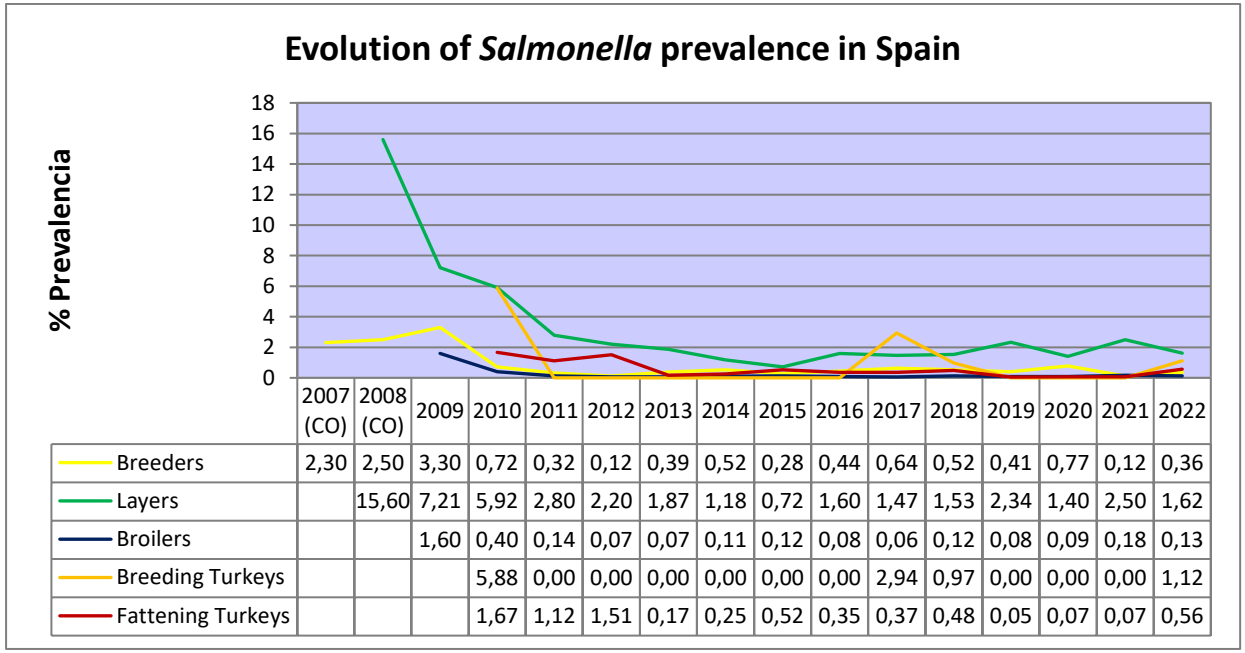
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2022)



	2007 (CO)	2008 (CO)	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Breeders	2,30	2,50	3,30	0,72	0,32	0,12	0,39	0,52	0,28	0,44	0,64	0,52	0,41	0,77	0,12	0,36
Layers		15,60	7,21	5,92	2,80	2,20	1,87	1,18	0,72	1,60	1,47	1,53	2,34	1,40	2,50	1,62
Broilers			1,60	0,40	0,14	0,07	0,07	0,11	0,12	0,08	0,06	0,12	0,08	0,09	0,18	0,13
Breeding Turkeys				5,88	0,00	0,00	0,00	0,00	0,00	0,00	2,94	0,97	0,00	0,00	0,00	1,12
Fattening Turkeys				1,67	1,12	1,51	0,17	0,25	0,52	0,35	0,37	0,48	0,05	0,07	0,07	0,56

b. Most prevalent serotypes of *Salmonella* in the different poultry populations (2022)

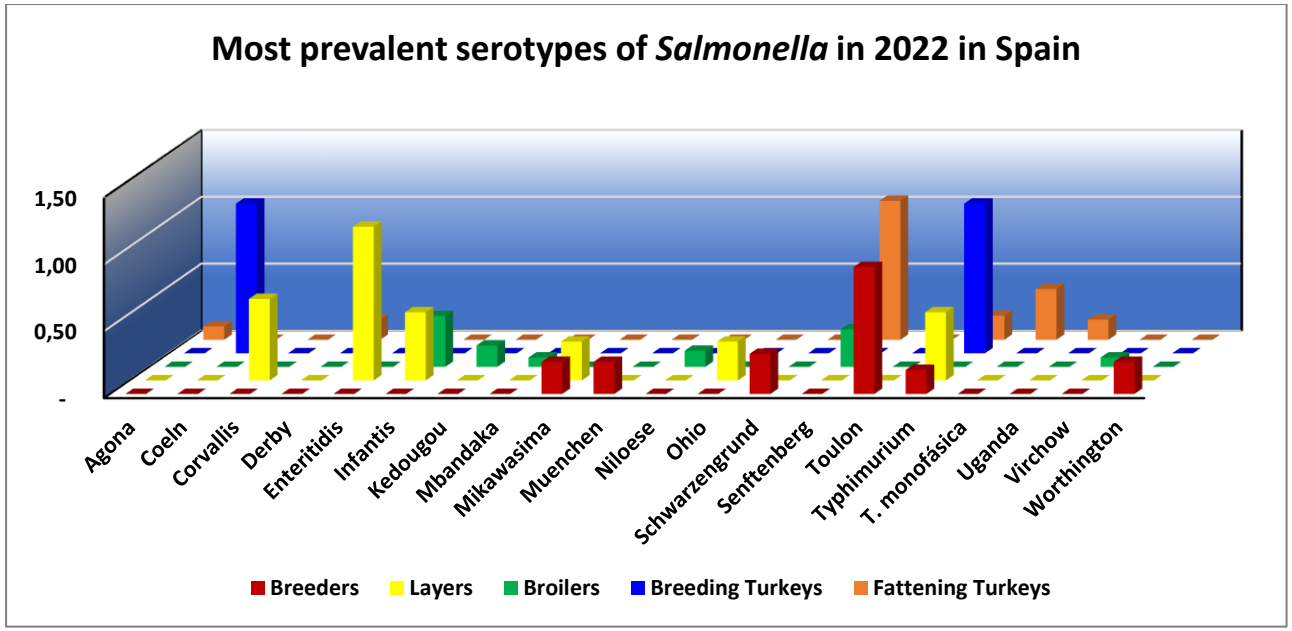

Most prevalent serotypes of *Salmonella* in 2022 in Spain
1,50
1,00
0,50
-
Agona
Coeln
Corvallis
Derby
Enteritidis
Infantis
Kedougou
Mbandaka
Mikawasima
Muenchen
Niloese
Ohio
Schwarzengrund
Senftenberg
Toulon
Typhimurium
T. monofásica
Uganda
Virchow
Worthington
Breeders
Layers
Broilers
Breeding Turkeys
Fattening Turkeys

Diagramme of veterinary services

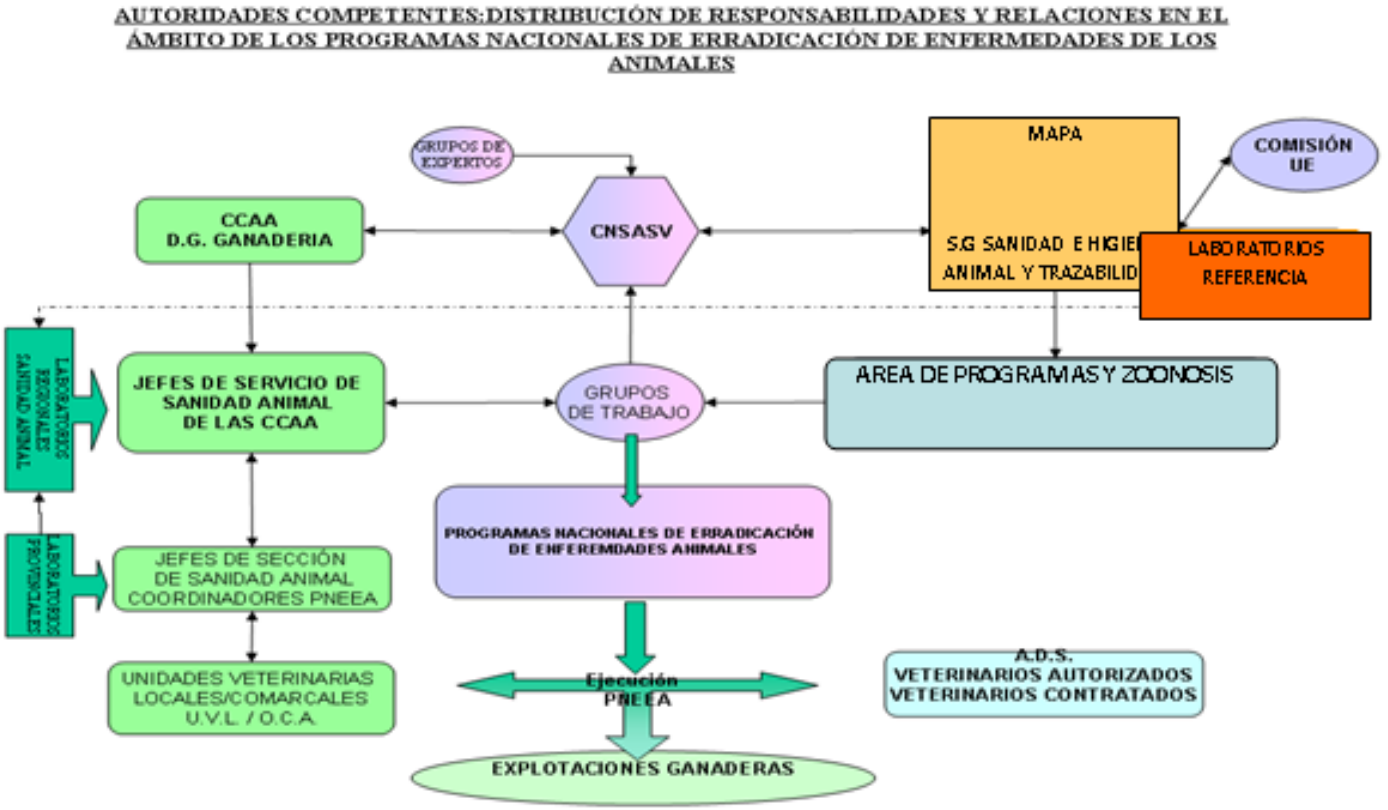
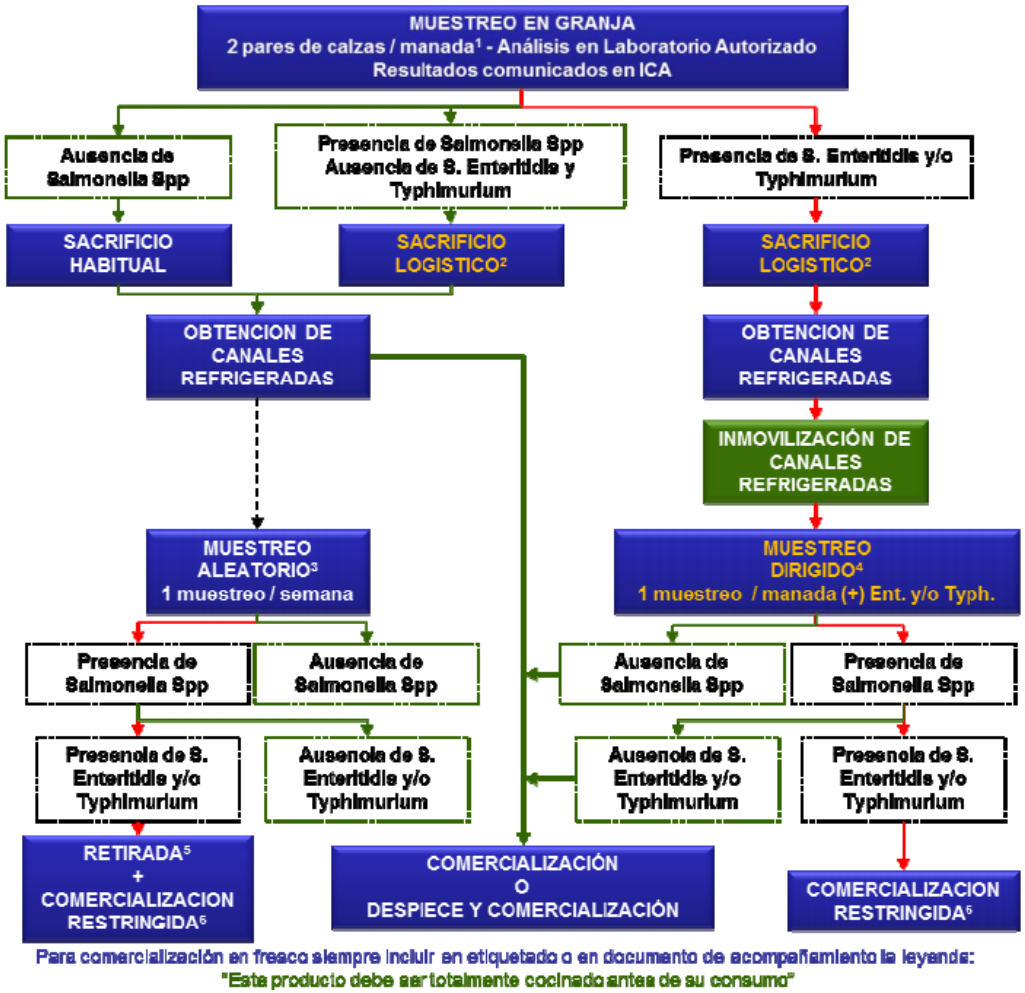


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):

FIGURA 6. SISTEMATICA DE ACTUACIÓN



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Zoonotic *Salmonella* Programme
Control programme – Reduction of prevalence of *Salmonella* serotypes in Fattening flocks of Turkeys

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*

Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.

For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	Spain
Disease	**ZOONOTIC SALMONELLA**
Animal population/Species	**Fattening flocks Turkeys**
Implementation Year	**2024**

CONTACT PERSON on Zoonotic *Salmonella* programme :

Name	Soledad Collado
e-mail	scollado@mapa.es
Job type within the CA	Head of Service of Zoonoses

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Salmonella in Fattening flocks Turkeys Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council,
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes ☒ No ☐

If no, please explain:

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of flocks of fattening turkeys remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Yes ☒ No ☐

If no, please explain:

The answer is yes, but S. Hadar, S. Infantis and S. Virchow are not target serovars.

The National Programme takes account of the specifications set out in Commission Regulation (EC) No 1190/2012 implementing Regulation (EC) No 2160/2003 with regard to the Community objective of reducing the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in turkeys. The target will be the reduction of the maximum percentage of fattening turkey positive to *Salmonella* Enteritidis and *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

For the purposes of verifying the attainment of the Community objective, a flock of turkeys shall be considered positive when:

a) the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:- (therefore different from the vaccine strains) has been detected in the flock, or

b) when antimicrobials or bacterial growth inhibitors have been detected in the flock.

Positive flocks of turkeys shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

If either of the two mentioned serotypes is detected or Salmonella spp is detected, the appropriate measures are explained in point 2.1.4.

For MS with less than 100 flocks of adult fattening turkeys, the Union target shall be that annually no more than one flock of adult fattening turkeys may remain positive.

Yes ☒ No ☐

If no, please explain:

(maximum 500 words)

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

Which countries will benefit from the project (directly and indirectly)?

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as Salmonella, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies that had the scientific assessment of EFSA for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence.

Therefore, the project is a continuation of the previous programmes for the control of Salmonella annually presented to the EU from the establishment of the objective of reduction of the prevalence, who was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to rise the level of public health and animal health in the EU, that at the same time enable the rational development of the farming sector and provides a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme has an harmonised surveillance, the results are comparable between MSs is based in an EU harmonised system, the results are comparable between MSs, and allow the analysis of the spatial and temporal trend at EU level.

It also has an international dimension, as it boostes the confidence not only of the EU Member States and its consumers but also of Third Countries, who can trust in a solid system which ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and economics, giving benefits worldwide.

1.4 Target population and Area of the implementation

This programme will be implemented on all Fattening flocks of turkeys

Yes ☒ No ☐

If no, please explain on which flocks:

It shall apply on all holdings where turkeys are reared for slaughter in accordance with point 1 of the Annex to Commission Regulation (EU) No 1190/2012.

In fattening turkey holdings from which the producer directly supplies small quantities of primary products to the final consumer or to a local retail establishment directly supplying primary products to the final consumer; at least 1 FBO control shall carry out in all flocks in the farm at that moment. The competent authorities of the Autonomous Communities shall take the steps necessary to ensure control and monitoring of salmonellosis of importance for public health.

This programme shall not apply to holdings that produce primary products intended for self-consumption (for private domestic use). Holdings to which the programme applies must be authorised and registered by the competent authorities.

For the purposes of the programme, an epidemiological unit shall be considered to be a flock of turkeys, defined as all poultry reared for the production of meat or eggs with the same health status kept on the same premises or within the same enclosure and constituting a single population in epidemiological terms; in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of turkeys shall have an individual identification. To identify the flocks on a holding a capital letter corresponding to the shed shall be used (this letter must be written on the door to the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

Fill in **Table 1**) **in the Annex** to this Form.

This programme will be implemented on the whole territory of the Member State

Yes ☒ **No** ☐

If no, please explain:

(maximum 500 words)

1.5 Notification of detection of target *Salmonella* serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ☒ **No** ☐

If yes, please describe the procedure briefly.

If no, please explain:

All legal or natural persons, and particularly veterinarians, must notify the competent authorities of any confirmed or suspected cases of *Salmonella*, whether or not they are related, and of action taken in the context of the national programmes for the control of salmonella. Accordingly, all confirmed or suspicious results from samples taken and analysed by operators for purposes other than those of the National Salmonella Control Plans (PNCS) must also be reported as if they were part of the plans.

When *Salmonella* spp. is isolated in samples taken in controls by the operator, the laboratories must carry out serotyping to be able to distinguish at least between the serotypes to be monitored under this programme and others. The laboratory itself may undertake serotyping

or commission another laboratory that is authorised for the purposes of the PNCS, as described at point 10 of this programme, to do so. If the serotyping shows positive for the serotypes to be monitored, for any other serotype or if the presence of these serotypes cannot be ruled out and the initial sample was taken in an own check, the competent authority must be notified as soon as possible, and never later than 24 hours after the laboratory and the owner of the holding receive the results of the analysis.

As soon as the operator becomes aware of the existence of a positive result, he shall be responsible for taking the appropriate measures, as set out in this programme for cases where the Salmonella serotypes concerned by the programme are detected. The competent authority may carry out a confirmatory analysis in exceptional cases and if considered appropriate.

It is mandatory to record all the results of own checks using the computer application developed to this end for the authorised laboratories to communicate the results, the provisions of the preceding paragraph notwithstanding.

To ensure suitable traceability of the samples taken during own checks and official monitoring and, in order to ensure suitable computer processing of the sampling data for this programme, the sampled flocks shall be identified as specified in point 3 of the programme.

The competent authority of the livestock service and Public Health shall, between them, ensure that there is sufficient information about the positive results.

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.
Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on S. Enteritidis and S. Typhimurium. During 2006, the monitoring and data collection of flocks of turkeys was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents. Since the beginning of the implementation of the *Salmonella* Control Programme in fattening turkeys until nowadays, the prevalence of *Salmonella* has dropped from 1,67% (2010) to 0,56% (2022), which corroborates the effectiveness of the programme. The most prevalent salmonellas with importance in public health are *S*. monophasic Typhimurium in first place, followed by *S*. Infantis.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of fattening flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to maintain adequate facilities for turkey production complying at the same time the necessary level of general biosecurity measures.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the *Salmonella* in Fattening Turkeys situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.
Yes ☒ No ☐

If yes, please make a short description of the most relevant biosecurity measures applied in order to prevent *Salmonella* contamination of their flock and please quote the document describing them, if any. Also please specify if biosecurity is part of the salmonella programmes or if there is national legislation in place for the implementation of biosecurity.

Specify if there is a national guidance available for the biosecurity measures to be implemented and if this guidance is easily accessible by the FBO's.

If no, please describe.

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (Royal Decree 637/2021, establishing basic rules for the management of poultry farms and national Animal Health Law 8/2003, that states general rules related with prevention, control and eradication measures, sector health organisation, authorisation and marketing of animal health and animal feed products, and the fees, inspections and sanctions in case of shortcomings). These rules are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic Salmonella in broiler farms and a general national work guideline for the prevention and control of Salmonella in all poultry populations, published to sum up the legal measures established in the legal provisions.

The guidelines and the information of general biosecurity are public and available at the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Within all these regulations, it is specified that the holder of the poultry farm must take protected husbandry measures to control the entry or contamination by Salmonella spp in the farm, and in particular that:

- the design and maintenance of the farm facilities is adequate.

- appropriate rodent control measures are carried out.

- adequate washing, cleaning and disinfection measures are carried out in the rearing sheds, production sheds, annexed structures and other structures, production facilities, annexed structures, as well as the material and utensils used in production activities.

- adequate measures are adopted to prevent the transmission of Salmonella spp. through drinking water.

- appropriate measures are taken to prevent the presence of Salmonella spp in raw materials and feedstuffs.

Therefore, without prejudice to the provisions of Royal Decree 637/2021, of July 27, establishing the basic rules for the management of poultry farms, the owner of the farm must take the necessary measures to control the entry or contamination by *Salmonella* spp in the farm, as described in the as described in section 14 of the national program.

Biosecurity measures will be checked at least once a year using the guideline protocol for checking biosecurity measures for holdings of fattening turkeys in this programme (see protocol in the programme available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx).

These measures will be checked at the same time as official sampling in the flock takes place. The data gathered in such surveys must be recorded using the computer application in the 'Biosecurity' section.

If, in the course of an inspection, shortcomings in the biosecurity measures are detected, this will be made known to the owner of the holding by means of a report in at least triplicate for

the owner of the holding and his legal representative or the person in charge of the animals, setting out all the shortcomings and the deadlines set for them to be remedied.

The official veterinarian shall adopt a proportionate and progressive approach in his work to enforce biosecurity rules and measures.

The competent authority may, if necessary, make use of the measures established in Chapter IV, Title V, of Law 8/2003 on animal health. This is without prejudice to other measures or penalties which may be adopted in respect of that flock or throughout the holding, depending on the type of shortcoming. The measures to be adopted to prevent health risks depend on the seriousness of the shortcoming and may range from shutting down the holding to the loss of the health authorisation for operating a holding.

The guideline protocol shall be observed in order to check and assess the biosecurity measures at holdings (biosecurity survey included in the programme and available in the MAPA website).

2.1.2 Minimum sampling requirements for food business operators

Samples at the initiative of the FBO's will be taken and analysed to test for the target *Salmonella* serovars respecting the following minimum sampling requirements:
All flocks of fattening turkeys within three weeks before slaughter.

Yes ☒ No ☐

The competent authority may authorise sampling in the last six weeks prior to the date of slaughter in case the turkeys are either kept more than 100 days or fall under organic turkey production according to Commission Regulation (EC) No 889/2008.

Yes ☒ No ☐

If no, please explain. Indicate also who takes the FBO samples. If the derogation is applied, how many holdings and flocks are concerned

In general terms, common turkey production cicles in Spain go beyond 100 days, and some FBO perform are authorised to do the sampling in the last six weeks prior slaughtering (in 2022, less than 100 flocks were authorised).

Samples shall be taken in accordance with the following minimum requirements:

Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding or may be carried out by qualified staff of the laboratory performing the analyses. The veterinarian responsible for the holding shall verify that the sampling protocol is being observed in accordance with the conditions set in this programme.

Samples of faeces from all flocks on the holding shall be taken using boot swabs during the three weeks prior to the birds' departure for the slaughterhouse. The results of the analyses on the samples must be known before the animals leave for the slaughterhouse. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

The competent authority may authorise sampling in the last six weeks prior to the date of slaughter in case the turkeys are:

- kept more than 100 days or;
- reared using organic production methods according to Commission Regulation (EC) No 889/2008.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding Salmonella, as reflected in section 14 of this program.

RECORDING OF RESULTS USING THE MINISTRY'S COMPUTER APPLICATION

The data and information obtained from holdings where own checks are performed (Own-check Sampling Annex) and the laboratory results shall be recorded using the computer application for the National Programme for the Control of Salmonella https://servicio.mapa.gob.es/

The results of the own-check samples must be recorded in the own-check application, together with the required accompanying data, within one month of the laboratory analysis result being obtained; the results must be obtained within 15 days of the sampling, on average, except in exceptional circumstances. All the data from the sampling annex must be properly filled in because it will not be possible to record the samples in the application if any data are missing. All the samples and data referring to the flocks sampled (official controls and own checks) that are not recorded in the Ministry's applications will not be valid for the purposes of the PNCS. Nevertheless, any positive result for *Salmonella*, which is considered to have public health significance, must be notified as laid down in the PNCS.

2.1.3 Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 1190/2012

Yes ☒ No ☐

If no, please explain

At least two pairs of boot swabs shall be taken.

All boot swabs may be pooled into one sample. In all sampling in which swabs are taken, before putting on the boot swabs, their surface shall be moistened by:

a) the application of maximum recovery diluents (MRD: 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water);
b) the application of sterile water;
c) the application of any other diluents approved by the national reference laboratory referred to in Article 11 (3) of Regulation (EC) No 2160/2003; or
d) being autoclaved in a container together with diluents.

The way to moisten boot swabs shall be to pour the liquid inside before putting them on or to shake them in a container of diluent.

Furthermore, measures must be taken to avoid the bacterial growth inhibitory effects which the disinfectants in the footbaths at the entrance to sheds may have. It shall be ensured that all sections in a house are represented in the sampling in a proportionate way. Each pair of boot swabs must cover about 50 % of the area of the house.

On completion of sampling, the swabs shall be carefully removed from the boots so as not to dislodge adherent material. Boot swabs may be inverted to retain material. They shall then be placed in a bag or pot and labelled.

Specific instructions for certain types of holdings

- For free range flocks of turkeys, samples shall only be collected in the area inside the shed.
- In flocks with fewer than 100 turkeys, where it is not possible to use boot swabs as access to the sheds is not possible, they may be replaced by hand drag swabs, where the boot swabs or socks are worn over gloved hands and rubbed over surfaces contaminated with fresh faeces, or if not feasible, by other sampling techniques for faeces fit for the intended purpose.

<u>Preparation of samples in the laboratory (official control and own checks)</u>

a) Absorbent boot swabs:

- The pair(s) of boot swabs must be unpacked carefully to avoid dislodging adherent faecal material. They must be submerged in 225 ml buffered peptone water that has been pre-warmed to room temperature. If necessary, more peptone water may be added so that free liquid remains around the sample to permit Salmonella to migrate.
- Swirl to fully saturate the sample and continue with the detection method.

b) Other samples of faeces and dust:

- The two faeces samples shall be combined and uniformly mixed and a 25 g sub-sample shall be collected for culture.
- The 25 g sub-sample shall be added to 225 ml of BPW that has been pre-warmed to room temperature and the resulting mixture swirled.
- Culture of the sample shall then be continued using the detection method indicated in this programme.

The dust sample shall preferably be analysed separately. However, for fattening flocks, the competent authority may decide to allow it to be pooled with the pair of boot/sock swabs for analysis.

UNE-EN ISO 6887-6 'specific rules for the preparation of samples taken at the primary production stage' may also serve as a guide when preparing all these samples.

Identification of samples and results of analyses

The samples sent must be properly preserved and identified (in accordance with the specimen report drawn up to accompany the samples to the laboratory: Sampling Sheet) There are two model sampling sheet annexes, one for official control and the other for own checks given that, in own checks, it is not necessary to collect so much information as in official controls. In both cases it must be clearly visible that the samples are for the purposes of the PNCS, so as to avoid confusion with the holding's own samples.

Those annexes must be completed in their entirety, because all the data collected therein are necessary for evaluating the PNCS.

A copy or duplicate of the sampling annex must be kept on the holding and must be kept together with the test results sent by the laboratory so that all the documentation relating to the samples (sampling annex and test results) is available on the farm. That documentation must be available to the official veterinary services when the official controls are carried out for the purposes of the PNCS. The documentation required may be in hard copy or electronic format. To ensure suitable traceability of the samples, the test result reports must record the following at least:

1. Date when samples were taken.
2. Identification of the flock. (REGA, CAPITAL LETTER IDENTIFYING THE SHED, DATE ON WHICH THE BIRDS ENTERED THE SHED (format mmyyyy).
3. Poultry population (breeders, layers, broilers, fattening or breeding turkeys)
4. Samples (specimen, number and weight or volume) arriving in the laboratory and how these have been pooled for analysis.

All statements of the results of analysis and sampling annexes for the purposes of the PNCS must include the following statement in clear, readily visible form.

'THESE SAMPLES FALL UNDER THE SALMONELLA NATIONAL CONTROL PROGRAMMES'

2.1.4 EU microbiological criteria in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*

If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g.

Measures implemented by the FBO (farm level)

If either of the two mentioned serotypes is detected in fattening turkey flocks, the appropriate measures shall be taken:

1. In positive turkey flocks, an in-depth epidemiological investigation shall be carried out to identify the cause and detect the source.
2. A thorough check of the biosafety measures for all the flocks in the holding will be carried out.
3. No movements of live turkeys to or from the area will be permitted unless prior authorisation has been obtained to leave the holding for slaughter or destruction. Transfer of animals must be accompanied by a health document.
4. Products obtained from these birds may be placed on the market for human consumption only in compliance with Community legislation on food hygiene and with part E of Annex II to Regulation 2160/2003. If not destined for human consumption, such products must be used or disposed f in accordance with Regulation 1069/2009 laying down health rules concerning animal by-products not intended for human consumption.
5. Once the birds have been removed, the holding will be cleaned efficiently, followed by disinfection, insect removal and rat extermination. A suitable time after disinfection is complete, environmental samples will be taken to check the effectiveness of the cleaning and disinfection.
6. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection. In those cases where the results of those tests prove the effectiveness of the cleaning and disinfection, the waiting period may be reduced to a minimum of 7 days.
7. The competent authorities shall be informed of the dates of departure of the birds in the flock, disinfection, taking of environmental samples and restocking, and all these processes shall be duly recorded for possible consultation by the competent authorities. Preventive depopulation of the shed in which the positive flock was kept must all take place under official supervision.
8. Results may be requested of laboratory analyses of the worker/s in order to determine whether there are any *Salmonella* spp. carriers among them.

If, however, a serotype not concerned by the control programme is identified, the following measures will be taken: an in-depth epidemiological investigation and thorough checks on the biosafety measures for all flocks on the holding.

In order to clarify the SNCP of poultry, this text is amended as a part of the Action Plan approved after the recommendation of report ref DSG(SANTE) 2019-6597 of the EU audit to evaluate SNCP carried out in November 2019, stating that the CA should ensure that only broiler and turkey flocks that have been sampled for Salmonella with a known test result can be sent for slaughter.

In accordance with Royal Decree 361/2009 on food chain information, the operator of the livestock holding must ensure that in all shipments of animals to the slaughterhouse, full information on the results of all analyses of samples taken that have importance for human health, in the framework of the surveillance and control of *Salmonella* is sent to the

slaughterhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or last analyses, if the samples have been taken in the near future) has been negative or positive to *Salmonella* spp. and, in this last case, in addition, if it is negative or positive to *S*. Enteritidis or *S*. Typhimurium, and the information of the result/s of such analysis must be included in the FCI (Food Chain Information) to be considered complete.

If a flock on the holding tests positive for *S*. Enteritidis or *S*. Typhimurium, the operator of the livestock holding must also ensure that no live birds are moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.

Measures implemented by the FBO (slaughterhouse level)

Slaughter at the slaughterhouse shall be carried out in accordance with the provisions of Regulation (EC) No. 853/2004, which lays down specific hygiene rules for food of animal origin, and in particular Section II of Annex III thereof.

When a positive herd is received at the slaughterhouse, it is logistically slaughtered, i.e. the herd is slaughtered last in the daily slaughter order to minimize the possibility of cross-contamination, followed by cleaning and disinfection. This is carried out in line with the provisions of Regulation (EU) 2019/627 with the aim of reducing contamination of other animals or their meat as much as possible. In addition, in accordance with the provisions of Regulation (EC) No. 2073/2005, slaughterhouses shall include in their sampling plans poultry carcasses from flocks whose Salmonella status is unknown or positive for Salmonella Enteritidis or Salmonella Typhimurium.

There is a “Manual for the broiler sector in Spain for compliance with Regulation (EU) No 1086/2011 amending Regulations (EU) No 2160/2003 and (EC) No 2073/2005”, which, although it is voluntary, can provide guidance as to the correct way of handling birds slaughtered in slaughterhouses in relation to Salmonella.

As an example of the possible system of action, we attached (see part IV. Maps) the management diagram of birds sent to a slaughterhouse, recommended in the "GUIDE FOR THE MEAT POULTRY SECTOR IN SPAIN FOR COMPLIANCE WITH REGULATION (EU) No. 1086/2011 AMENDING REGULATIONS (EU) No. 2160/2003 AND (EC) No. 2073/2005", with some additional issues that are carried out voluntarily by the slaughterhouses that apply the guide, such as the immobilization of the carcasses sampled until the results are available.

Guide available through: https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf

Measures implemented by the CA (farm and slaughterhouse level)

The official veterinarian is responsible for verifying that the correct food chain information is passed on as required pursuant to RD 361/2009: accordingly, he or she must check that the livestock holdings are passing this information to the slaughterhouses in a consistent and effective, valid and reliable manner and ensure that the relevant animal health and food safety

information, including that relating to the results of *Salmonella* testing, is also passed on. Provision is thus made for slaughterhouses to only accept animals for which the relevant information on the holding of origin has been received. As a general rule, the information should be received at least 24 hours prior to the arrival of the animals.

Slaughter in slaughterhouses must take place in accordance with Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, and in particular Section II of Annex III.

Official controls must be carried out in accordance with Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules regarding the performance of official controls on meat production and regarding production and relaying areas for live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627, of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council and Commission Regulation (EC) No. 2074/2005 of the European Parliament and of the Council. No. 2074/2005 of the Commission as regards official controls.

The provisions of Regulation (EC) No 2073/2005, on microbiological criteria for foodstuffs, also apply in relation to the criteria for *Salmonella* in poultry meat. Once positive results for *S*. Enteritidis or *S*. Typhimurium are found in a consignment, the official veterinarian will ensure that targeted sampling and tests using the EN/ISO 6579 methodology or a validated alternative method are carried out, and lastly that the carcasses are withdrawn from the market and destroyed or that the destination previously given for the product is changed.

2.1.5 Laboratory accreditation

Laboratories in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation.

Please provide the list of the laboratories accredited to perform the analytical method for *Salmonella*.

Yes ☒ No ☐

If no, please explain

The Central Veterinary Laboratory in Algete (Madrid) of the Ministry of Agriculture, Fish and Food is the National Reference Laboratory for all serotypes of Salmonella in animals.

Laboratories analysing official samples as part of the programme must be established, recognised or designated by the competent bodies in the Autonomous Communities. These official laboratories must operate and have access to accredited tests for Salmonella in all matrices monitored under the PNCS with which they work and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or must apply quality assurance systems in accordance with that

standard. They must also participate in the ring tests organised or co-ordinated by the National Reference Laboratory. The laboratories participating in the programme for the purposes of carrying out own checks must be recognised by the competent authorities of the Autonomous Communities in which they are established and must operate and have access to accredited tests for *Salmonella* in all matrices monitored under the PNCS with which they work, and be accredited in accordance with Standard EN/ISO 17025 on general requirements for the competence of testing and calibration laboratories, or apply quality assurance systems in accordance with that standard. Laboratories must also regularly participate in collaborative testing organised or co-ordinated by the National Reference Laboratory.

The list of participating laboratories must be published, for information purposes, at least on the MAPA website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/listadolaboratoriosatcycoporccaasalmonella_15062022_tcm30-431063.pdf

The competent authorities of the Autonomous Communities shall notify the Ministry of Agriculture, Fish and Food of the laboratories referred to in the previous paragraph or of any modifications to them so that the list may be published at least on the departmental website for information purposes. Where a laboratory serves at the same time as an Autonomous Community's official laboratory and participates in the own-check programme, it must notify the relevant competent authority or authorities and ensure that the two activities are managed separately, and it is subject to monitoring and periodic inspection by the competent authority to check that these are separate. If it fails to notify the authorities, or cannot guarantee that the activities are kept separate, it cannot operate as an official laboratory. The results obtained by authorised laboratories for both official monitoring and own checks shall be valid and applicable throughout the country. Laboratories must reject samples which do not meet the requirements specified in this programme.

2.1.6 Analytical methods

The **analytical methods** used for the detection of the target *Salmonella* serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ ISO 6579-1:2017/Amd 1:2020. "Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of *Salmonella spp*. – AMENDMENT 1: Broader range of incubation temperatures, AMENDMENT to the status of Annex D, and correction of the composition of MSRV and SC".
Serotyping is performed following the Kaufman-White-Le Minor scheme.

Yes ☒ No ☐

If no, please describe the alternative method(s) used.

For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.

Yes ☒ No ☐

If no, please explain. If time limits are exceeded, please indicate what is done.

Salmonella spp. shall be isolated in accordance with Standard EN/ISO 6579-1. Horizontal method for the detection of *Salmonella* spp. in animal faeces and in samples at primary production level" which uses a semi-solid culture medium (modified semi-solid Rappaport - Vassiladis - MSRV) as a single selective enrichment medium. The semi-solid medium should be incubated at 41.5 ± 1 °C for 2x (24±3) hours. At least one isolate from each sample showing a positive reaction shall be typed, in accordance with the Kaufmann-White-Le Minor scheme. Laboratories may type their own Salmonella isolates or send them other laboratories authorised within the PNCS to be typed. The laboratory where typing takes place must issue a report including its results and send it to the laboratory that sent the isolates to be typed. The recording of results in the application and the notification of results as indicated in this programme are the responsibility of the laboratory that isolated the Salmonella. To prevent any delays in obtaining and notifying the results of typing:

- The isolate must be sent to another laboratory for typing no more than 24 hours following isolation.
- Typing must begin in the laboratory no more than 24 hours following receipt of the isolate in the laboratory.
- The issue and dispatch of the results report from the typing laboratory to the laboratory that sent the isolate, or the notification of the results, as appropriate, must take place no more than 24 hours after the results are obtained in the laboratory.
- The recording in the application and the notification of positive results by the isolating laboratory must take place within the deadlines laid down in this programme.

Alternative methods

Alternative methods may be used instead of the methods referred to above, if validated in accordance with the latest version of EN ISO 16140-2 (for alternative detection methods).

Storage of strains

At least the strains isolated from samples collected by the competent authority shall be stored for possible further characterization and antimicrobial susceptibility testing, as determined by Implementing Decision (EU) 2020/1729 of 17 November 2020 on antimicrobial resistance surveillance and reporting Decision 2013/652/EU of 12 November 2013 on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, using normal culture collection methods, which should ensure the integrity of the strains for at least two years.

Pursuant to that Decision, strains isolated from the own-check samples may also be stored to that end if the competent authority so decides.

To that end, the official control laboratories must send all strains of *Salmonella* isolated in the framework of the PNCS to the National Reference Laboratory (Algete). Own-check laboratories must also send the National Reference Laboratory (Algete), on request, any strains obtained in the framework of the PNCS. The frequency of dispatch of such strains shall be as agreed between the National Reference Laboratory and the laboratories.

2.1.7 Transportation and storage of samples

Samples are transported and stored in accordance with point 2.2.4 and 3.1 of the Annex to Regulation (EU) No 200/2012. In particular samples examination at the laboratory shall start within 48 hours following receipt and within 4 days after sampling.
Yes ☒ No ☐

If no, please explain the actions taken in case time limits are exceeded

Samples shall be packed to ensure identification and safety of contents up to their arrival at the laboratory, using sterile, hermetically sealed containers. Samples shall be sent to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection, preferably by express mail or courier. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat (over 25°C) and exposure to sunlight are avoided. At the laboratory samples shall be kept refrigerated until examination, which shall be started, if possible, within 48 hours of receipt and certainly within 96 hours of sampling.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease. This Subdirectorate is the main responsible for the programme and for the coordination of it, through regular communications and meetings with regional authorities and with NRL and stakeholders.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health for zoonoses. Its tasks include the following:

a) Coordinating animal health actions across the different administrations.

b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.

c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.

d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity[1] indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc, and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an aditionnal quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website:
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf
https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.8.

2.3.1 Official controls at feed level

Please describe the **official controls at feed level** (including sampling)

Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities.

As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of *Salmonella* spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to

ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for Salmonella (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for Salmonella, an identification of the serotype must be requested. Only in the case of S. Enteritidis, S. Typhimurium, S. Infantis, S. Virchow and S. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp, the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of Salmonella and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of Salmonella in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food:

https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including Salmonella. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding and flock level

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as Salmonella control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of Salmonella. There are "Guides to Good Hygiene Practice for the prevention of zoonotic Salmonella in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Food and the Environment. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves_bioseguridad.aspx

Turkey holding operators shall have a code of good hygiene practice adapted from that applying to fattening turkeys holdings to achieve the aim of this national *Salmonella* surveillance and control programme, and shall ensure that the health information is kept up-to-date. The following records must be kept at holdings:

a) A record of the type and source of feed supplied to the animals.

b) A record of the outbreak of diseases that could affect the safety of animal by-products.

c) An up-to-date visitors' register listing the people and vehicles that have entered the holding.

d) A record of medicinal treatments, containing the information specified under Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products.

e) All the results of the *Salmonella* analyses and controls performed on the holding during the production stage. The results of the analyses of any samples taken in the incubator relating to that flock must also be kept. All these records shall be kept by the holder for at least three years. Those relating to the last 12 months shall be kept on the holding itself.

f) All movements of flocks entering and leaving the holding must be recorded in the holding register. The flock sheet must be kept for at least three years after the flock is slaughtered.

g) There must also be a documentary record of:

1. The protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).
2. Analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of Salmonella with public health significance.
3. The programmes and records of insect and rat extermination operations (dates, products used, procedure to check the effectiveness of the programme, etc.).

h) Producers of rearing chickens must report on the health status of the breeding flock of origin and on any vaccinations and own checks during the rearing of the chickens; this information must accompany the chickens when they are transferred to the producing holdings.

The holder shall have all the mandatory health documentation and record all the necessary details to enable the competent authority to perform ongoing checks on compliance with the holding health programme and the code of good hygiene practice, and in particular the records mentioned above under a), b), c), d), e), f) and g).

All holdings included in the programme shall be placed under the veterinary supervision of both the official veterinary services and of the authorised or competent veterinarians responsible for the holding, as laid down in Law No 8/2003 on animal health.

Without prejudice to Royal Decree No 637/2021, the owner of the holding must adopt protective livestock rearing measures to control the introduction of or contamination by Salmonella spp on the holding. In particular:

a) The design and maintenance of the installations must be suitable for preventing the entry of *Salmonella* spp.;
b) Appropriate measures must be taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease. A rat extermination programme must be carried out either by the holding itself or by authorised establishments;
c) Day-old poults are obtained from breeding turkey holdings and hatcheries which have satisfactorily passed inspections to prevent the vertical transmission of *S*. Enteritidis and *S*. Typhimurium, including its single-phase variant, the supplier must certify that the said chicks come from holdings free from the said serotypes, and documentation including the results and dates of the laboratory analyses (own checks and official sampling) performed since the last official sampling at the source holding must be made available to the purchaser;
d) Appropriate washing, cleaning, disinfection and rat extermination measures are taken in the production sheds and ancillary structures and on the materials and tools used in the production activities;
e) Tests are carried out to ensure that the cleaning and disinfection operations were performed appropriately. To verify cleaning and disinfection one or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or

any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipments, watering equipments, belts, pilars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV). These samples must be analysed in laboratories authorised under the national *Salmonella* monitoring and control programmes. The detection methods used must be the same as those used for all other SNCP samples.

The results must be recorded in the computerised own-check application of MAPA. These samples shall be recorded within the samples of the outgoing flock. The Annex for own-check samples shall be used to send the samples to the laboratory.

The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, shall authorise installations to be occupied by new animals.

f) Adequate measures must be taken to prevent the transmission of *Salmonella* spp through drinking water.

g) The appropriate measures must be taken to prevent the presence of *Salmonella* spp in raw materials and feedingstuffs. Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for *Salmonella* has been carried out and make express provision for such tests in the relevant HACCP system. The checks must include analysis of the corresponding samples, which shall be made available to the health managers of the holdings receiving the feed. The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis;

h) Suitable training courses for operators and, if necessary, for the owners of the holding shall be carried out;

i) Suitable health checks must be carried out to detect the possible source or sources of Salmonella contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation;

j) Appropriate sampling and analyses are carried out to detect *Salmonella* spp.;

k) Appropriate measures are taken in the event of positive cases of salmonellosis caused by either of the two *Salmonella* serotypes;

l) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.

b) Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:

- in one flock of fattening turkeys per year on 10% of holding comprising at least 500 fattening turkeys;

Yes ☒ No ☐

If no, please explain. Indicate also : 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples must be taken by the qualified or authorised veterinarian or in some cases by sufficiently trained authorised personnel under veterinary supervision. The sample collection sheet shall identify the person performing the sample and his/her job position.

The official sampling shall cover at least:

This shall be done once a year, on at least one flock on 10% of the holdings with at least 500 fattening turkeys and may be repeated whenever the competent authority considers this appropriate.

In any Autonomous Community with fewer than 10 holdings an official control shall be conducted on at least one farm.

Among the risk criteria for choosing 10% of the holdings the following shall be taken into account:

a) characteristics of holdings:

- Type of production.
- Size of the farm (poultry population) .
- Poultry density in the province (measured in this case by the number of holdings).

b) historical record of holdings

- Changes in the results obtained in the sampled holdings in previous years.
- Priority to be given to those holdings on which no information is available.

c) cases of non-compliance

- Priority to be given by assigning a greater risk to those holdings on which shortcomings in the biosafety surveys have not been remedied and those on which positive results have been obtained.

Sampling shall take place within the last three weeks before the birds are sent for slaughter.

Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check).

If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals in order to determine whether there are any *Salmonella* spp. carriers among them.

All data and information gathered on holdings on which official sampling has been performed (SAMPLING SHEET AND BIOSAFETY PROTOCOLS ANNEX) and the laboratory results shall be recorded in a dedicated computer application developed for the National Programme for the Control of *Salmonella*. https://servicio.mapama.gob.es/

Other official samples

Whenever the competent authorities see the need, official samples of animal feed, drinking water and environmental samples may be taken to check the effectiveness of cleaning and disinfection measures. Other types of samples may also be taken.

The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling on a case-by-case evaluation of epidemiological parameters, such as biosecurity conditions, the distribution or size of the flock.

c) If confirmatory samples taken at the holding (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery):

After positive official samples at the holding

☐ Always
☐ Sometimes (criteria apply)
☒ Never

After positive FBO samples at the holding

☐ Always
☐ Sometimes (criteria apply)
☒ Never

When official confirmatory sampling is performed, additional samples are taken for checking the presence of antimicrobials:

☐ Always
☐ Sometimes
☒ Never

Please insert any comments. Describe the criteria used to determine if confirmatory sampling is performed. Indicate also which samples (if any) are taken to check the presence of antimicrobials.

Confirmatory analyses are not carried out for fattening turkeys.

d) Antimicrobial control
Article 2 of Regulation (EC) No 1177/2006 (**antimicrobials** shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).
For samples please describe the samples taken, the analytical method used, the result of the tests.

The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the *Salmonella* serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the birds have been removed, the holding will be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks will be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples will be taken to check the effectiveness of the cleaning and disinfection and to make sure that Salmonella is no longer present in the environment.

The competent authorities will check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and, where appropriate, will authorise restocking with new animals.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes.

The detection methods used must be the same as for the other samples under the PNCS.

The results for the same must be recorded using the MAPA computer application for own checks.

The samples must be recorded alongside the samples for the outgoing flock.

The sampling sheet for own checks must be used when sending such samples to the laboratory.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (*Salmonella enteritidis, Salmonella typhimurium*)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target *Salmonella* serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain
Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonosis and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning. A reference study was made of prevalence at Community level of *Salmonella* in turkey flocks of the species Meleagris gallopavo between October 2006 and September 2007. Analyses were made and samples taken from selected flocks of turkeys in accordance with Community guidelines as laid down in Commission Decision 2005/662/EC. According to information obtained from the study, prevalence of *S*. Enteritidis and *S*. Typhimurium serotypes in breeding turkey flocks was 0% and 2.8% in turkeys for fattening, rising to 5.3% in breeding turkeys and 56.3% in turkeys for fattening for *Salmonella* spp. The evolution of the prevalence of the types of *Salmonella* covered by checks on fattening turkey flocks is shown in the attached graphic (see part IV. Maps).

2.3.5 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks
The obligation to register livestock holdings in Spain derives, firstly, from Article 39 of Law No 8/2003 of 24 April 2003 on Animal Health More specifically, and in terms of poultry keeping, the obligation to register poultry-keeping holdings is regulated by the following legislation: Royal Decree No 479/2004 of 26 March 2004 setting up and regulating the general register of livestock holdings. This applies to all livestock species.

They must be registered with a registration code/number and be classed in one of the following groups:

- Meat-producing farms, and
- Breeding farms.

Royal Decree 1084/2005 of 16 September 2005 regulating poultry rearing for meat Applicable to holding that breed or keep poultry for meat production, excluding own-consumption holdings, as set out in Article 2(b).

Legislative measures and provisions concerning identification of the flocks:

The programme shall cover fattening turkey flocks since individual animals are not identified.

Poultry flocks shall be defined in accordance with Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

For the purposes of the programme, an epidemiological unit shall be considered to be a flock of turkeys, defined as all poultry reared for the production of meat or eggs with the same health status kept on the same premises or within the same enclosure and constituting a single population in epidemiological terms; in the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of turkeys shall have an individual identification. To identify the flocks on a holding a capital letter corresponding to the shed shall be used (this letter must be written on the door to the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

REGA+SHED (CAPITAL LETTER)+ ENTRY DATE OF THE BIRDS (mm/yyyy)

2.3.6 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation
The official veterinary services of the Autonomous Communities (ACs) organise compulsory slaughter and are responsible for providing slaughter compensation. The ACs are responsible for financing this. For broiler chickens and fattening turkeys, slaughter in the case of positive flocks is not compulsory and therefore is not compensated.

2.3.7 System to monitor the implementation of the programme

Please describe
Taking account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission; lastly, it is responsible for reporting on the development of the disease. The

Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Finally, a plan to control own checks and inspect own-check laboratories is in place.

With a view to ascertaining that the own checks are being performed correctly, the competent authority may carry out the following plan to control own checks and inspect own-check laboratories (document available in the MAPA website).

The official veterinary services shall perform a quality control of the own checks in a certain percentage of holdings, selected annually on the basis of the following prioritised risk criteria: Holdings in which own checks have shown negative results for the serotypes covered by the checks and official controls have shown positive results. Holdings in which own checks have shown negative results for the serotypes covered by the checks and in which there has been some Public Health communication regarding positive results. Holdings with negative results for own checks relating to the serotypes covered by the checks and positive LOD effectiveness control analysis.

Holdings in which own checks have shown negative results for the serotypes covered by the checks and in which there are no official controls, chosen at random.

The checks performed during the inspection shall consist of a series of questions to ascertain whether the stipulations of the programme are being fulfilled and an on-site inspection of the own-check sampling.

In this case, the own-check sampling shall be performed in the presence of an official veterinarian who, as an observer, shall try to identify practices that are not in line with the sampling procedures that are set out in the National Programmes and applicable to both CO and AUT. They must check critical aspects of these that can presumably have an impact on the results (e.g. use of enriched peptone water in boot swabs, origin, expiry, representativeness of the sample, number of steps and surface area used, where relevant, dispersion of the aliquots of faeces in order to generate sufficient representativeness in the pools, etc.). How and where the samples are kept before being sent to the laboratory must also be investigated, as must compliance with the deadlines for their being received in the laboratory.

During this inspection, the competent authority shall ask any questions it deems relevant and request the necessary documents regarding implementation of the own checks.

The official veterinarian must note down the results of the control in an inspection report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, shall be used by the competent authority to draw up an appraisal report. If any anomalies are detected, they shall be reported to the producer as quickly as possible so that they may be corrected immediately for use in successive own checks, irrespective of the administrative effects that could arise in this case in particular. The

competent authority shall give a copy of the report to the person responsible for the own-check sampling.

If the competent authority considers it appropriate, duplicate samples shall be taken. One of the samples shall be taken by the official veterinarian, using his own materials, and shall remain in his possession. This sample shall be sent to an official laboratory, together with the sampling sheet. The other sample shall be taken by the person in charge of own-check sampling and shall be taken using materials provided by this person. It shall remain in his possession and must be analysed like any other own check.

Whenever there are large discrepancies between the official control results and the own-check results on the same flock, the competent authority may request, if it deems it necessary, the isolated strains of the said flock from the own-check laboratory that analysed them in order to perform an analysis of them in an official laboratory in its Autonomous Community.

The inspections in the laboratories shall take place in accordance with the document attached above. Within two years, each Autonomous Community must have inspected all the laboratories in its territory.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

***Note:** Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.

2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and especificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledgement of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated turkey meat. Impact on public	Rigorous accomplishment of the control programme and of the next stages of the agri-

	health, on food safety, on farmer's production. (Medium risk)	food chain (hygiene process, slaughtering process). Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and corrective actions established in the SNCP (in case the cause of contamination was at farm level).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Knowledgement of the SNCP requirements in advance.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August-September (year N)	Intermediate follow-up technical report (data of first semester).

Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

*Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)*

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agri-food chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level

of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.

- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of fattening turkey flocks remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement “funded by the European Union”.

The programme will be available in the MAPA’s website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the *Salmonella* Control Programme.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Flocks subject to the programme

	Number of holdings
Total number of holdings with fattening turkeys in the MS	**690**
Total number of houses in these holdings	**4250**
Number of holdings with more than 500 fattening turkeys	**685**

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: “MAPA "

II. Targets for 2024

Table 2: Targets on laboratory tests on official samples from fattening flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	90
Serotyping	60
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	15

Table 3: Targets on official samples from fattening flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	5	4250
N of flocks in the programme	5	4250
N of flocks planned to be checked (b)	2	85
No of flock visits to take official samples (c)	2	88
N of official samples taken	2	90
Target serovars (d)	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
	☒ SE+ ST	☒ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	0	10

(a) Including eligible and non-eligible flocks
(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
(c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
(d) *Salmonella enteritidis* and *Salmonella typhimurium* = SE + ST; *Salmonella enteritidis, typhimurium, hadar, infantis, virchow* = SE+ ST + SH +SI + SV

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

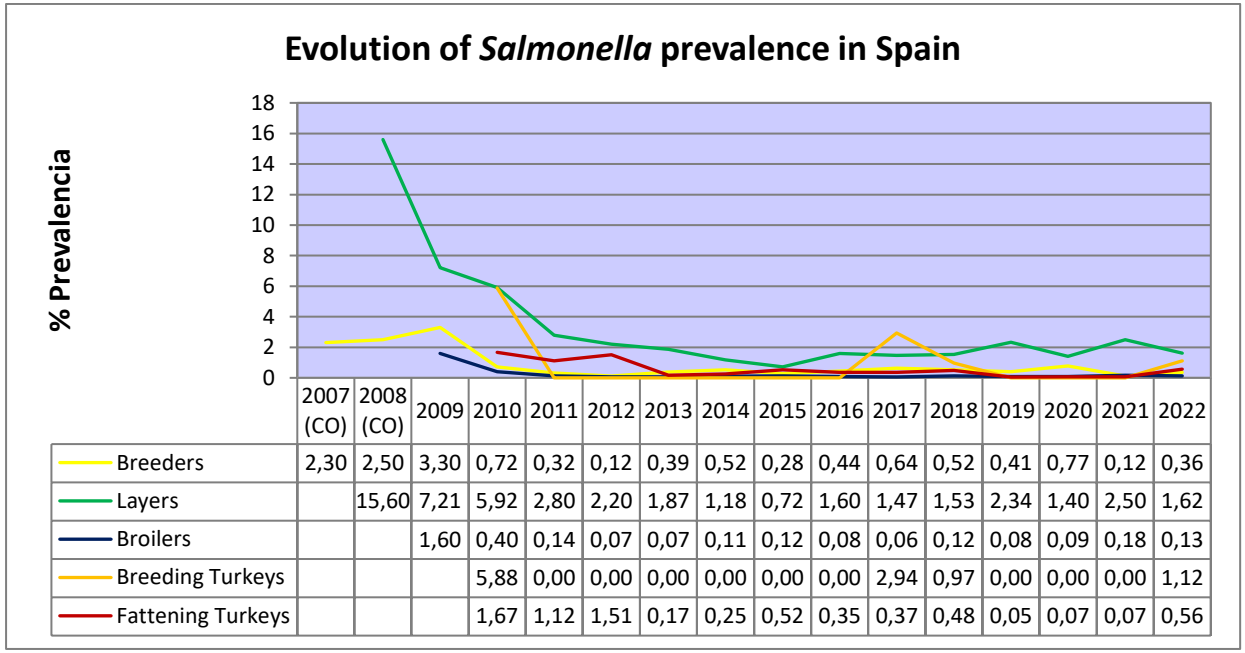
- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of Salmonella Enteritidis and Salmonella Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R1190-20190310&qid=1652941712941
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224

- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2022)



	2007 (CO)	2008 (CO)	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Breeders	2,30	2,50	3,30	0,72	0,32	0,12	0,39	0,52	0,28	0,44	0,64	0,52	0,41	0,77	0,12	0,36
Layers		15,60	7,21	5,92	2,80	2,20	1,87	1,18	0,72	1,60	1,47	1,53	2,34	1,40	2,50	1,62
Broilers			1,60	0,40	0,14	0,07	0,07	0,11	0,12	0,08	0,06	0,12	0,08	0,09	0,18	0,13
Breeding Turkeys				5,88	0,00	0,00	0,00	0,00	0,00	0,00	2,94	0,97	0,00	0,00	0,00	1,12
Fattening Turkeys				1,67	1,12	1,51	0,17	0,25	0,52	0,35	0,37	0,48	0,05	0,07	0,07	0,56

b. Most prevalent serotypes of *Salmonella* in the different poultry populations (2022)

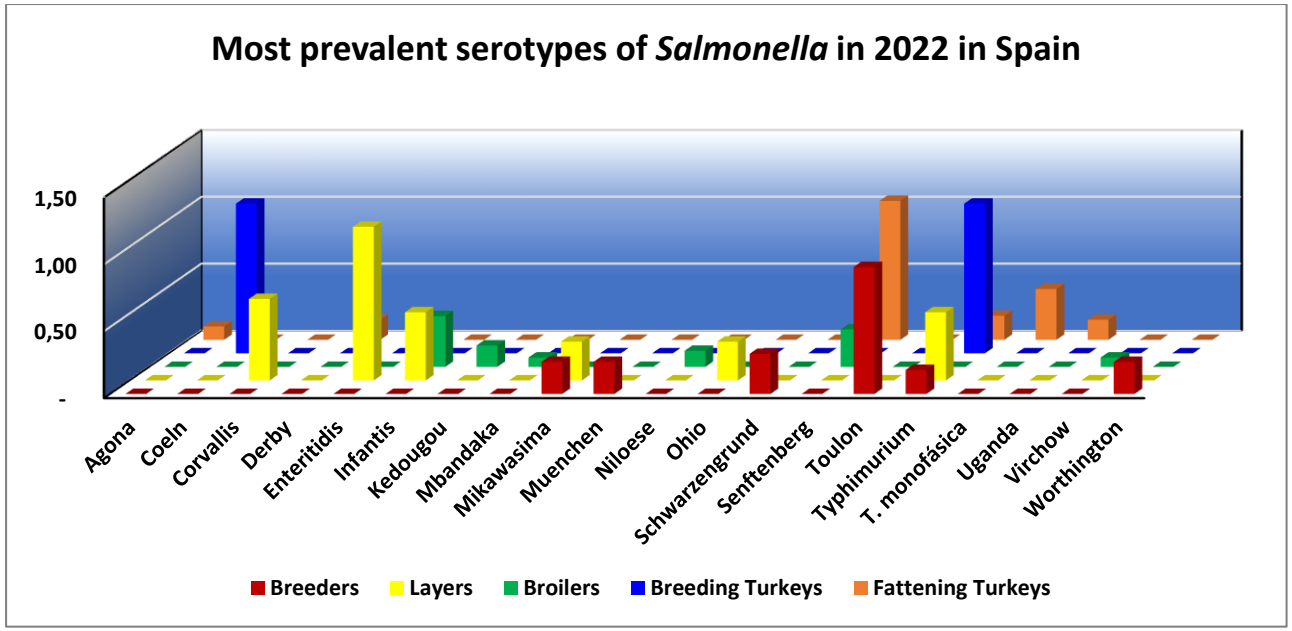

Most prevalent serotypes of *Salmonella* in 2022 in Spain
1,50
1,00
0,50
-
Agona
Coeln
Corvallis
Derby
Enteritidis
Infantis
Kedougou
Mbandaka
Mikawasima
Muenchen
Niloese
Ohio
Schwarzengrund
Senftenberg
Toulon
Typhimurium
T. monofásica
Uganda
Virchow
Worthington
Breeders
Layers
Broilers
Breeding Turkeys
Fattening Turkeys

Diagramme of veterinary services

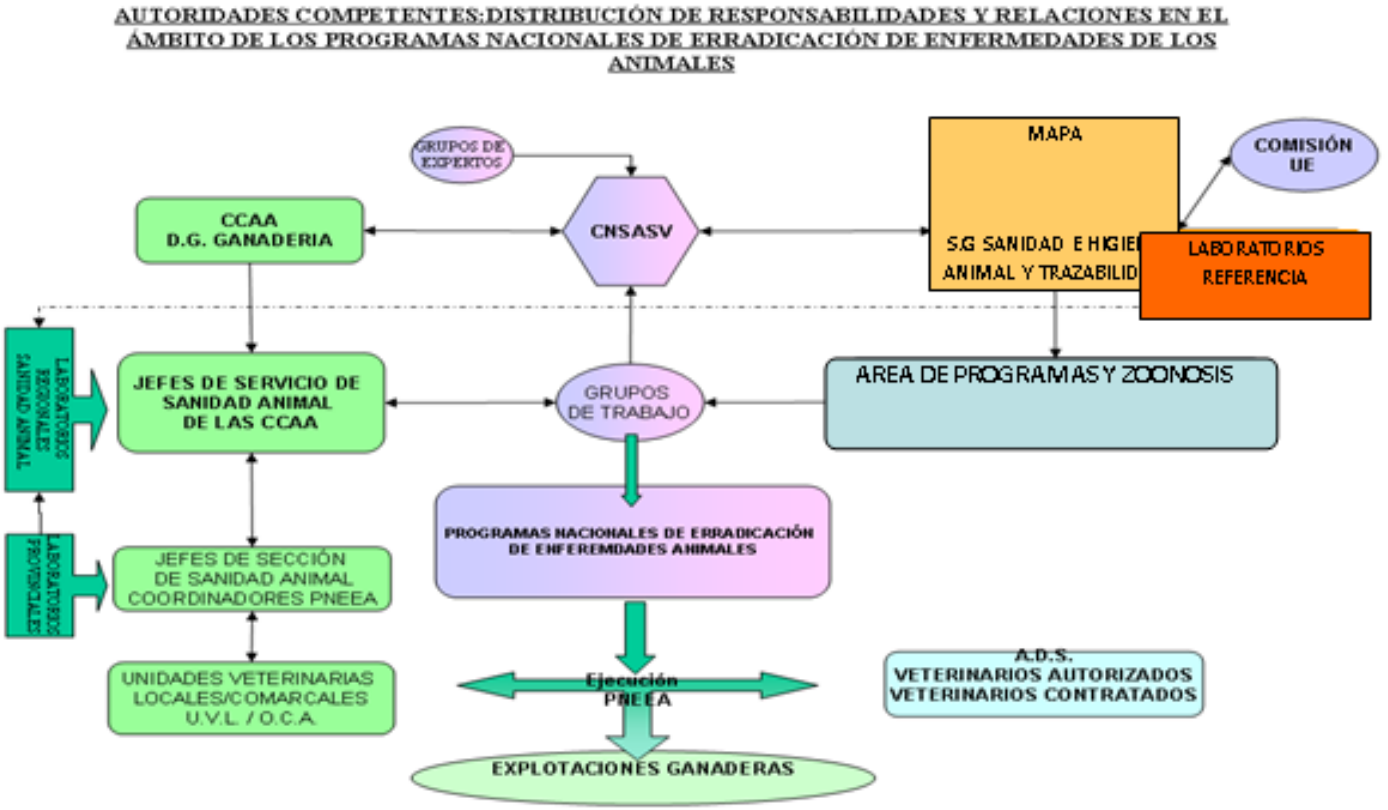
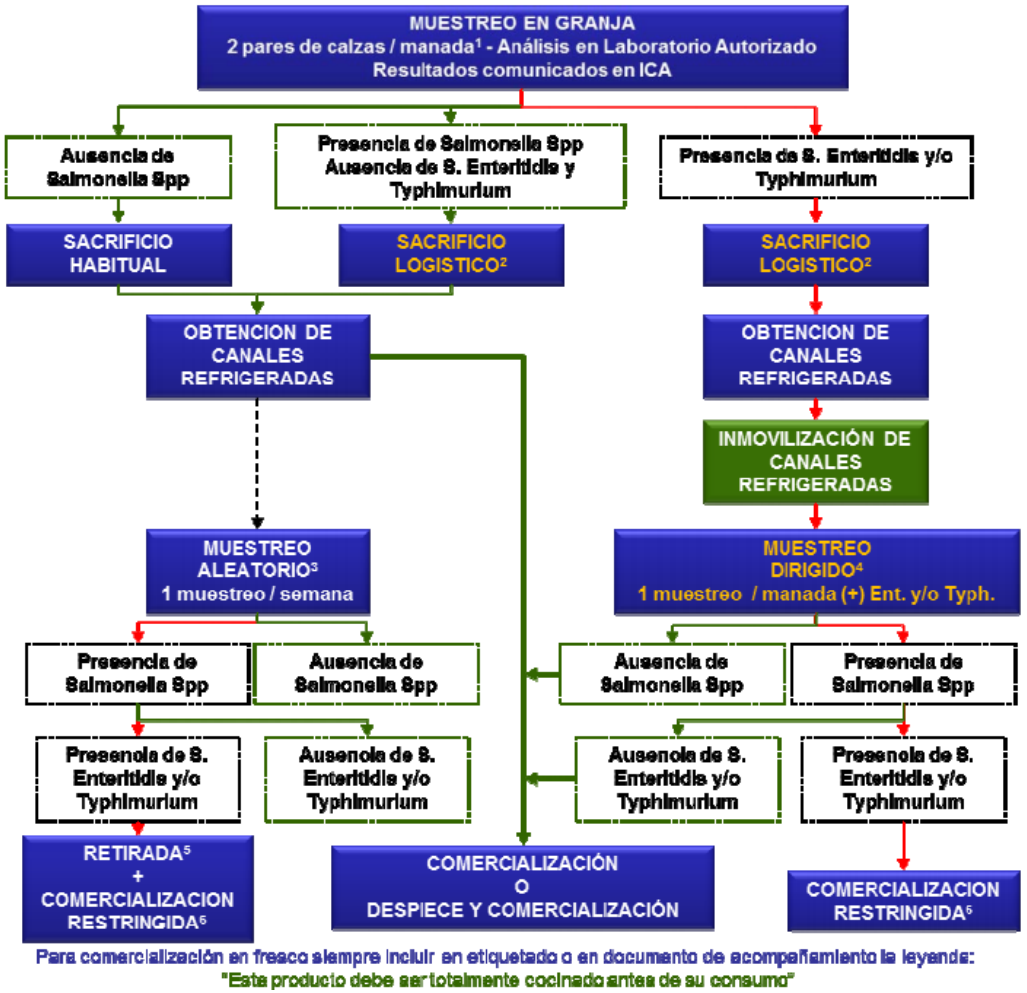


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):

FIGURA 6. SISTEMATICA DE ACTUACIÓN



Associated with document Ref. Ares(2024)510496 - 23/01/2024

Single Market Programme (SMP Food)

EU co-funded BSE programme for year 2024

Associated with document Ref. Ares(2024)510496 - 23/01/2024

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)
Department A Health and Food Unit A2 EU4Health/SMP

SUBMISSION FORM: DESCRIPTION OF THE ACTION
(Annex 1 – Description of the action (part B))

Bovine Spongiform Encephalopathy Programme
Surveillance, Control and Eradication programme

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (*Annex 1 - Description of the action (part B)*) **completely filled in**, **by the 31 May** of the year preceding its implementation (*Part 2.1 of Annex I to the Single Market Programme Regulation).*
Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.
For questions on the information requested in this Form, please contact: HADEA-VET-PROG@ec.europa.eu.
For more information or questions on the eGRANTS Portal Submission System, please access GoFund or contact the IT Helpdesk.

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	**BOVINE SPONGIFORM ENCEPHALOPATHY**
Animal population/Species	**Bovine animals**
Implementation Year	**2024**

CONTACT PERSON on BSE programme:

Name	ESTHER PRIETO CABALLERO
e-mail	meprieto@mapa.es
Job type within the CA	HEAD OF SERVICE OF VETERINARY PROGRAMES

Associated with document Ref. Ares(2024)510496 - 23/01/2024

Bovine Spongiform Encephalopathy Programme - 2024

1.RELEVANCE

1.1 Background and general objectives (*in relation to the Call*)

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular: - Regulation (EC) No 999/2001 of 22 May 2001 (latest consolidated version 1 January 2023) laying down rules for the prevention, control, and eradication of certain transmissible spongiform encephalopathies
Yes ☒ No ☐ If no, please explain: ***(maximum 200 characters)***

1.2 Needs and specific objectives

Please give a short description of the programme
This programme has a **double objective**: - to monitor the epidemiological situation in cattle population in relation to BSE, and - to detect the presence of BSE disease and, when necessary, implement the appropriate control and eradication measures. In 2024 the specific objective for the BSE programme is to continue to comply with requirements in order to maintain Spain's classification as a country with negligible BSE risk status, achieved in 2016. ***(maximum 500 characters)***

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field. Illustrate the European dimension of the activities: MS follow different testing scheme for bovine animals coming from MSs not listed or from third countries, does MS implement other mitigate measures to minimize the risk, react promptly following suspicion and/or confirmation, etc. Which countries will benefit from the project (directly and indirectly)? *Reference can be made that the programme implements Regulation (EC) No 999/2001*
The surveillance programme has been updated and modified, according to the regulatory requirements. Bovine Spongiform Encephalopathy (BSE) is a TSE disease of cattle. BSE was first diagnosed in the UK in 1986 and reached epidemic.

The Commission introduced the first EU legislation on BSE in July 1989. By the middle of 1990, basic EU legislation on BSE was in place. Today, Regulation (EC) No 999/2001 ("the TSE Regulation") forms the legal basis for almost all legislative actions on TSEs. It gathers together all BSE measures adopted over the years into a framework consolidating and updating them in line with scientific evidence and international standards.

The main provisions of the TSE Regulation can be summarised as follows: **Monitoring, Feed ban, Removal of Specified Risk Material (SRM) BSE status Classification**: negligible risk, controlled risk and undetermined risk. **Control and Eradication of TSEs**, **Placing on the market, export and import**.

Monitoring conducted in Spain, provided for in Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals, has been changing on several occasions to adapt it to new scientific knowledge on the subject and to Community rules.
This approach of gradual changes to the monitoring programme has made it possible to steadily raise the age of cattle for compulsory sampling. This explains the slight but continuous reduction in the number of BSE tests carried out, which was particularly marked in 2014, following the decision to stop sampling healthy cattle slaughtered for human consumption.
The main changes to relax the rules on BSE monitoring in Spain were introduced on 4 June 2009, following publication of the amendment to the Spanish Royal Decree to bring it into line with Decision 2008/908/EU (repealed by Decision 2009/719/EC) authorising certain Member States to revise their annual BSE monitoring programmes, including Spain.
Since then, the successive amendments to Decision 2009/719/EC have been transposed into Spanish law to continue raising the age of cattle for compulsory sampling.
The most recent amendment was adopted by the Commission Implementing Decision of 4 February 2013 (Decision 2013/76/EC), authorising certain Member States to stop active BSE monitoring in healthy animals slaughtered in slaughterhouses. This and other measures to relax the rules are set out in Order PRE/1550/2013, which has been in force in Spain since 14 August 2013.

SPAIN, as the other MS, must carry out an annual monitoring programme for TSEs based on active surveillance and passive surveillance. The monitoring programme provides a reliable insight into the prevalence and evolution of TSEs in the MS and at the same time ensures that no BSE cases are being slaughtered for human consumption.
The active surveillance covers testing of two categories of bovine animals:
The results of this surveillance programme are useful for other countries. Spain as MS carries out **an annual report** on the monitoring and testing for the presence of TSEs to provide an overview of the monitoring results and epidemiology of TSEs, which assists the development of policy for the protection of human and animal health. In this report, it can be observed the trend analysis for the time series 2002-2022 which shows that the decline is significant for the whole series. Mantel test for trend p< 0,001 (Abramson, J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6.

maximum 500 characters)

1.4 Target population and Area of the implementation

This programme will be implemented on bovine animals. Please specify groups: healthy/risk/age groups. Please specify age limit for testing of suspect bovine animals.
The categories of bovine animals to be submitted for BSE testing are defined in the TSE Regulation and are based on a combination of age (age limits have been changed over time) and surveillance target groups: 1. Risk animals: 48 months animals from Member States (MS) authorised to review their programme and 24 months when coming from MS not authorised to review their programme. We include 3 categories: a. Emergency slaughtered b. Animals with clinical signs ante-mortem. c. Fallen stock. 2. Other categories: a. Healthy slaughtered: Born before 2001 and coming from herds with BSE positive cases. b. Animals clinically suspected of being infected with BSE: no age limit. c. Animals culled under BSE eradication measures: no age limit. ***(maximum 500 characters)***
Fill in **Table 1**) **in the Annex** to this Form.
Does the programme apply to the whole territory of the country?
Yes ☒ No ☐ If no, please explain: ***(maximum 500 characters)***

1.5 Notification of BSE cases

Please explain the procedure in place as regards the notification of the disease – reference to the national legal basis. Please confirm that confirmed cases of BSE are reported to the EC and other MSs in accordance with Regulation 999/2001.
BSE disease is officially declared in accordance with Royal Decree 526/2014 that states the list of notifiable animal diseases and lays down the rules for reporting them. Furthermore, this notification must be made via RASVE (a computer application), as laid down by the RASVE Committees and the specific working groups for the coordination and following-up of the Programme for Surveillance and Control of TSEs.

The owners or persons in charge of the animals and the veterinary official who attends the holding must, on the emergence of any of the clinical symptoms consistent with BSE, notify the Autonomous Community in order to implement the measures detailed in the section below on 'suspicion of disease'.

For each confirmed primary case (outbreak), the competent authority for animal health responsible for notification of the outbreak will send MAPA as soon as possible, and in any event within one month of confirmation of the outbreak, the following additional epidemiological information:

- Clinical symptoms (if any, and if it is a suspected case), e.g. decline in milk production, ataxia, weight loss, changes in behaviour, etc.
- vaccine type (meat/milk);
- indicate whether the positive case was confirmed on the holding or herd of birth (yes/no);
- herd type (meat/milk/mixed production purpose);
- Feed system during the first year of life, e.g., feed concentrate, mixed, grass, etc.;
- If the cohort ate the same feed as the positive case: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- If there was an age cohort: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- If there was offspring: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- Father data (if available): indicate whether samples were taken, the number of samples and the number of positive and negative results.
- Mother data (if available): indicate whether samples were taken, the number of samples and the number of positive and negative results.

This information is sent in accordance with Chapter B of Annex III to Regulation 999/2001, since each year the EFSA asks Member States that have declared positive BSE cases for this information, so that it can be included in the summary report on TSE trends and sources in the EU.

1.6. Measures following the suspicion and confirmation of a BSE case

Give a short description of the procedure – reference to the national legal basis.

Whenever TSE is suspected in a holding, the competent authority must be notified, and the holding must be put under official control including moving restrictions until the final testing results are available. If TSE is confirmed, the entire body of the animal concerned must be disposed of. An inquiry to identify all animals at risk of having TSE must be carried out. For BSE, all animals at risk must be culled and disposed of as well as the products derived from them.

National legal basis for measures following suspicion and confirmation: Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals.

SUSPECTED DISEASE.

An animal suspected of being caused by a TSE shall be considered as any live, sacrificed, or dead animal that presents or has presented neurological or behavioral abnormalities or a progressive deterioration of the general condition attributable to a disorder of the central nervous system, with respect to which No other diagnosis can be made on the basis of clinical examination, response to treatment, post-mortem examination, or ante- or post-mortem laboratory analysis. Any bovine subjected to a rapid diagnostic test for BSE with a positive result shall also be considered as suspected of being affected by BSE.

- The competent bodies of the Autonomous Communities, in the event of notification of suspicion, as well as in cases in which they have data that suggests the possible existence of the disease, will adopt the following measures:

- Verification visit by the Official Veterinary Services.

- Immediate isolation of suspected animals and immobilization of animals present on the affected farm.

- If the competent bodies of the Autonomous Communities could not rule out the existence of the disease, they will proceed to:

- Sacrifice of the suspected animal. If it has been suspected due to clinical symptoms, I send the tissues to the National Reference Laboratory (LNR) for analysis, as detailed in the Sample Collection Manual and its referral to the LNR.

- Sampling (in all other cases). In the event of death of the animal on the farm itself, samples will be taken in situ, or in places authorized for this purpose, provided that the optimal conditions for obtaining the sample are guaranteed in both cases.

- All parts of the body of the suspected animal, including the skin, will be kept under official surveillance in the manner determined by the competent bodies of the Autonomous Communities, until the diagnosis has been proven or until they have been hygienically destroyed by incineration. or other authorized method.

If the analytical results rule out the existence of the disease, the competent bodies of the Autonomous Communities will lift the isolation and immobilization measures of the farm.

When the suspicion occurs in the slaughterhouse during the ante-mortem inspection, action will be taken at the farm of origin of the animal following the guidelines defined above.

CONFIRMATION of a BSE case:

When the disease is confirmed by the National Reference Laboratory for TSEs (Algete NRL), the General Subdirectorate for Animal Health and Hygiene and Traceability will notify the competent authority of the CCAA in order to make the official declaration of the disease outside and proceed to carry out the epidemiological investigation and apply the focus eradication measures.

1 Official declaration of the disease.

It is carried out in accordance with point 1.5. of this document.

2 Epizootiology investigation.

When a BSE is diagnosed, an investigation will be carried out that should identify the following points:

a) All other ruminants present on the farm where the animal in which the disease has been confirmed is kept.

b) In cases in which the disease has been confirmed in a female, all her descendants, who have been born in the two previous years or after the clinical appearance of the disease.

c) All animals of the same age group as the animal in which the disease has been confirmed. For these purposes, age group shall be understood as all bovines on the farm during the twelve months before or after the birth of the affected bovine and in the same herd as the latter, or that during their first twelve months of life were raised in some moment with an affected bovine and that it will be able to consume the same feed that the affected animal consumed during its first twelve months of life.

When possible, it will require:

d) The possible origin of the disease.

e) Other animals on the farm of the animal in which the disease has been confirmed or on other farms, which may have improved results due to the agent causing the TSE, due to having received the same thoughts or having been exposed to the same source of pollution.

f) The circulation of possibly contaminated feed, other materials or any other means of transmission that may have transmitted the TSE agent to or from the farm in question.

1.7 Epidemiological situation background

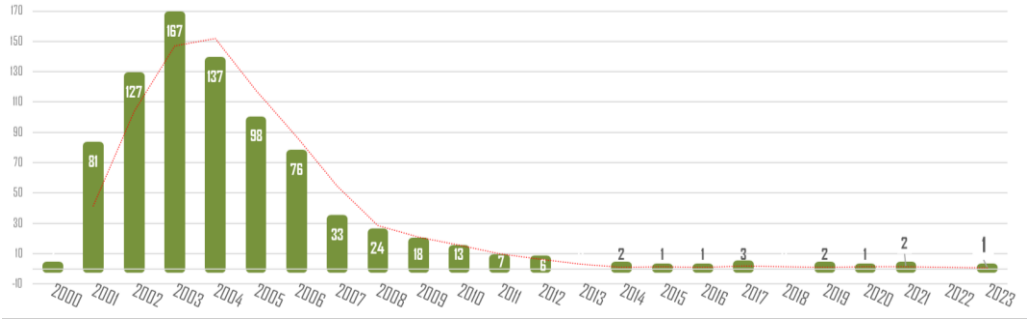
Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of BSE cases.

Total number of cases in the MS so far:

Number of cases during the last year	*Total N*	*N of classical cases*	*N of atypical cases*	*N of undetermined cases*
BSE	*1*	*0*	*1*	*0*

Last case date	*Classical*	*Atypical*	*Undetermined*
BSE	*25/07/2014*	*03/02/2023*	

Since confirmation of the first case of BSE in Spain in 2000 and 15 may 2023, a total of **802** outbreaks (index case) were detected.

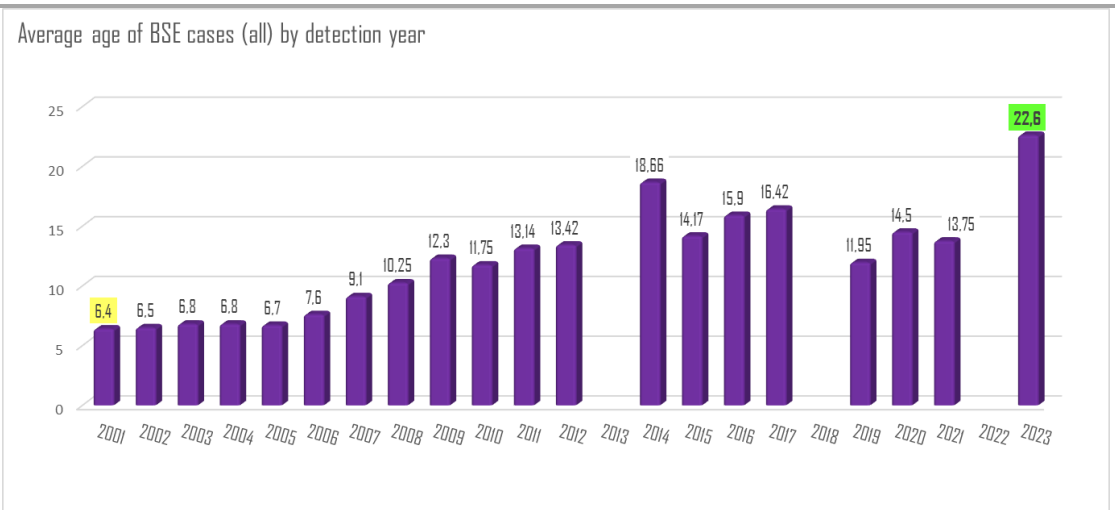


The graph showing the annual number of outbreaks in Spain in this period shows a peak in 2003 followed by a constant reduction, typical of a pattern of eradication of the disease (Annex I). Thus, the trend analysis for the time series 2002-2022 shows that the decline is significant for the whole series (Mantel test for trend p< 0.001 (Abramson J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6).

For a better understanding of the distribution of BSE in recent years it is necessary to analyse the age of the animals, grouping the cases by the year of birth of the positive animals. The pattern of distribution of the cases grouped using this criterion is similar to that of its appearance (a peak followed by a gradual reduction). The greatest proportion of the cases detected corresponds to animals born during the period 1995-1998, and the maximum number of positive animals were born in 1997.

We thus detect a period of seven years between the maximum births of cases testing positive for BSE (1997) and the year when the greatest number of cases of BSE were detected (2003).

Analysis of the average age of the cases detected shows that this has risen since surveillance began, from an average of 6,4 years of age to 15.9 years of age (the average in 2016) with a peak average age of 22,6 years in 2023. The most recent cases detected in 2023 and 2021 in animals born in 2000 and 2008 were cases of atypical BSE, which should not be considered in the joint assessment of the average age of positive animals since their condition is not linked to the consumption of contaminated feed. In the risk analysis conducted to demonstrate the efficacy of the control measures, entering data that are not linked to those measures might skew the results obtained. However, given that the emergence of these cases in the EU is relatively recent and the European Commission has not set out guidelines for the independent notification of atypical strains, in Spain these positives are included in the assessment of the evolution of the disease until all the Member States reach a consensus on how they should be notified.



The last case of classical BSE was detected on 25th July 2014 (date of sampling) and the last case of atypical BSE was detected on 2nd February 2023.

Conclusions from the epidemiological evolution of BSE:

• A constant decline in the number of BSE cases has been observed in Spain, with the peak decline of 46% recorded in 2007.

• The trend analysis for the time series 2002-2022 shows that the decline is significant for the whole series.

• The increase in the average age indicates progress in eradicating BSE.

• The reduction in the number of cases and the increase in the average age of the animals detected demonstrate the effectiveness of the control measures adopted and the progress made in eradicating this disease.

• It may be concluded from the results of the retrospective discriminatory study that the prevalence of the atypical strains during the 2003-2022 period remained low and constant and was concentrated in animals of advanced years. Bearing in mind that these results are similar in the other Member States studied, the data obtained reinforce the hypothesis that atypical BSE is a spontaneous, sporadic disease.

• In light of the favourable development of the epidemiological indicators, Spain asked the World Organisation for Animal Health (WOAH) to recognise it as a country with negligible BSE risk status. Our request was granted in May 2016 and that status will be maintained provided that the requirements giving rise to the request continue to be met.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

The programme activities/measures shall be clear, suitable to address the needs and to achieve desired outcomes/ impact. They have to be adapted to the BSE in bovine animals situation/risk and feasible in terms of the capacities for their implementation.

Clearly describe planning and implementation arrangements/methodology; ensure technical quality and logical links between the identified problems/needs and solutions/activities proposed to help

improvement; mention timeline for the implementation of specific activities. Further instructions are provided below.

2.1.1 Targets monitoring and culling measures after detection of cases on bovine animals

Targets have been set up for
- the rapid testing on bovine animals based by age and risk group (Table 2 of the Annex)
- confirmatory testing other than rapid tests (Table 3 of the Annex)
- discriminatory tests (Table 4 of the Annex)
- culling/destroying bovine animals following suspicion and/or confirmation of a BSE case (Table 5 of the Annex)

If no, please describe.

- **Rapid testing targets:**

	target surveillance group	ME authorised to review their program	ME no authorised to review their program [1] + third countries[2]
RISK ANIMALS	Emergency slaughter	> 48 months	> 24 months
	Antemorten sintomatology (different from BSE)		
	Fallen stock/ Not Slaughter for Human consumption		
OTHERS	Slaughter for Human consumption	Born before 2001 and coming from herds with BSE positive cases	> 30 months
	BSE Suspectos	no age limit	no age limit
	Animals culled under BSE eradication measures		

(1): Romania and Bulgary
(2) born or not in Great Britain and imported from Great Britain since 01/01/2021 are included

.

A) <u>ACTIVE SURVEILLANCE.</u>

The active surveillance included in the National Program, is adapted to the regulatory changes, both community and national, related to the modifications of the ages of the animals subject to obligatory sampling.

The active monitoring program is aimed at the effective search for the disease, through the control of certain populations of animals for consumption and animals at risk.

In the period 2023, the following animal subpopulations will be monitored by performing rapid diagnostic tests in laboratories authorized by the Autonomous Communities.

A.1. Animals slaughtered for human consumption: BSE tests will be performed on:

A.1.1.- All animals born in countries included in the Annex to Decision 2009/719/EC and amendments, authorizing certain Member States to revise their annual BSE monitoring program, of the following age groups:

(a) Over forty-eight months (48) of age provided that they are:

- 1st.-Animals subjected to emergency slaughter.

- 2º.-Animals that during the ante-mortem inspection are suspected of suffering from a disease or being in a state of health that can harm human health, except for animals slaughtered in the framework of an eradication campaign that do not present clinical signs of the disease.

b) All healthy animals slaughtered for human consumption that were born before January 1, 2001, as long as they come from farms in which BSE outbreaks have been diagnosed. This condition will be recorded in the documentation foreseen in article 6 of Royal Decree 728/2007, of June 13, establishing and regulating the General Register of Livestock Movements and the General Register of Individual Animal Identification.

A.1.2.- All animals born in third countries and EEMM not included in the Annex of Decision 2009/719/CE and amendments and therefore are countries not authorized to review their annual BSE monitoring program, of the following age groups:

(a) Over thirty months (30) of age provided that they are:

- 1º.- Animals slaughtered in a normal manner for human consumption. Animals born or not in Great Britain and imported from Great Britain since 01/01/2021 are included; or

- Animals slaughtered within the framework of the execution of Royal Decree 2611/1996, of December 20, 1996, which regulates the national programs for the eradication of animal diseases, as long as in the latter case they do not present clinical signs of the disease.

b) Older than twenty-four months (24) of age if they are:

- 1º.- Animals submitted to emergency slaughter.

- 2º.- Animals that during the ante-mortem inspection are suspected of suffering a disease or being in a state of health that can harm the health of people, except for animals slaughtered within the framework of an eradication campaign that do not present clinical signs of the disease.

The term "emergency slaughter", according to section I, chapter VI, point 1 of Annex III of Regulation (EC) 853/2004, means the slaughter of an animal that, being otherwise healthy, must have suffered an accident that prevented its transport to the slaughterhouse, taking into account its welfare.

"Ante-mortem inspection", according to Regulation (EC) 2017/625, means the verification, prior to slaughtering tasks, of compliance with human health and animal health and welfare requirements, including, where appropriate, the clinical examination of each animal, and the verification of the agri-food chain information referred to in Annex II, Section III, of Regulation (EC) No 853/2004.

Animals without clinical symptoms of the disease, slaughtered in the framework of a disease eradication campaign of those established in Royal Decree 2611/1996, will be exempted from this consideration and will be considered under the corresponding epigraph according to the final destination of those carcasses.

Animals born or not in Great Britain and imported from Great Britain since 01/01/2021 are included.

A.2. Animals dead and not slaughtered for human consumption, older than forty-eight (48) months:

All bovine animals over forty-eight months of age that have died or have been slaughtered, but were not slaughtered as part of an epidemic, as is the case with foot and mouth disease, shall be tested for BSE. However, in the case of animals born in third countries (Including animals born or not in Great Britain and imported from Great Britain since 01/01/2021) and EEMM not listed

in the Annex to Decision 2009/719/EC and amendments, all bovine animals over twenty-four months of age shall be tested for BSE.

The following subpopulations are specifically included:

- Bovine animals which have died on farm or during transport.

- Bovine animals that have been slaughtered, but not for human consumption or in the framework of an epidemic, either on the farm or, exceptionally, in a slaughterhouse until specific establishments or facilities are available, including animals from disease eradication campaigns of those established in Royal Decree 2611/1996, culling or similar not destined for human consumption.

NOTE: Any animal that, having shown symptoms compatible with BSE, dies or is slaughtered on the farm, will be classified within the subpopulation of suspect animal, and therefore will be treated as described in section B explained below.

Bovine animals slaughtered as an application of the eradication measures of a BSE outbreak, and belonging to the population at risk (offspring and age cohort) will all be sampled based on the epidemiological investigation carried out in that outbreak.

B.- PASSIVE SURVEILLANCE.

The passive surveillance of the disease consists, basically, in the detection of positive animals due to the communication by veterinarians or farmers/animal handlers or the appearance of animals with clinical symptomatology compatible with TSEs.

All animals suspected by symptomatology (defined in section 4.6.B of this program) will be submitted to control, independently of their age, by means of confirmatory tests established in the OIE Manual, in the National Reference Laboratory for TSEs (LCV).

They shall be submitted to control by means of confirmatory tests established in the OIE Manual, at the National Reference Laboratory:

B.1.- All animals suspected by symptomatology (any live, slaughtered or dead animal that presents or has presented neurological or behavioral abnormalities or CNS disorder, for which no other diagnosis can be established on the basis of clinical examination, response to treatment, post-mortem examination or following ante or post-mortem laboratory analysis).

B.2.- All animals of groups A1 and A2 specified above, whose sample has been positive or doubtful to rapid tests in authorized laboratories.

At all times, the animals described as TSE suspects will be submitted to control by means of methods and protocols of confirmation, established in the OIE Manual, in the National Reference Laboratory for TSEs (LCV).

confirmatory testing other than rapid tests : In case the result of the rapid tests performed is positive or doubtful, the sample will be referred for analysis by confirmatory testing to the National Reference Laboratory for TSEs (NRL).

- **discriminatory tests:** whenever a case of positive case is obtained , it will be necessary to discrimination of BSE strain that affects them, culling/destroying bovine animals following suspicion and/or confirmation of a BSE case

- **culling/destroying bovine animals following suspicion and/or confirmation of a BSE case**

In the case of confirming a BSE, or in the case of suspicion in which the presence of a TSE cannot be ruled out after carrying out the appropriate clinical, laboratory and/or ante-post mortem analyses, a sacrifice will be carried out. of total or selective eradication of the populations indicated below:

a) All other bovines present on the farm where the animal in which the disease has been confirmed is kept.
b) In cases in which the disease has been confirmed in a female, all her descendants, who have been born in the two previous years or after the clinical appearance of the disease.
c) All animals of the same age group as the animal in which the disease has been confirmed.

However, with respect to the slaughter of all bovines present on the holding where the animal in which the disease has been confirmed is found, the competent authority may exempt the following animals from slaughter:

i. All those who have joined the holding in question in the last twelve months prior to the appearance of the case, provided they came from another holding, as well as their possible offspring in said period.
ii. In those farms in which the affected animal had entered the same during the last twelve months, the total slaughter of the bovine cattle present on the farm will not be carried out. In this case, the slaughter and complete destruction of at least the bovines indicated in sections b) and c) of point 1 must be carried out, as well as those animals that, since there is no perfect traceability, cannot be ruled out. their membership in these groups.

The competent authority may exempt from slaughter all bovines present on the farm where the animal in which the disease has been confirmed is kept, proceeding to eradicate it by selective slaughter.

In this case, and provided that identification and traceability is guaranteed through computer systems or birth records, the risk populations defined by the World Organization for Animal Health (the age group defined in Regulation 999 as well as all the offspring born in the last two years) will be slaughtered. Likewise, all those bovines in which perfect traceability cannot be guaranteed through computer systems or birth records will be slaughtered.

The reintroduction of animals on the farm will be carried out with prior authorization from the competent bodies of the Autonomous Communities.

Exception to sacrifice: Both for the immediate total and selective slaughter of the cohort of positive animals, the use in Spain of vulnerable bovines is authorized until the end of their productive life after official confirmation of the presence of BSE. Said exception may be applied with prior authorization from the Ministry of Agriculture, Fisheries and Food after analyzing whether the requirements contained in the Commission Implementing Decision of **15** March **2013** authorising the use of at risk bovine animals until the end of their productive livesare met.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Central authority in charge of supervising and coordinating the departments responsible for implementing the programme.

• The **central authority** responsible for the coordination and follow-up of the departments responsible for carrying out the programme: the General Subdirection for Animal Health and Hygiene and Traceability (Ministry of Agriculture, Fisheries and Food – MAPA) is responsible for coordinating the programme and for informing the Commission concerning the development of this disease.

The 'National Committee for the Veterinary Health Alert System', set up under Royal Decree 1440/2001 of 21 December 2001 establishing the veterinary health alert system, is responsible for studying and proposing measures to eradicate diseases and monitoring the development of the epidemiological situation for diseases subject to eradication programmes. The committee is a collegiate body on which all the authorities responsible for coordinating and executing the measures planned in this Programme are represented.

• **National Reference Laboratories:** the following are recognised as National Reference Laboratories:

a) Algete (Madrid): Central Veterinary Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for the diagnosis of Bovine Spongiform Encephalopathy (BSE).

b) Food and Agriculture Arbitration Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for testing for the presence of animal products or remains, including meat and bone meal, in substances intended for feeding to production animals.

Description and delimitation of the geographical and administrative areas in which the programme is to be applied.

• Competent authorities **at regional level:** the Veterinary Services for Animal Health and Production, and for Public Health and Quality Control of Food and Agriculture in the Autonomous Communities, are responsible for implementing the Programme and compiling, evaluating and computerising the data obtained in their territory and sending it to the central authorities.

• Authorised or recognised laboratories: the competent authorities in the Autonomous Communities will designate laboratories located within their areas of jurisdiction to be responsible for the analytical monitoring of encephalopathies, including rapid post-mortem tests and the diagnostic techniques defined in the OIE's Diagnostics Manual and checks on the substances intended to feed production livestock. These laboratories may be public or private.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity[1] indicators) - please describe for different programme activities.

- e.g. all clinically suspect animals tested
- tools applied to check/confirm that all bovine animals are tested based on the age group (relevant only for some MSs) (no bovine animals skipped the testing)

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

All rapid test positive results obtained by the approved official regional laboratories are contrasted and confirmed by the NRL. The NRL verifies the results of laboratory tests by performing comparative tests and harmonising methodological procedures and organisation and implement in-laboratory and inter-laboratory controls to the approved official regional laboratories participate in interlaboratory testing in order to validate their techniques, coordinated by the NRL.

On quarterly basis, the SGSHT monitors all data recorded in RASVE contrasting with all analysis realized by NRL (Algete) in order to supervise not only the accuracy of the data but also that monitoring by each Autonomous Community has been performed.

These results are presented and analysed once a year in RASVE Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme. The results of the program are also shared with the national stakeholders associations in a specific meeting after the results are endorsed by the RASVE Committee.

2.3.1 System for the registration of holdings

Give a short description of the system for the registration of holdings and identification of holdings. Please describe briefly the national procedure and reference to Reg 2016/429

Article 38(1) of Law 8/2003 of 24 April 2003 on animal health states that all livestock holdings must be registered in the Autonomous Community where they are located and that the basic information on those holdings is to be included in a national information register.

On that basis, Royal Decree 479/2004 of 26 March 2004 setting up and regulating the General Register of Livestock Holdings (REGA) was approved. It is a multi-species register containing data provided by each of the Autonomous Communities on all farms in Spain.

REGA is part of the Integrated Animal Traceability System (SITRAN) together with the Movements Register (REMO) and the Individual Animal Identification Register (RIIA), the legal basis for which is Royal Decree 728/2007 of 13 June 2007 setting up and regulating the General Register of Livestock Movements and the General Individual Animal Identification Register.

SITRAN is a heterogeneous and distributed database that feeds the records in the various Autonomous Communities into a centralised register, through specifically developed information exchange mechanisms.

Apart from Spanish legislation (in force) to mention EU legislation that supports it:

- Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT
- Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

2.3.2 System for the identification of animals

Give a short description of the system for the identification of bovine animals

Royal Decree 1980/1998, of September 18, establishes a system of identification and registration of bovine animals, the elements that make up the identification system of this species are collected and consist of 2 ear tags with the same code (ear tags), a bovine identification document (DIB), a record book of the farm where the animal is located and a computerized database. In Spain, this database is called SITRAN, which is made up of the General Registry of Livestock Farms (REGA), the Individual Animal Identification Registry (RIIA) and the Movement Registry (REMO).

Apart from Spanish legislation (in force) to mention EU legislation that supports it:

- Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT
- Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.
- Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

2.3.3 Laboratory diagnosis

Describe laboratory protocol for testing on BSE (specify laboratory scheme for testing of different bovine categories - e.g. No of rapid tests used; specify laboratory protocol for confirmation of the disease)

TESTS TO BE CARRIED OUT FOR THE DIAGNOSIS OF BSE IN BOVINE SPECIES

1 RAPID DIAGNOSTIC TESTS

Those authorized for the bovine species in point 4 of Chapter C of Annex X of Regulation 999/2001 and its subsequent amendments are:

- ✓ immunoblotting test based on a Western blot procedure for the detection of the PrPRes fragment resistant to proteinase K (Prionics-Check Western test),
- ✓ dual functionality immunoassay (sandwich method) for the detection of PrPRes (short assay protocol), analyzed after a denaturation phase and a concentration phase (Bio-Rad TeSeE SAP Rapid test),
- ✓ microplate-based immunoassay (ELISA) for the detection of PrPRes resistant to proteinase K with monoclonal studies (Prionics-Check LIA test),
- ✓ immunoassay using a chemical polymer for selective capture of PrPSc and a monoclonal screening requirement directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA and HerdChek BSE-Scrapie Antigen (Idexx Laboratories)) ,
- ✓ lateral flow immunoassay using two different monoclonal assays for the detection of fractions of PrP resistant to proteinase K (Prionics Check PrioSTRIP),
- ✓ Dual function immunoassays using two different monoclonal assays directed against two epitopes present in highly expanded bovine PrPSc (Roboscreen Beta Prion BSE EIA Test Kit),

2 CONFIRMATION TESTS.

All animals from surveillance groups whose result have been doubtful or positive, as well as all animals clinically suspected of being infected by BSE shall be immediately subjected to confirmation methods and protocols.

The confirmation methods will also be those authorized in Regulation 1148/2014, in accordance with the technical guidelines established in the WOHA Manual on diagnostic tests and vaccines, in its latest edition: immunohistochemistry, SAF immunotransfer or an alternative authorized by the WOHA, observation of the characteristic fibrils by electron microscopy, histopathological examination or combination of rapid diagnostic tests.

When the result of the histopathological examination is doubtful or negative, the tissues will be examined by one of the other confirmatory methods.

The samples for confirmation will be sent to the National Reference Laboratory (NRL) for TSEs (Central Veterinary Laboratory) where the techniques considered necessary to confirm or rule out the disease will be carried out. If the result of these confirmation methods is negative, the animal will be considered negative.

When the result of said analyzes is positive, the animal will be considered positive to BSE.

In the case of positive animals, it will be necessary to discriminate the BSE strain that affects them, classifying them as: Classic type BSE, Low type BSE (L) or High type BSE (H). This

discrimination will be carried out at the NRL for TSEs (LCV), as a laboratory authorized by the EU Reference Laboratory (LR-UE), following the methods approved for this purpose.

Confirmation of suspected cases by rapid tests:

Rapid diagnostic tests may be used as a confirmatory method of BSE following the following guidelines issued by the Community Reference Laboratory (LR-UE):

- The confirmation is carried out in a National Reference Laboratory for TSE.

- One of the two rapid diagnostic tests has to be immunoblotting.

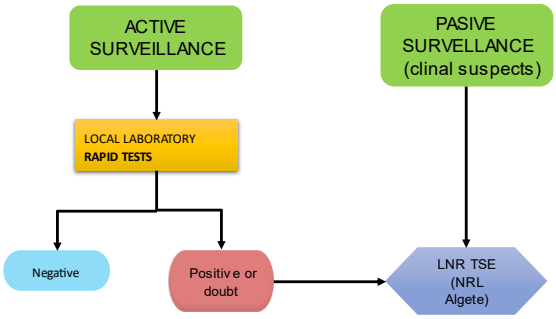
- The second rapid diagnostic test used:

  - Include a negative control tissue and a BSE sample as a positive control tissue.
  - Is of a different type than the test used for primary screening.

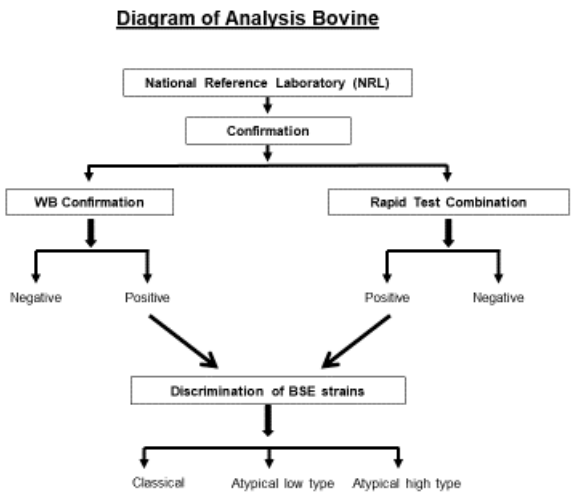
- Whether the first rapid diagnostic test is immunoblotting, the result must be documented and submitted to the NRL.

- When the result of the primary screening is not confirmed by the subsequent diagnostic test, the sample must be subjected to another examination by one of the confirmation methods. In case of performing a histopathological examination and the result is negative or inconclusive or when the material has autolyzed, the tissues will be analyzed by one of the other confirmation methods.

The following flow chart shows the sample flow scheme to the NRL for TSEs:

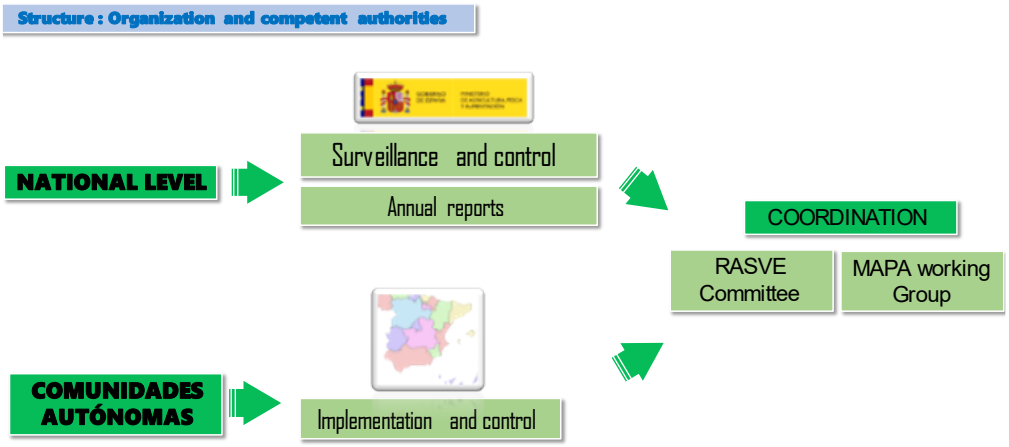


Next figure shows the analysis diagram that is carried out in the NRL for the TSEs of the Bovine species.



2.3.4 System to monitor the implementation of the programme.

Please describe



The Spanish State, represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and eradication program.

Spain submits all data and results obtained directly as eXtensible Markup Language (XML) files by using their own system for the automatic upload of data into the EFSA Data Collection Framework (DCF. The electronically submitted data is extracted from the RASVE database and further processed and validated to summarise the information.

The Autonomous Communities are responsible for the direct implementation and control of monitoring of the activities to be carried out under the programme. Data obtained is recorded in RASVE by the Autonomous Communities.

The information is thus subject to double review:

On a quarterly basis, the Competent Authorities of the Autonomous Communities will record the following reports, collected in the **RASVE computer application** according to the following structure:

A) Bovine monthly epidemiological surveillance: number of analyzes and positives found in the month of sampling. The deadline for completing the recording of these data will be 5 weeks after the end of the quarter in question. Information will be included in the following fields or subpopulations of animals:

- Bovine object of sacrifice for human consumption, that come from third countries or EU countries not authorized to review their BSE program, as well as for healthy bovines slaughtered for human consumption born before January 1st, 2001, and coming from holdings in which a case of BSE has been diagnosed.

- Emergency slaughter bovines.

- Cattle with clinical signs of some pathology in the ante-mortem inspection at the slaughterhouse (other than TSEs).

- Cattle slaughtered as a BSE eradication measure in application of Reg. 999/2001.

- Bovine slaughtered not for consumption and/or fallen stock.

- Suspected cattle: correspond to animals detected with clinical symptoms compatible with BSE.

- In relation to the animals slaughtered in campaigns to eradicate other diseases, they will be included in the subpopulation that corresponds to them based on the final destination of the carcasses of mentioned animals.

According to the European Commission guidelines derived from the conclusions of the Commission's TSE expert group, the analysis carried out on a bovine from Spain with a positive result in another MS will be recorded in the monthly epidemiological surveillance (with the criteria of sampling month) of the CCAA of origin, as long as it is shown that said AC is epidemiologically responsible.

B) Positive eradication cattle: all positive cases from eradication measures will be characterized. They will be recorded in the month corresponding to their sampling, and with the corresponding information after confirmation by the LNR.

The General Subdirectorate for Animal Health and Hygiene and Traceability (SGSHT)must be notified in writing of any incident related to the execution of epidemiological surveillance: among others, possible problems and incidents that may arise when sampling animals from a specific subpopulation.

With quarterly frequency, the SGSHT reviews all data recorded by Autonomous communities confronting data with results from NRL Algete.

On an annual basis, the SGSHT will request from the Autonomous Communities the additional epidemiological information required by EFSA for the preparation of the Annual Report on TSEs in the European Union, as established in Chapter B of Annex III of Regulation 999/2001.

2.4 Risk management

Critical risks and risk management strategy Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them. Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures. ***Note:*** *Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*		
Risk No	Description	Proposed risk-mitigation measures
1	**Decrease of EU funding for 2024. High risk**	**None**
	Lack of reporting of suspects, inefficient passive surveillance. Low risk.	**Continuous training and awareness campaigns aimed at the stakeholders(farmers) and private veterinarians.** **Transparent and constant risk-communication, update epidemiological situation reports.** **Maintain regular meetings with the sector**

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress. Note: Deliverables (*e.g. intermediate or final report on the implementation of programme measures*) are not milestones.		
Name	Due date (in month)	Means of verification
Initiation of sampling and testing_1	**8**	Documentation on sampling and testing checks
Completion of sampling and testing_2	**12**	Documentation of the completion of the activities

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view) Who are the target groups? How will the target groups benefit concretely from the project and what would change for them? Define the short, medium and long-term effects of the project. Possible example: eradication in general/or particular area *i.e. reference can be made that the programme implements Regulation* (EC) No 999/2001
General benefits of BSE program are avoiding direct and indirect economic costs due to market losses and public investment. Considering its **economic impact**, we classify under two aspects: • Direct: o Death and loss of production of affected animals. (Short effect) o Veterinary control and eradication measures on affected farms and affected natural spaces: sacrifices and expenses on sanitary programs. in the stage of eradication of the programme this aspect is nowadays limited. But we cannot forget the number of animals that were killed and disposed at the beginning of the control of this disease. (Long – term effect) • Indirect o Derived from trade restrictions imposed on affected countries. Not only that, in Spain, although last case of Classical BSE was on 2014 and we get the status of negligible risk that we maintain since 2016, but the declaration of atypical BSE cases also entails that some third countries impose export restrictions or do not open commercial trade with the country. (Long – term effect) On the other hand, from the point of view of **public health**, many epizootics are zoonoses that affect human health. Therefore, this is quite obvious in the case of this disease, that had in the early 2000 a big impact in public opinion. (Short effect) Main target group in both (economic and public health aspects) are stakeholders, specifically farmers, and economic impact is the main one. But also, public administration (economic impact of policies and control programs for animal health but also for public health). Moreover, we cannot forget environmental impact: Lost wildlife of endangered species can occur. CWD in wild life has been diagnosed in the north of Europe. (Long – term effect)

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

Communication and dissemination EU public:

Training programs

In order to raise awareness in sector as well as prompt notification of any suspected disease, it is necessary that veterinarians, farmers and other related professionals are well informed of the epidemiological situation, of the economic consequences for the sector, as well as of the possible options in the application of control and eradication measures financed by EU funding.

Meetings and information sessions

In order to raise the awareness and collaboration of these professionals, the CCAAs will organize meetings and information sessions. In this sense, all available information will be sent regularly for dissemination, ensuring an adequate flow of information in both directions on any incident related to this disease.

The MAPA will collaborate with the Autonomous Communities by participating in Conferences whose objective will be the training of trainers. These conferences must be organized by the CCAAs and communicated to the MAPA sufficiently in advance.

Visibility

All information about BSE eradication program, including EU funding, is published in the web page of MAPA (https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/encefalopatias-espongiformes-transmisibles/EETs.aspx) which is regularly updated.

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

Sustainability and continuation:

Project should continue, specially the part of testing. This will be ensured and needs the sustain in long term by public funding. It is very important to get the support of farmers, not only in testing animals but also, and most important, in culling compensations measures. This always encourages farmers to communicate suspicion of diseases and collaborate in eradication measures.

Long-term impact: it is very important continuation of this program, specially testing of risk animals, in order to establish and maintain export agreements with third countries regarding

meat and meat products of bovine as far as live animals for breeding. This programme grants a secure that adequate surveillance is carried out in order to maintain negligible risk of BSE granted by WOHA.

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX

I. **Baseline population data**
II. **Targets for 2024**
III. **Legal basis for the implementation of the programme**
IV. **Maps (as relevant)**

I. Baseline population data

Table 1: Bovine categories subject to the programme

	Number
Estimated population of bovine animals:	6.604.520
Estimated population of bovine animals above (2) (4) years old	**Bovines older than 24 months** 3.274.266 **Bovines older than 24 months and younger than 48 months** 1.000.455 **Bovines older than 48 months** 2.273.811

The above data refer to 01/01/2023; **Source of the data**: SITRAN (Spanish Integrated Animal Traceability System) REPORT 2023

II. Baseline population and targets for 2024

Table 2: Targets on rapid tests on bovine animals

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests	Estimated number of rapid tests used for confirmation
Healthy slaughtered bovine animals born in MS listed in Annex to CD2009/719/EC	**72**	0	0	0
Risk animals born in MS listed in Annex to CD 2009/719/EC	**48**	60000	60000	5
Healthy slaughtered bovine animals NOT born in MS listed in Annex to CD 2009/719/EC	**30**	20	20	2
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	**24**	10	10	1
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)	**No limit age**	5	5	1

Table 3: Targets on confirmatory tests other than rapid tests as referred in Annex X Chapter C of Regulation (EC) No 999/2001

	Estimated number of tests
Confirmatory tests in Bovine animals	**10**

Table 4: Targets on discriminatory tests (Annex X.C point 3.1 (c) and 3.2 Chapter (c) (i) of Regulation (EC) No 999/2001

	Estimated number of tests
Primary molecular testing on Bovine animals	**4**

Table 5: Targets on culling/destroying bovine animals following suspicion and or confirmation of a BSE case

	Estimated number of culled/destroyed animals
Bovine animals culled and destroyed following suspicion	**5**
Bovine animals culled and destroyed following confirmation	**10**

III. Legal basis for the implementation of the programme)

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

- Regulation (EC) No 999/2001 of 22 May 2001 (latest consolidated version 1 January 2023) laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001R0999-20230101

- COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL The TSE Road map 2 A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015

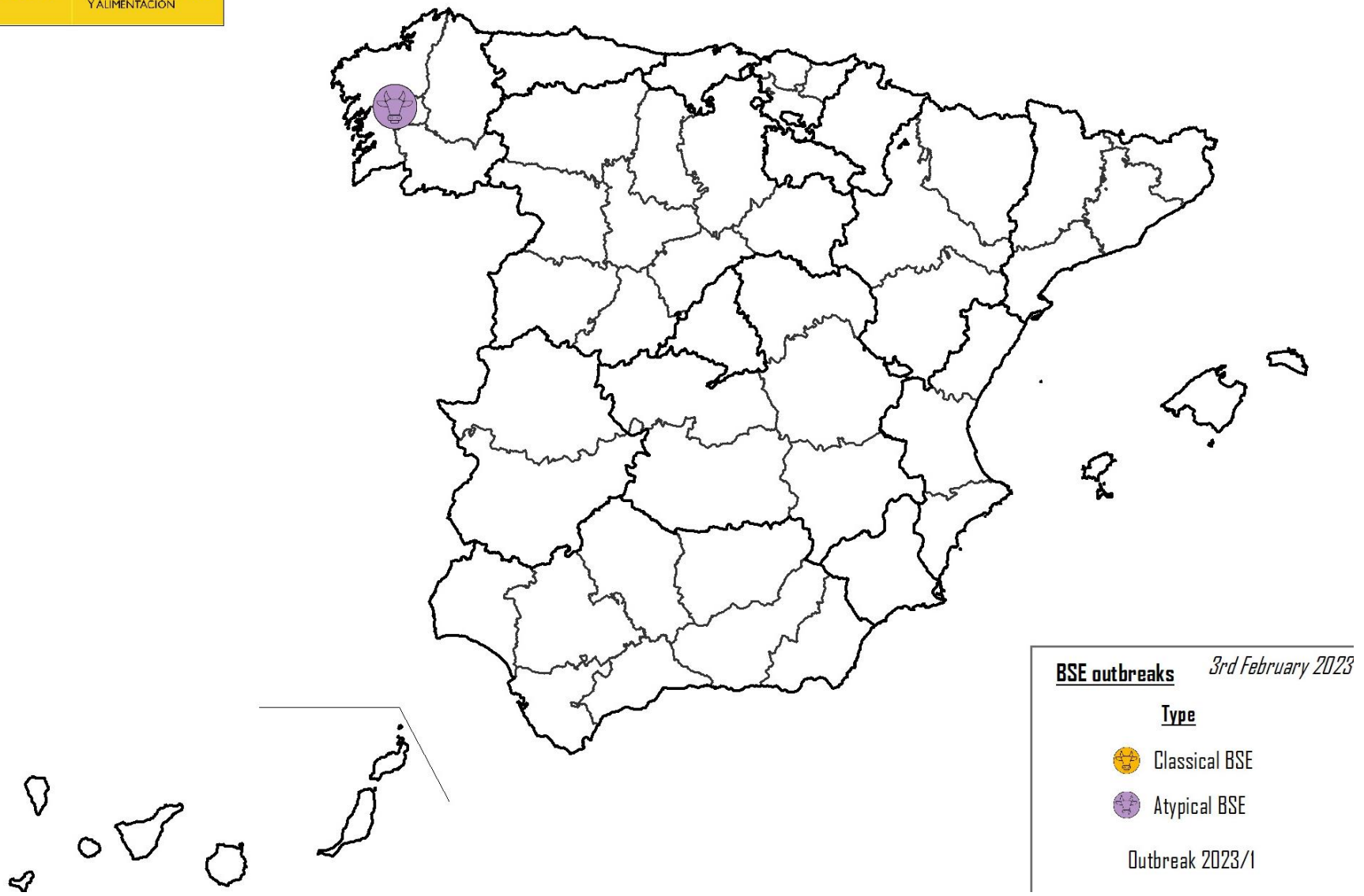
- COMMUNICATION FROM THE COMMISSION … Subject: TSE Roadmap (2005)

IV. Maps (as relevant)

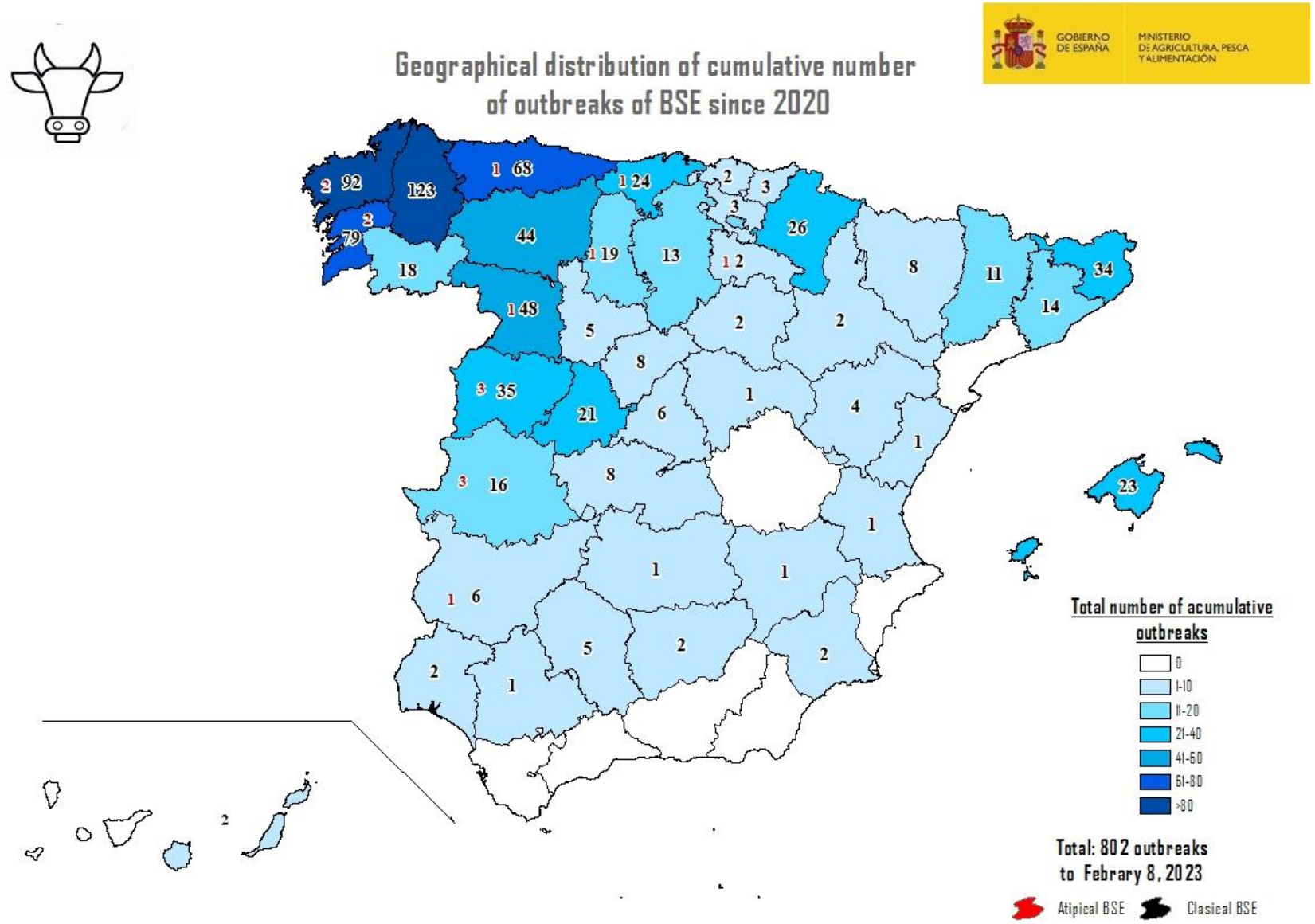
Associated with document Ref. Ares(2024)510496 - 23/01/2024

GOB.ERNO DE ESPAÑA
MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

SPAIN. BSE Outbreaks. 2023



Associated with document Ref. Ares(2024)510496 - 23/01/2024



SMP Lump Sum MGA – Mono/Multi: v1.0
Associated with document Ref. Ares(2024)510498 - 23/01/2024

ANNEX 2

ESTIMATED BUDGET (LUMP SUM BREAKDOWN) FOR THE ACTION

	Estimated EU contribution			
	Estimated eligible lump sum contributions (per work package)			Maximum grant amount[1]
	WP1 AVIAN INFLUENZA SURVEILLANCE PROGRAMME 2024	WP2 Salmonella control programme 2024	WP3 BSE programme 2024	
Forms of funding	Lump sum contribution	Lump sum contribution	Lump sum contribution	
	a	b	c	d = a + b + c
1 - MAPA	106 335.70	2 269 167.59	185 396.25	2 560 899.54

[1] The 'maximum grant amount' is the maximum grant amount fixed in the grant agreement (on the basis of the sum of the beneficiaries' lump sum shares for the work packages).

Associated with document Ref. Ares(2024)510496 - 23/01/2024

FINANCIAL STATEMENT FOR THE ACTION FOR REPORTING PERIOD [NUMBER]

	EU contribution											
	Eligible lump sum contributions (per work package)											Requested EU contribution
	WP1 [name]	WP2 [name]	WP3 [name]	WP4 [name]	WP5 [name]	WP6 [name]	WP7 [name]	WP8 [name]	WP9 [name]	WP10 [name]	WP [XX]	
Forms of funding	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	[Lump sum contribution]/[Financing not linked to costs]	
Status of completion	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**COMPLETED**	**PARTIALLY COMPLETED**	**PARTIALLY COMPLETED**	**COMPLETED**	**NOT COMPLETED**	
	a	b	c	d	e	f	g	h	i	j	k	l = a + b+ c + d+ e+ f+ g+ h+ i+ j+ k
1 – [short name beneficiary]												
1.1 – [short name affiliated entity]												
2 – [short name beneficiary]												
2.1 – [short name affiliated entity]												
X – [short name associated partner]												
Total consortium												

The consortium hereby confirms that:

The information provided is complete, reliable and true.

The lump sum contributions declared are eligible (in particular, the work packages have been completed and the work has been properly implemented and/or the results were achieved; see Article 6).

The proper implementation of the action/achievement of the results can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 19, 21 and 25).

Associated with document Ref. Ares(2024)510496 - 23/01/2024

ANNEX 5

SPECIFIC RULES

INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS — ACCESS RIGHTS AND RIGHTS OF USE (— ARTICLE 16)

Rights of use of the granting authority on results for information, communication, dissemination and publicity purposes

The granting authority also has the right to exploit non-sensitive results of the action for information, communication, dissemination and publicity purposes, using any of the following modes:

- **use for its own purposes** (in particular, making them available to persons working for the granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)
- **distribution to the public** in hard copies, in electronic or digital format, on the internet including social networks, as a downloadable or non-downloadable file
- **editing** or **redrafting** (including shortening, summarising, changing, correcting, cutting, inserting elements (e.g. meta-data, legends or other graphic, visual, audio or text elements extracting parts (e.g. audio or video files), dividing into parts or use in a compilation
- **translation** (including inserting subtitles/dubbing) in all official languages of EU
- **storage** in paper, electronic or other form
- **archiving** in line with applicable document-management rules
- the right to authorise **third parties** to act on its behalf or sub-license to third parties, including if there is licensed background, any of the rights or modes of exploitation set out in this provision
- **processing**, analysing, aggregating the results and **producing derivative works**
- **disseminating** the results in widely accessible databases or indexes (such as through ‘open access’ or ‘open data’ portals or similar repositories, whether free of charge or not.

The beneficiaries must ensure these rights of use for the whole duration they are protected by industrial or intellectual property rights.

If results are subject to moral rights or third party rights (including intellectual property rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they

comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned).

Access rights for third parties to ensure continuity and interoperability

Where the call conditions impose continuity or interoperability obligations, the beneficiaries must make the materials, documents and information and results produced in the framework of the action available to the public (freely accessible on the Internet under open licences or open source licences).

Different rights of use in Standardisation actions

In view of the specific business model of standardisation organisations (and unless otherwise agreed with the granting authority), access rights in European Standardisation actions do not include the following:

- the right to **make available** standards and standardisation deliverables to persons working for other EU services (including institutions, bodies, offices, agencies, etc.) other than the granting authority or to persons working for an EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services

- the right to **distribute to the public** standards and standardisation deliverables (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)

- the right to **edit or redraft** standards and standardisation deliverables

- the **translation** of standards and standardisation deliverables

- the **processing**, analysing, aggregating of standards and standardisation deliverables received and **producing derivative works**.

COMMUNICATION, DISSEMINATION AND VISIBILITY (— ARTICLE 17)

Communication and dissemination plan

Where imposed by the call conditions, the beneficiaries must provide a detailed communication and dissemination plan, setting out the objectives, key messaging, target audiences, communication channels, social media plan, planned budget and relevant indicators for monitoring and evaluation.

Additional communication and dissemination activities

The beneficiaries must engage in the following additional communication and dissemination activities:

- **present the project** (including project summary, coordinator contact details, list of participants, European flag and funding statement and project results) on the beneficiaries' **websites** or **social media accounts**

- upload the public **project results** to the Single Market Programme Project Results

platform, available through the Funding & Tenders Portal

SPECIFIC RULES FOR CARRYING OUT THE ACTION (— ARTICLE 18)

Specific rules for PPI Grants for Procurement

When implementing procurements in PPI Grants for Procurement, the beneficiaries must respect the following conditions:

- avoid any conflict of interest and comply with the principles of transparency, non-discrimination, equal treatment, sound financial management, proportionality and competition rules

- assign the ownership of the intellectual property rights under the contracts to the contractors (unless there are exceptional overriding public interests which are duly justified in Annex 1), with the right of the buyers to access results — on a royalty-free basis — for their own use and to grant (or to require the contractors to grant) non-exclusive licences to third parties to exploit the results for them — under fair and reasonable conditions — without any right to sub-license

- allow for all communications to be made in English (and any additional languages chosen by the beneficiaries)

- ensure that prior information notices, contract notices and contract award notices contain information on the EU funding and a disclaimer that the EU is not participating as contracting authority in the procurement

- allow for the award of multiple procurement contracts within the same procedure (multiple sourcing)

- where the call conditions impose a place of performance obligation: ensure that the part of the activities that is subject to the place of performance obligation is performed in the eligible countries or target countries set out in the call conditions

- to ensure reciprocal level of market access: where the WTO Government Procurement Agreement (GPA) does not apply, ensure that the participation in tendering procedures is open on equal terms to bidders from EU Member States and all countries with which the EU has an agreement in the field of public procurement under the conditions laid down in that agreement, including all Horizon Europe associated countries. Where the WTO GPA applies, ensure that tendering procedures are also open to bidders from states that have ratified this agreement, under the conditions laid down therein.

Specific rules for blending operations

When implementing blending operations, the beneficiaries acknowledge and accept that:

- the grant depends on the approved financing from the Implementing Partner and/or public or private investors for the project

- they must inform the granting authority both about the approval for financing and the financial close — within 15 days

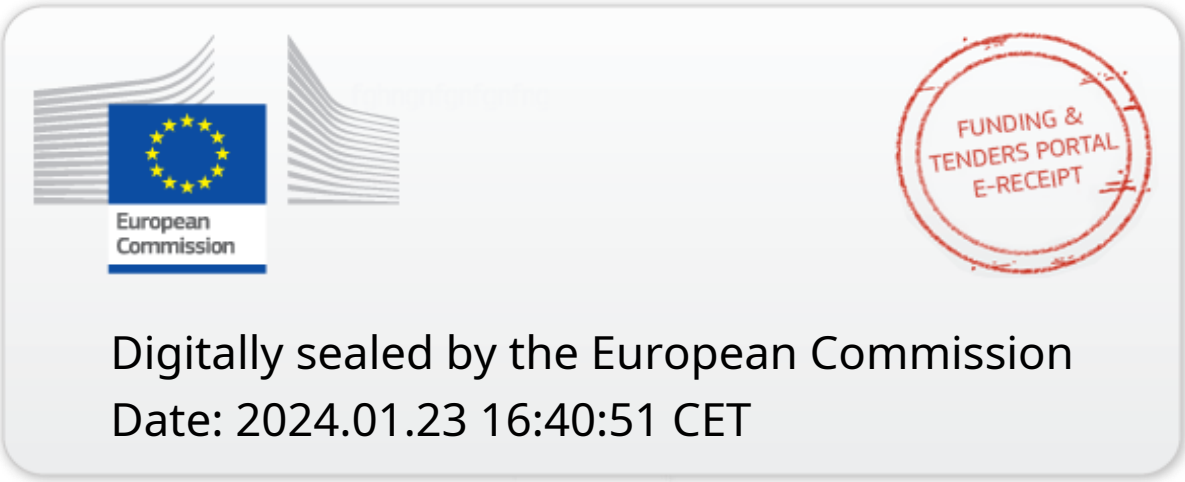
- the payment deadline for the first prefinancing is automatically suspended until the granting authority is informed about the approval for financing

- both actions will be managed and monitored in parallel and in close coordination with the Implementing Partner, in particular:

    - all information, data and documents (including the due diligence by the Implementing Partner and the signed agreement) may be exchanged and may be relied on for the management of the other action (if needed)

    - issues in one action may impact the other (e.g. suspension or termination in one action may lead to suspension also of the other action; termination of the grant will normally suspend and exit from further financing and vice versa, etc.)

- the granting authority may disclose confidential information also to the Implementing Partner.



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