EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

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

GRANT AGREEMENT

Project 101101732 — SPANISHVETPROGR2023

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)

Annex 1 Description of the action[1]

Annex 2 Estimated budget for the action

Annex 3 Accession forms (if applicable)[2]

Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)[3]

Annex 4 Model for the financial statements

Annex 5 Specific rules (if applicable)

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

TERMS AND CONDITIONS

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DATA SHEET

1. General data

Project summary:

Project summary
Veterinary Programmes 2023

Keywords:

- Animal health
- Zoonosis
- Tuberculosis, TSEs, Salmonella Control Programmes, Avian Influenza

Project number: 101101732

Project name: SPANISH VETERINARY PROGRAMMES 2023

Project acronym: SPANISHVETPROGR2023

Call: SMP-FOOD-2022-VETPROGR-LS-IBA

Topic: SMP-FOOD-2022-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 2023

Project end date: 31 December 2023

Project duration: 12 months

Consortium agreement: No

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	4 047 560.38
Total						4 047 560.38

Coordinator:

- MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION (MAPA)

3. Grant

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

Maximum grant amount (Annex 2)	Maximum grant amount (award decision)
4 047 560.38	4 047 560.38

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:

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)

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".

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 **101101732 — SPANISHVETPROGR2023** ('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).

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.

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

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

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."

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).

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

- 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)

- 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

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:

(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).

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).

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:

(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

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.

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

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

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.

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,

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

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.

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

- 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

Step 1 — Calculation of the revised total accepted EU contribution

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.

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).

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

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.

Project reviews (including project review reports) will be in the language of the Agreement.

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.

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

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 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

[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).

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.

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

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

(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

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.

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 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.

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.

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

(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

(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.

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,

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).

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).

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

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

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 17/03/2023 at 09:08:28 (transaction id SigId-44422-Md4M2wVAxQHgpdwgUKlH6N9PWV9orh3pD3fdIHU5aWrHcRSkRQ0bzfiZ1qjcgcOcy2izfyw3qQa26BQFecIgCy-yntOf97TTHqze7pG7O2zsV0-QhdvnANoqBMISBEvnq4Fzqgr5ihGyUbDY8lS8zsG7gKPuzgWe5PQgcR3XDvzgILlVy0jXsNBNLJl1afxXLQOEx0).
Timestamp by third party at
2023.03.17 09:08:35 CET

For the granting authority

Signed by Agnes MATHIEU-MENDES with ECAS id mathiag as an authorised representative on 17-03-2023 14:47:42 (transaction id SigId-50749-0l2wSVm46zWiIl34qEGzJavP0mH5pDvRpjRpQdBccNnbsWGiba7AN1zWprYgLTnhmWO8qhTgU7IK3ix6jcivmF0-yntOf97TTHqze7pG7O2zsV0-KKNWniU2sFmc5diPtzycQGzLKpzzzuIc2wDjL1RMNqIJc5azOqnzbjMvgvzVHg4w0URqv9YzPdcR1rwlei1MSY4e0)
2023.03.17 14:47:48 CET

European Commission

ANNEX 1

Single Market Programme (SMP)

Description of the action (DoA)

Part A

Part B

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:	101101732
Project name:	SPANISH VETERINARY PROGRAMMES 2023
Project acronym:	SPANISHVETPROGR2023
Call:	SMP-FOOD-2022-VETPROGR-LS-IBA
Topic:	SMP-FOOD-2022-VETPROGR-LS-IBA
Type of action:	SMP-LS
Service:	HADEA/A/02
Project starting date:	fixed date: 1 January 2023
Project duration:	12 months

TABLE OF CONTENTS

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.*
Veterinary Programmes 2023

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	AI programme	1 - MAPA	1.00	1	12	D1.1 – AI_INTERMEDIATE REPORT D1.2 – AI_FINAL REPORT
WP2	Salmonella programme	1 - MAPA	1.00	1	12	D2.1 – Salmonella_INTERMEDIATE REPORT D2.2 – Salmonella_FINAL REPORT
WP3	TSE programme	1 - MAPA	1.00	1	12	D3.1 – TSE_INTERMEDIATE REPORT D3.2 – TSE_FINAL REPORT

Work package WP1 – AI programme

Work Package Number	WP1	Lead Beneficiary	1. MAPA
Work Package Name	AI programme		
Start Month	1	End Month	12

Objectives
Early detection of AI

Description
Surveillance program avian influenza

Work package WP2 – Salmonella programme

Work Package Number	WP2	Lead Beneficiary	1. MAPA
Work Package Name	Salmonella programme		
Start Month	1	End Month	12

Objectives
prevalence targets bellow 1%

Description
control programmes on targeted serovars

Work package WP3 – TSE programme

Work Package Number	WP3	Lead Beneficiary	1. MAPA
Work Package Name	TSE programme		
Start Month	1	End Month	12

Objectives
Surveillance of BSE, eradication of scrapie

Description
Monitoring progrmme of BSE in bovines and scrapie in small ruminants

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

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_INTERMEDIATE REPORT	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	8
D1.2	AI_FINAL REPORT	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	12
D2.1	Salmonella_INTERMEDIATE REPORT	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	8
D2.2	Salmonella_FINAL REPORT	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	12
D3.1	TSE_INTERMEDIATE REPORT	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	8
D3.2	TSE_FINAL REPORT	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	12

Associated with document Ref. Ares(2023)1889941 - 15/03/2023

Deliverable D1.1 – AI_INTERMEDIATE REPORT

Deliverable Number	D1.1	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 implementation first 6 months

Deliverable D1.2 – AI_FINAL REPORT

Deliverable Number	D1.2	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 D2.1 – Salmonella_INTERMEDIATE REPORT

Deliverable Number	D2.1	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 implementation first 6 months

Deliverable D2.2 – Salmonella_FINAL REPORT

Deliverable Number	D2.2	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 D3.1 – TSE_INTERMEDIATE REPORT

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

Description
Intermediate report implementation first 6 months

Deliverable D3.2 – TSE_FINAL REPORT

Deliverable Number	D3.2	**Lead Beneficiary**	1. MAPA
Deliverable Name	TSE_FINAL REPORT		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	12	**Work Package No**	WP3

Description
Final Report

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	Initiation of sampling and testing_1	WP3, WP1, WP2	1-MAPA	Documentation on sampling and testing checks	8
2	Completion of sampling and testing_2	WP3, WP1, WP2	1-MAPA	Documentation of the completion of the activities	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 campaings for stakeholders
2	foreseen in advance the number of farms to be depopulated and the associated compensation in breeding hens	WP2	update in the interim report
3	to reach the minimun sample size of 10.000 goats to be tested at slaugherhouse (animals for human consumption)	WP3	montly follow up
4	no EU contribution for 2023		none

submitted for obtaining EU financial contribution

Annex IV: Programme for the surveillance of Avian Influenza in poultry and wild birds

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Avian Influenza

This program is multi annual : no

Request of Community co-financing for year : 2023

Request year for multiannual programme : *2023*

1. Contact data

Name	Germán Cáceres Garrido	Phone	+(34) 91 347 8351
Email	gcaceres@mapa.es	Your job type within the CA :	Head epidemiology department

Submission Date

09/12/2022 16:03:49

Submission Number

1670598231480-19261

2. Description and implementation of the surveillance programme in poultry

2.1.1 Designation of the authorities in charge of supervising coordinating and implementing the programme. Please describe in details who designs, who implements, and who monitors the programme in poultry. (Roles of central authority, local authorities, vets, farmers, labs, hunting associations, etc.)

(max. 32000 chars) :

According to the Spanish Legal framework, the Autonomous Communities have the implementation competences, 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. 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.

2.1.2 Description of System in place for the registration of holdings

(max. 32000 chars) :

Spain has a Registry of Livestock Holdings (REGA) established by Royal Decree 479/2004 of 26 March 2004 establishing and regulating the general registration of livestock holdings included in the Comprehensive National Animal Traceability System (SITRAN). This register includes all commercial poultry holdings, but it is not compulsory for all non-professional holdings, which are quite numerous in the case of birds, particularly in rural areas. However, the regional Autonomous Communities in Spain have been making enormous efforts in recent years to conduct a census of smallholdings, starting with areas classified as risky, for which is mandatory the registration of backyard holdings according to Article 5.3 of Order APA/2442/2006. The ultimate aim is to incorporate this register into the REGA register and, in the meantime, to have access to information that reflects the current situation regarding poultry holdings.
According to Article 16 of Royal Decree 637/2021, all Spanish avian holdings must be registered, including backyards regardless number of animals kept.

2.1.3 Design (risk based surveillance, or surveillance based on representative sampling taking into account criteria in Annex II of Commission Delegated Regulation (EU) 2020/689.

Provide justification for the choice of the design. Please refere also explicitly to the objectives of the surveillance programme as mentioned in section 2 of Annex II Commission Delegated Regulation (EU) 2020/689.

(max. 32000 chars) :

The main objective of the programme to be implemented in Spain is to monitor, early detect and inform the competent authority about the detection of avian influenza virus circulation, both of high and low pathogenicity, by means of a surveillance system that includes a passive and an active component.
The programme is based on the recommendations set out in Annex II to COMMISSION Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards surveillance rules, eradication programmes and disease-free status with regard to certain listed and emerging diseases.
1) Passive surveillance component:
The passive component aims at the early detection, reporting and immediate investigation by the Official Veterinary Services (OVS) of any sign of disease or abnormal mortality in domestic birds. It must be implemented throughout the national territory and at all times, 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.
Passive surveillance aims at detecting clinical signs of avian influenza in the flock. Monitoring of production parameters (e.g. increased mortality, decreased feed and water consumption, presence of clinical signs suggestive of respiratory disease or reduced laying) is important for the early detection of the presence of infection with avian influenza viruses. Specifically, the following suspicion criteria must be observed:
- Reduction of feed and water intake by more than 20%, without justification.
- A reduction in egg production of more than 5% for more than two days, without justification.
- A weekly mortality rate of more than 3%, without justification.
- Any clinical signs or post-mortem lesions suggestive of avian influenza.

This information must be reported by vets and/or farmers attending the holding.
2) Active surveillance component:
The objective of the active surveillance component is the detection of:
- Subclinical infections of low pathogenic avian Influenza of subtypes H5 and H7 that can easily spread between poultry flocks of laying hen categories, including those with free range systems, turkeys for fattening and breeding and poultry of Galliformes species for supplying game birds to be released into the wild, in particular in areas with a high density of poultry establishments, taking into account their potential to mutate into HPAI, in order to detect aggregations of LPAI infections and to control the risk of spread.
- Infections with HPAI in ducks, geese, quails and poultry of the order Anseriformes species for supplying game birds to be released into the wild, in holdings within the national territory, which normally do not show significant clinical signs.
In accordance with Annex II to Commission Delegated Regulation (EU) 2020/689 of 17 December 2019, establishments shall be selected on the basis of risk criteria according to the following principles:
Risk-based surveillance for the detection of circulating LPAI virus should, if possible, be applied 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 considered to be more likely. The assessment to select establishments for targeted surveillance 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.

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.
In order to make the selection of holdings to be sampled on the basis of risk, in addition to the criteria mentioned above and included in Annex II of the COMMISSION Delegated Regulation (EU) 2020/689 of 17 December 2019, 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/19/2021 of 18 January amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza. The following map 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 will be based on a recent risk assessment carried out 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. This risk assessment 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 the last 20 years.
- Survival of the virus, evaluating the days of survival based on monthly temperatures (2012-2017) 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 origin between2015-2018.
- Domestic poultry movements between 2016-2019.

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.

2.1.3.1 Short description of predominant poultry population and types of poultry production.

Please provide also a table with the number of poultry holdings and birds existing for each poultry type, and map with the geographic distribution and density of poultry holdings.(If not available, please explain)

(max. 32000 chars) :

The avian census in Spain is 490.3 million animals (in January 2022).
The poultry Holdings are classified as:
- Breeder farms (chickens): may be part of the vertical structure of a production company, or an independent company dedicated to producing hatching eggs. They are divided into two kinds of holding:
a) Selection holdings: those which produce hatching eggs for the production of breeding poultry (the grandmothers of broilers).
b) Breeder holdings: those which produce hatching eggs for the production of productive poultry (the mothers of broilers).
- Broiler holdings: These farms may be owned by the company or more frequently belong to the worker (farmer) who signs a service contract with the productioncompany or integrated company. The payment received by the farmer depends on the technical results of the flock (live weight, conversion rate, mortality, output at the slaughter house, including the percentage of 'seconds').
- Other poultry production: At primary production level, the most important in number are turkey's holdings, partridge farming, while pheasant and pigeon production often corresponds to craft activities of scant commercial relevance.
According to SITRAN, the Autonomous Communities with the highest number of birds (including hens, ducks and turkeys) are Galicia and CLM (with 22,23% and 19.81% of the total census), followed by Aragon, Castilla y León and Catalonia. The total number of poultry in January 2022 was 490.3 million animals.

Most of this census, up to a total of 473.7 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 15.09 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 593.000 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.

2.1.3.2 Criteria and risk factors for risk based surveillance (1) Please describe the risk factors as regard the criteria set in Annex II of Commission Delegated Regulation (EU) 2020/689.

(max. 32000 chars) :

In accordance with Annex II to Commission Delegated Regulation (EU) 2020/689 of 17 December 2019, establishments shall be selected on the basis of risk criteria according to the following principles:
Risk-based surveillance for the detection of circulating LPAI virus should, if possible, be applied 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 considered to be more likely. The assessment to select establishments for targeted surveillance 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.
Firstly, the total number of holdings foreseen for Spain (as described in 4.5) 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.
In order to make the selection of holdings to be sampled on the basis of risk, in addition to the criteria mentioned above and included in Annex II of the COMMISSION Delegated Regulation (EU) 2020/689 of 17 December 2019, 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/19/2021 of 18 January amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza. The following map 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 will be based on a recent risk assessment carried out 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. This risk assessment 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 the last 20 years.
- Survival of the virus, evaluating the days of survival based on monthly temperatures (2012-2017) 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 origin between2015-2018.
- Domestic poultry movements between 2016-2019.
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.

(1) Including maps showing target sampling sites identified as being particularly at risk for the introduction of avian influenza virus, taking into account criteria set out in Annex II of Commission Delegated Regulation (EU) 2020/689.

2.2 Target populations

Please explain:

1) The strategy of selection of the holdings to be sampled. (Random, risk based, geographic distribution)

2) The number of holdings sampled, with regard to the minimum requirements set in Annex II section 9 to Commission Delegated Regulation (EU) 2020/689.

3) The number of samples taken in each holding with regard to the minimum requirements set in Annex II section 9 to Commission Delegated Regulation (EU) 2020/689.

(max. 32000 chars) :

For the purpose of this Programme, 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 in the programme, the following categories of poultry may also be sampled in exceptional circumstances:
a) Chickens for meat, only if they are kept in significant numbers in extensive conditions and 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.
The table in the Annex attached shows the number of domestic poultry holdings in May 2022.
Holdings to be sampled are selected within each Autonomous Community on the basis of a risk-based prioritisation systems including three complementary elements (described in point 4.3):
- Prioritisation of poultry holdings located in municipalities included in special risk areas and special surveillance zones defined in Spain through Order APA/19/2021 of 18 January 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.
Sampling in each selected holding: for poultry birds, random blood samples for serological analysis shall be collected from all 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.

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

2.2.1 POULTRY HOLDINGS [(a)] (except ducks, geese and farmed game birds (waterfowl e.g. mallards) to be sampled

Serological investigation according to Annex I to Commission Decision 2010/367/EU

Targets for year **2023**

Category : laying hens

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
SPAIN	756	60	20	1 200	1 200	ELISA test	X
SPAIN					20	HI-test (H5)	X
SPAIN					20	HI-test (H7)	X
SPAIN				30	30	PCR test	X
Total					1 270		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) 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
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

Category : free range laying hens

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
SPAIN	696	60	10	600	600	ELISA test	X
SPAIN					20	HI-test (H5)	X
SPAIN					20	HI-test (H7)	X
SPAIN				20	20	PCR test	X
Total					660		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) 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
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

Category : farmed game birds (gallinaceous)

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	321	60	10	600	600	ELISA test	X

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					50	HI-test (H5)	X
					50	HI-test (H7)	X
				150	150	PCR test	X
Total					850		

Add a new row

(a) *Holdings or herds or flocks or establishments as appropriate.*
(b) *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*
(c) *Total number of holdings of one category of poultry in concerned NUTS 2 region.*

Category : fattening turkeys

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	762	60	10	600	600	ELISA test	X
					40	HI-test (H5)	X
					40	HI-test (H7)	X
Total					680		

Add a new row

(a) *Holdings or herds or flocks or establishments as appropriate.*
(b) *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*
(c) *Total number of holdings of one category of poultry in concerned NUTS 2 region.*

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

Category : turkey breeders

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	15	15	10	150	150	ELISA test	X
					20	HI-test (H5)	X
					20	HI-test (H7)	X
Total					190		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) 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
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

Category : broilers (only when at risk)

delete this category

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)

NUTS (2) (b)	Total number of holdings(c)	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	4 987	60	15	900	900	ELISA test	X
					56	HI-test (H5)	X

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					56	HI-test (H7)	X
				100	100	PCR test	X
Total					1 112		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) 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
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

Add a category

Totals	Total number of tests	Total number of samples
Total poultry 2023	4 762	4 350

2.2.2 DUCKS ,GEESE AND FARMED GAME BIRDS (WATERFOWL e.g. MALLARD) HOLDINGS (a) to be sampled.

Serological investigation according to Annex I to Commission Decision 2010/367/EU

Targets for year **2023**

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

Category : farmed game (waterfowl e.g. mallards) **delete this category**

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)

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	103	80	20	1 600	1 600	ELISA test	X
					700	HI-test (H5)	X
					400	HI-test (H7)	X
				200	200	PCR test	X
Total					2 900		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Category : fattening ducks **delete this category**

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)

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	88	59	20	1 180	1 180	ELISA test	X
					500	HI-test (H5)	X
					300	HI-test (H7)	X
				200	200	PCR test	X
Total					2 180		

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Category : fattening geese

delete this category

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)

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	32	32	20	640	640	ELISA test	X
					50	HI-test (H5)	X
					50	HI-test (H7)	X
				50	50	PCR test	X
Total					790		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Category : duck breeders

delete this category

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)

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	12	12	20	240	240	ELISA test	X

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

					20	HI-test (H5)	X
					20	HI-test (H7)	X
Total					280		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Category : geese breeders

delete this category

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)

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	10	10	20	200	200	ELISA test	X
					20	HI-test (H5)	X
					20	HI-test (H7)	X
Total					240		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Category : Qails

delete this category

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)

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

NUTS (2) (b)	Total number of duck and geese holdings	Total number of duck and geese holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis	
Spain	138	80	20	1 600	1 600	ELISA test	X
					50	HI-test (H5)	X
					50	HI-test (H7)	X
				150	150	PCR test	X
Total					1 850		

Add a new row

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested

Add a category

Totals	Total number of tests	Total number of samples
Total ducks and geese and farmed game birds 2023	8 240	6 060

TOTALS for Poultry (2.2.1) + Ducks and Geese (2.2.2) and farmed game birds for year : 2023

Poultry + Ducks/Geese /farmed game birds	Total number of tests
Grand Total	13 002
Grand Total ELISA	9 510

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Grand Total agar	0
Grand Total HI tests (H5)	1 546
Grand Total HI tests (H7)	1 046
Grand Total Virus Isolation test	0
Grand Total PCR test	900
Grand Total Samplings	10 410

2.3 Sampling procedures, sampling periods and frequency of testing taking into account criteria set out in Annex II of Commission Delegated Regulation (EU) 2020/689.

For each poultry category please detail the place of sampling (holding or slaughterhouse), the period and frequency of the testing, and who is in charge of the sampling.

(max. 32000 chars) :

-The place of sampling will be the holding.
-The sampling procedure:
- For Laying hens, free range laying hens, breeding turkeys, fattening turkeys, poultry of Galliformes species, the number of poultry holdings that must be included in the sample has been established to ensure that at least one infected poultry holding is detected if there is at least a 5 % prevalence of infected poultry holdings, with a confidence level of 95 %.
- The number of duck, goose, quail and Anseriformes holdings to be sampled has been established as to ensure the detection of at least one infected poultry holding where the prevalence of infected poultry holdings is at least 5 %, with a 99 % confidence level.
-Risk-based sampling will be intensified on those types of holdings considered to be of higher risk:
- The species present on the premises;
- The production cycle and duration of production;
- The presence of different poultry species;

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- The presence of poultry flocks of different ages;
- The presence of long-lived poultry;
- The practice of all-in-all-out;
- The length of the waiting period between flocks; and
- Biosecurity practices and poultry housing conditions.

-The sampling period shall be adapted to the seasonality of production; it may also be adapted to another type of periodicity identified locally 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.

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

- It is recommended the use of samples collected for other purposes, in order to increase the efficiency of the economic and human effort made.

-Virological sampling shall not be used as an alternative to serological sampling, except in the case of farmed game birds and where serological sampling is not possible, and should only be carried out in the framework of follow-up investigations of positive serological test results.

-Sampling shall be carried out between 1st January and 31st December of each year.

2.4. Laboratory testing: description of the laboratory tests used.

Please describe the tests to be used and their purpose (screening test or confirmatory test or follow-up investigations) for each category of poultry.

Please explain the number of tests calculation for each poultry category, and if it is in line with Annex II to Commission Delegated Regulation (EU) 2020/689.

Description of the used serological tests : (max 32000 chars)

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

(a) The analysis of the samples shall be carried out by laboratories authorised by the corresponding Autonomous Communities, working under the control of the National Reference Laboratory (LNR). The NRL shall provide the necessary technical support and reference materials to the official regional laboratories.

(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 preferably be subjected to laboratory testing by serological methods. Where for technical or other reasons sampling

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for serology is not appropriate, virological testing may be carried out.
(d) Samples must be subjected to laboratory testing by virological methods when taken for the early detection of HPAI in poultry and when it is used to complement surveillance for HPAI in poultry species not normally showing significant clinical signs and for the follow-up of seropositive results.
(e) In case of positive serological results (H5, H7), 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 generic and specific PCR (H5, H7, N1), sequencing, chick embryo inoculation, etc.
(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. The NRL shall retain samples of positive sera to H5 or H7 viruses.

3. Description and implementation of the surveillance programme in wild birds

3.1.1 Designation of the authorities in charge of supervising, coordinating , and implementing the programme and relevant collaborating partners (e.g. epidemiologists, ornithologists, nature bird observation and hunter organisations).

Please describe in detail who designs, who implements, and who monitors the programme in wild birds.

Please detail the system in place to detect the dead wild birds; please explain who delivers the wild birds to the laboratory.

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(max. 32000 chars) :

The Animal Health Services of each Autonomous Community shall be responsible for the implementation of the programme in their respective regions. Nonetheless, in the case of wild birds, they may require the collaboration – to comply with their responsibilities – of natural environment and hunting authorities, which will receive the necessary updated information on the epidemiological situation of the disease, particularly in those periods when there is a higher risk of introduction and spread of the avian influenza virus in Spain. The competent natural environment and hunting authorities in the Autonomous Communities will in turn pass this information on to hunting and ornithology organisations. Samples taken from dead or sick birds will be forwarded to the corresponding Animal Health official regional 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 for wild life surveillance.
Under the Directorate General for Health in Primary Production of the Ministry of Agriculture, Fisheries and Food, the Sub-Directorate General for Animal Health and Hygiene and Traceability is responsible for the NRL for Avian Disease (Central Veterinary Laboratory in Algete), and is the authority in charge of the supervision and coordination of the activities carried out by the activities carried out by the Autonomous Communities and the authorised regional laboratories.

3.1.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

max. 32000 chars) :

The program must be implemented throughout the whole national territory and at all times along the year.
However, surveillance in both its active and passive components in wild birds will be reinforced and/or particularly focused on the areas and periods of the year of highest risk. This risk-based reinforcement will be based on two complementary risk assessments the risk categorisation of municipalities located in special risk areas and special surveillance zones established for each Autonomous Community in Annexes II and III of Order APA/19/2021, of 18 January, amending Order APA/2442/2006, of 27 July, establishing specific protection measures in relation to avian influenza , as weel as taking account of the risk categorisation by livestock districts, based on the risk analysis model based on the TOPSIS method that has been developed by the MAPA. TOPSIS risk assessment model is in process to be automated for the risk assessment of introduction of the disease via migratory wild birds into Spain. This risk assessment model, in addition to offering a categorisation of the livestock district risk based on historical criteria, allows for a constant and adaptation of the livestock district risk in real time (weekly), which is especially useful in times of maximum risk coinciding with migratory periods of the different species when outbreaks occur in other EU Member States.

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3.1.3 Estimation of the local and/or migratory wildlife population

Please provide main species, number of birds, migratory routes, geographic distribution or risk areas.

(max. 32000 chars) :

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
Nombre científico Nombre común
Anas acuta Ánade rabudo
Anas clypeata Cuchara común
Anas crecca Cerceta común
Anas penelope Silbón europeo
Anas platyrhynchos Ánade real
Anas querquedula Cerceta carretona
Anser anser Ansar común
Aythya ferina Porrón común
Athya fuligula Porrón moñudo
Fulica atra Focha común
Larus canus Gaviota cana
Larus ridibundus Gaviota reidora
Limosa limosa Aguja Colinegra
Netta rufina Pato colorado

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Pluvicalis apricaria Chorlito dorado
Vanellus vanellus Avefría
Additionally, other high-risk wildlife species are included according to EFSA report EFSA-G-2017-00649) in the programme:
- Accipiter gentilis - Azor
- Accipiter nisus - Gavilán común
- Alopochen aegyptiacus- Ganso del Nilo o egipcio
- Anas strepera – Ánade friso
- Anser albifrons albifrons – Ánsar careto grande (raza europea)
- Ánser brachyrhynchus – Ánsar de pico corto
- Anser errythropus – Ansar careto chico
- Anser fabalis – Ánsar campestre
- Ardea cinerea – Garza real
- Aythya marila- Porrón bastardo
- Botaurus stellaris- Avetoro común
- Branta bernicla – Barnacla de cara negra
- Branta canadensis – Barnacla canadiense
- Branta leucopsis – Barnacla de cara blanca
- Branta ruficollis – Barnacla cuelliroja
- Bubo bubo – Búho real
- Bucephala clangula- Porrón osculado
- Buteo buteo – Busardo ratonero
- Buteo lagopus – Busardo calzado
- Carina moschata – Pato real
- Cygnus atratus- Cisne negro
- Coconia ciconia – Cigüeña blanca
- Circus aeroginosus – Aguilucho lagunero
- Chroicocephalus ridibundus- Gaviota reidora
- Cygnus colombianus – Cisne silbador
- Cygnus Cygnus – Cisne cantor
- Cygnus olor – Cisne común
- Egretta garzetta- Garceta común
- Egretta alba- Garceta grande o garza blanca
- Falco peregrinus – Halcón peregrino
- Falco tinnunculus – Cernícalo común

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- Haliaeetus albicilla- Pigargo europeo
- Larus marinus - Gavión atlántico
- Larus argentatus- Gaviota argéntea
- Marmaronetta angustirostris – Cerceta pardilla
- Mergus albellus – Serreta chica
- Mergus merganser- Serreta grande
- Milvus migrans – Milano negro
- Milvus milvus – Milano real
- Pelecanus crispus- Pelícano Ceñudo
- Pelecanus onocrotalus- Pelícano común
- Phalacrocorax carbo – Cormorán grande
- Philomachus pugnax – Combatiente
- Pica pica – Urraca
- Podiceps cristatus – Somormujo lavanco
- Podiceps nigricollis – Zampullín cuellinegro
- Porphyrio porphyrio – Calamón
- Somateria mollissima- Eider común
- Tachybaptus ruficollis – Zampullín chico
- Tadorna tadorna- Tarro blanco
- Tringa ochropus- Andarríos grande
- Turdus pilaris- Zorzal real

From all these, 6 species have been identified and analysed in detail (Anas acuta, Anas platyrhynchos, Anas strepera, Anser anser, Aythya fuligula and Fulica atra), according to the HPAI notifications during 3 years in Europe, the migration routes and census in Spain. The results obtained include:
1) The migration maps from bird bandings and recoveries obtained from SEO.
2) The % of birds that come from each country of origin and identification of whether these countries have been affected or not in those 3 years
3) The census per province of these species in Spain, and the areas of higher risk according to their concentrations.
4) The maximum migratory distances that the species could make

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

3.2 Design, criteria, risk factors and target population(3)

(max. 32000 chars) :

The objective of the surveillance programme for avian influenza in wild birds is the timely detection of HPAI in wild birds in order to protect poultry in poultry holdings and safeguard veterinary public health, and it is implemented on the basis of the recommendations laid down in Annex II of Delegated Regulation 689/2020

Passive-surveillance seems to have proved useful and efficient as early-detection tools, and should therefore be continued indefinitely and rendered as efficient as possible.

a) 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.

b) 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.

• Where possible, wild birds that have come into contact with these dead or dying birds shall also be sampled.

• Dead or sick birds found in unusual, suspect or doubtful circumstances shall be immediately removed and transported for post-mortem examination and collection of samples.

• For live wild birds taken to a wild fauna recovery centre or similar site, samples shall be taken and sent for analysis in all cases where it cannot be ruled out a priori that the reason for admission was avian influenza. Such birds shall be housed separately from others and adequate biosecurity measures will be taken until the test results become available.

c) In areas close to the sea, lakes or wetlands, particularly where there are domestic bird holdings nearby and in high-density areas, as well as in the risk areas and special surveillance areas defined in Annexes II and III to Order APM/233/2017, of 7 March 2017, passive-surveillance measures shall be enhanced using information campaigns targeted at the population and local authorities, placing particular emphasis on target species.

d) Close cooperation with epidemiologists and ornithologists and the competent authority for nature conservation shall be ensured in the preparation of the surveillance programme, assisting in species identification and optimising sampling adapted to the national situation.

e) Surveillance work should be intensified whenever the epidemiological situation concerning highly pathogenic avian influenza warrants this.

f) Detection of the highly pathogenic avian influenza virus in neighbouring countries or those linked epidemiologically by the movement of target species should also lead to increased passive-surveillance measures.

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

(3) Areas at risk (wetlands in particular where links with high density poultry populations), previous positive findings as referred to in Annex II to Commission Delegated Regulation (EU) 2020/689 should be taken into account and if possible complemented by a map.

3.2.1 WILD BIRDS focussed on target species

Investigations according to the surveillance programme set out in conformity with Annex II to Commission Delegated Regulation (EU) 2020/689

Targets for year **2023**

NUTS (2) code/region (a)	Total number of wild birds to be sampled	Estimated total number of wild birds to be samples for passive surveillance	Type of test	Number of tests	
Spain	1 000	1 000	PCR test	2 000	X
			Virus isolation test	15	X
Total	1 000	1 000		2 015	

Add a new row

(a) 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.

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

	Total number of tests
Total number of tests	2 015
Total Virus isolation tests	15
Total PCR tests	2 000
Total Other tests	0
Total number of wild birds to be sampled for passive surveillance	1 000

3.3 Sampling procedures and sampling periods

Please also explain which samples are taken from wild birds

max 32000 chars :

The wild bird sampling procedure shall comply with the following criteria:
a) Sampling procedures shall be applied in accordance with Annex II of Delegated Regulation 689/2020
b) Wild bird surveillance is based on virological surveillance, hence there is the need for cloacal and tracheal or oropharyngeal swabs and/or tissue samples (brain, heart, lungs, trachea, kidneys and intestines).
c) Special care shall be taken when storing and transporting samples in order 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. In the event that 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.
d) All avian influenza viruses isolated from wild birds shall also be sent to the NRL. H5 or H7 subtypes shall immediately be analysed using general characterisation tests, in accordance with Annex II of Delegated Regulation 689/2020
e) Sampling shall take place between 1 January and 31 December of each year.
f) Results shall be communicated every six months via the RASVE website, including the information detailed in Annex III and a description of the test methods used.
g) 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.

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h) All results shall be sent to the EURL for verification.

3.4 Laboratory testing: description of the laboratory tests used .

Please explain also which laboratory do the tests for the wild birds, and which, and how many tests are planned for each wild bird

max 32000 chars :

For laboratory analyses, the following requirements shall be met:
a) The same laboratory methods for virological and/or serological samples shall be used as for domestic birds. Tests shall comply with the procedures detailed in the Diagnostic Manual, adapted as appropriate should the CRL so decide. Accordingly, virological tests shall include: generic and specific PCR, sequencing, and inoculation of chicken embryos.
b) Samples shall be analysed by laboratories in the Autonomous Communities that can guarantee official results, that have obtained satisfactory results in the most recent comparative laboratory test, and that will work under the supervision of the NRL in Algete. The NRL shall provide the necessary technical support and reference materials to all other laboratories.
c) Up to five samples from the same species collected simultaneously in the same place may be pooled in the laboratory.

4. Short description of the epidemiological situation of the disease in poultry during the last five years

max 32000 chars :

In February 2017, an outbreak of HPAI H5N8 was reported in a fattening duck farm in Girona, in the municipality of Sant Gregori. The farm had moved live ducks to seven other national farms destined for Catalonia, also proving positive for the virus. On March 1, two additional duck farms located within a 3 km radius of the primary outbreak were declared affected. After confirmation, the measures contemplated in the legislation were taken, including a protection zone and a surveillance zone in which clinical and laboratory surveillance was carried out to prevent the spread of the disease, as well as the slaughter of all birds present on the farm, the destruction of all the materials present on the farm that could carry the virus and their subsequent cleaning and disinfection. From June 2, 2017, the entire Spanish territory regained the status of a country free of mandatory declaration avian influenza as established in the OIE code, not detecting any outbreak of highly pathogenic avian influenza in poultry farms in Spain between the years 2018-2021.
On January 18, 2022, the Central Veterinary Laboratory of Algete confirmed the detection of the highly pathogenic avian influenza virus H5N1 in a

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

fattening turkey farm located in the livestock region of Cantalejo, province of Segovia, considering wild birds as a possible source of focus. In this same Autonomous Community, in the month of February, two additional H5N1 outbreaks were reported in the livestock region of Olmedo, province of Valladolid, in two laying hen farms with a close relationship between them.
Additionally, between February 2 and March 21, 2022, 28 outbreaks have been detected in Andalucía, 6 of them in the province of Huelva (5 in the livestock region of La Palma del Condado and 1 in Cartaya) and 22 in the province of Sevilla (5 of them in the livestock region of Carmona, 4 in Écija, 10 in Osuna and 3 in the livestock region of Marchena). In the 28 cases in Andalucía the H5N1 subtype was confirmed.
In all the outbreaks detected in 2022, the measures established in Commission Delegated Regulation (EU) 2020/687 have been adopted. In accordance with the minimum periods established in Commission Delegated Regulation (EU) 2020/687, after a minimum of 30 days from the completion of the preliminary cleaning and disinfection tasks in the last affected farm, and taking into account that no additional positive results have been obtained in the clinical inspections and laboratory analyzes carried out in the farms located in the protection radius and surveillance as well as in contact farms, the restrictions of the protection and surveillance zones corresponding to the last affected farms have been lifted on May 2, 2022, considering all the HPAI outbreaks in poultry in Spain as closed upon completion of the planned actions

5. Short description of the epidemiological situation of the disease in wild birds during the last five years

(max. 32000 chars) :

In January 2017, two wild geese (Anser anser) were found dead in the La Nava de las Fuentes lagoon, in the province of Palencia (Castilla y León). The Central Veterinary Laboratory of Algete confirmed the detection of the HPAI H5N8 virus in both species. Weeks later, in February, a new case of HPAI H5N8 was confirmed in a stork (Ciconia ciconia) found dead in the Parc Natural dels Aiguamolls de l'Empordà area, in the province of Girona (Cataluña).
During the years 2018 and 2019, the disease was not detected in wild birds in Spain.
In the 2020-2021 season, 3 cases of HPAI H5N8 were detected in wild birds in Cantabria (a peregrine falcon in the Marismas de Santoña, Victoria and Joye Natural Park), Girona (3 storks and a goose in the Natural Park dels Aiguamolls de l'Empordà) and Zamora (a greylag goose in the Laguna Grande de Villafáfila).
In 2022, a total of 38 cases (36 H5N1 cases and 2 H5NX cases) have been detected in the provinces of Lérida, Girona, Ávila, Segovia, Palencia, Valladolid, Salamanca, Seville, Huelva, Cádiz, Córdoba, Madrid, Guipúzcoa, Caceres and Badajoz.
The cases were reported to the European Commission and the OIE, and the following measures were applied:
• Census of all commercial and non-commercial farms that were within a radius of 3 and 10 km.
• Intensification of surveillance of wild birds.

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• Dissemination of information on the epidemiological situation.

6. *Measures in place as regards the notification of the disease*

Please explain also briefly the measures implemented in case of suspicion or confirmation of the disease

(max. 32000 chars) :

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.
Managers, owners, breeders and all staff working in facilities for captive birds shall also report any of the following signs immediately to the competent animal health authorities:
- A drop in consumption of food or water of over 20%
- A reduction of over 5% in eggs laid for two days
- Mortality over 3 % in one week
- Any clinical or post-mortem symptoms or signs that might indicate the presence of the disease.

Suspicions that the disease is present may result from the presence of clinical signs on the holding, suspicion because of epidemiological reasons (presence of the disease on neighbouring holdings or epidemiological links to another affected holding through vehicles, persons or movements of birds or products).
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

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

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 measures laid down in the EU for suspected or confirmed outbreaks of avian influenza shall be adopted as set out in the Practical Operational Manual for combating AI.
All the measures, in case of suspicion and confirmation of AI, are established in the specific Manual available in MAPA Website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022_tcm30-437988.pdf

7. Costs

7.1 Detailed analysis of the costs

7.1.1 Poultry including ducks, geese and farmed game birds

Please also check the consistency between the numbers mentioned in tables 2.2.1, 2.2.2, 7.2.1, and the information provided in box 2.3 and 2.4. Please comment also the cost-efficiency aspects of the programme

(max. 32000 chars) :

The cost estimate is set out in the corresponding tables in relation to the number of samples to be collected and tests to be carried out. The measures resulting from the surveillance programme require numerous serological and virological tests to be carried out. In addition to the cost of both laboratory and field personnel, this involves the purchase of laboratory diagnostic kits, as well as various other consumables. These costs are defrayed to differing extents by both MAPA and the Autonomous Communities

7.1.2 Wild birds

Please also check the consistency between the numbers mentions in tables 3.2.1, 7.2.2 and the information provided in box 3.3 and 3.4.

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

(max. 32000 chars) :

The cost estimate is set out in the corresponding tables in relation to the number of samples to be collected and tests to be carried out.

7.2 Summary of the annual costs :

7.2.1 Poultry surveillance including ducks, geese and farmed game birds : Detailed analysis of the cost of the programme - poultry

Costs of the planned activities for year : **2023**

Laboratory testing

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution	
Testing	ELISA test - poultry	9 510	4.57	43460.7	yes	75	32 595,53	X
Testing	AGID test - poultry	0	11.55	0	yes	75	0	X
Testing	HI-Test for H5	1 546	5.77	8920.42	yes	75	6 690,31	X
Testing	HI-Test for H7	1 046	5.77	6035.42	yes	75	4 526,56	X
Testing	Virus isolation test - poultry	0	56.65	0	yes	75	0	X
Testing	PCR test - poultry	900	22.72	20448	yes	75	15 336	X

Sampling

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution	
Sampling	Domestic animals sampled	10 410	2.78	28939.8	yes	75	21 704,85	X

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Other measures

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution
			Total with Union funding request (€):	107,804.34	including		80853.25
			Total without Union funding request (€):	0			= requested EU contribution in €

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7.2.2 Wild bird surveillance : Detail analysis of the cost of the programme - wild birds

Costs of the planned activities for year : **2023**

Laboratory testing

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution	
Testing	Virus isolation test - wild birds	15	56.65	849.75	yes	75	637,31	X
Testing	PCR test - wild birds	2 000	22.72	45440	yes	75	34 080	X

Sampling

Cost related to	Specification	Number of wild birds to be sampled	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution	
Sampling	Wild birds sampled	1 000		0	yes	75	0	X

Other measures

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution	

Total with Union funding request (€):	46289.75	including	34717.31
Total without Union funding request (€):	0		= requested EU contribution in €

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

TOTALS for Poultry, duck, geese, farmed game birds (7.2.1) + WILD BIRDS (7.2.2) for year : 2023

Total with Union funding request (€):	154,094.09	including	115,570.56
Total without Union funding request (€):	0		= requested EU contribution in €

C. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

(max. 32000 chars) :

Sampling is carried out by the official veterinary services, and for that reason it is financed from public funds.

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b) Implementing entities **- testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

(max. 32000 chars) :

Sample analysis are carried out by the official laboratories, and for that reason it will be paid for from public funds.

c) Implementing entities **- compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

(max. 32000 chars) :

In the event of compensation for compulsory slaughter, the costs will be paid from public funds (shared between central government and the governments of the Autonomous Communities).

d) Implementing entities **- vaccination** : who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

(max. 32000 chars) :

Not envisaged

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

e) Implementing entities - **other essential measures**: who implements this measure? Who provides the equipment/ service? Who pays?

(max. 32000 chars) :

Non planned

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

☒*yes*
☐*no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
4) IT CAN TAKE ***SEVERAL MINUTES TO UPLOAD*** *ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Annex holdings and maps for 2023 programme.pdf	Annexholdingsandmapsfor2023programme.pdf	729 kb
			Total size of attachments :	729 kb

submitted for obtaining EU financial contribution

Annex II: Control programme – Reduction of prevalence of Salmonella serotypes in certain poultry populations

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Salmonella

Animal population Breeding flocks of Gallus gallus

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Soledad Collado Cortés	Phone	0034 91 347 15 94
Email	scollado@mapa.es	Your job type within the CA :	Head of Service of Zoonoses

Submission Date

30/11/2022 13:59:06

Submission Number

1669813152036-18915

A. Technical information

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.

As a consequence, the following measures will be implemented during the whole period of the programme:

1. 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: *Salmonella* Enteritidis (SE), Typhimurium (ST)(including the antigenic formula 1,4,[5],12:i:-), Hadar (SH), Infantis (SI) and Virchow (SV).

   For a MS with less than 100 adult breeding flocks of *Galus 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.

The objective of the National Programme is to control the presence of the five most frequent serotypes of human salmonellosis: 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.

2. The programme will be implemented on the **whole territory** of the Member State.

☒ *yes* ☐ *no*

If no please explain.

3. 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 will take place
Rearing flocks	1 020		1 020	5
Adult flocks	1 720	1 700	1 720	1 700
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		1 700	1 720	1 700

NB : All cells shall be filled in with the best estimation available.

Comments (max. 32000 chars) :

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 (for harmonisation purposes). 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)

4. Notification of the 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 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 this Programme.

The competent livestock service and health authorities must keep each other suitably informed of the positive results.

5. Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.

☒*yes* ☐*no*

If no please explain. if yes,describe also the biosecurity measures that shall be applied, quote the document describing them (if any) and attach a copy

Biosecurity measures will be verified in accordance with the protocol included in this programme for checking biosecurity measures on breeding poultry holdings.

These checks will take place in the course of each of the official inspections provided for on the holdings, at the frequency indicated in this 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 attached procedure will be followed to check and improve biosecurity measures in breeding poultry holdings.

6. Minimum sampling requirements for food business operators :

Samples at the initiative of the FBOs will 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)

Comments - 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

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 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.
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. 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: OWN-CHECK 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 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 10-15 days of the sampling, on average, except in exceptional circumstances. All of 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.

7. 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 OWN 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 of 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 filled with the test report sent by the laboratory so that all of 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"

(this text was added after a request of the FBO in order to clarify the status of the flock and to avoid trade misunderstanding).

8. 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):

☒ *yes* ☐ *no*

If no please explain. Indicate also if birds are slaughtered or killed and destroyed, and if eggs are destroyed or heat treated.

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:
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 off 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 the programme, which describes that 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. For the cleaning and disinfection procedure to be considered valid, a minimum of 10 samples (dust, fabric swabs, chamois or similar sampling materials) must be taken at various points on the holding and must yield negative results for Salmonella spp. Samples may be combined to produce a single culture. The use of cotton swabs or brushes is not recommended as they only pick up very small quantities of sample.
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 of 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, it may be requested the results 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. (This text was requested by the sector)

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 to 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.

9. Please describe the measures that shall be implemented in a flock (rearing and adult) where ***Salmonella*** **Hadar, Infantis or Virchow is detected**:

(max. 32000 chars) :

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 8.

10. 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 is amended as a part of the Action Plan aproved 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 slaugtherhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or the results of last analyses, if several 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 off 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, attached is 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.

11. 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.
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.

12. 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 6579-2002/Amd1:2007. `*Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. -- Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage*'.

    Serotyping is performed following the Kaufman-White-Le Minor scheme.

☒*yes* ☐*no*

If yes, please describe the alternative method(s) used.

Salmonella spp. shall be isolated in accordance with Standard EN/ISO 6579-1 (update to Regulation (EU) 2019/268). 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 to 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.

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 timelimits are exceeded, please indicate what is done.

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). (Update to Regulation (EU)2019/268).

13. 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.

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.

14. Please describe the **official controls at feed level** (including sampling).

Comments (max. 32000 chars) :

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 Regions.
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.

15. Official controls at holding, flock and hatchery 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.

(max. 32000 chars) :

"Guides to Good Hygiene Practice for the prevention of zoonotic Salmonella in holdings for the selection, breeding and rearing of flocks of Gallus gallus" 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.
They are also available for consultation on MAPA's website: http://www.mapa.es/.
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 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). (harmonised sampling method to verify C&D processes).
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) 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.

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 are 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 serovars

☐*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 in incubators 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 are 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. A minimum of three separate official checks on all of 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.

Sampling protocol it is the same as the protocol described in point 7 of the programme (sampling in adult breeding flocks) (clarify the protocol applied).

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, it may be requested t he results of laboratory analyses of the worker/s in charge of the animals, or anyone who can be considered as a risk (this text shall be added because it was requested by the sector), 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:

- [x] 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

Comments - Describe also if any other measures are implemented*(max. 32000 chars)* :

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 own checks, the competent authority may decide to carry out confirmatory analyses:
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.

There is a national protocol with the minimum criteria for authorizing a confirmatory sampling requested by the FBO, that include terms of type of production, epidemiological health situation and health history of the farm. Additionnal information can be found in the attached confirmatory protocol.

1	2	3	4
For routine samples taken at the holding	No of flocks positive to SE / ST	Out of the flocks in column 2, No of cases where official confirmatory samples[3] were taken	Out of the cases in column 3, No of cases where confirmatory samples were negative
FBO samples[1]	5	3	2
Official samples[2]	1	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

What happened to the flocks counted under 4 (re checked for the presence of Salmonella (on the progeny? on the same flock)? Checked for the presence of antimicrobials?) (max. 32000 chars) :

In 2021, 4 confirmatory test were made and 3 flocks resulted negative and the infection of the flock with target serovars of Salmonella was discarded.
In 2 of the flocks where confirmatory tests were negative the birds followed the productive cicle with the correlative routine sampling of the FBO and Official samples according to the EU regulation and the national programme, until the end of the productive period with the slaugthering of the birds. The premises were cleaned and disinfected and disinsected and before entering new birds it was made the sampling for verification of cleaning and disinfection, with negative results.
In the other flock with negative confirmatory sampling, the birds were slaughtered and the premises cleaned and disinfected and verified by the proper samples, with negative results.

f. 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, sampletaking) 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.

(max. 32000 chars) :

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 dectect 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.

16. Salmonella vaccination

- [x] Voluntary
- [ ] Compulsory
- [ ] Forbidden

Use of *Salmonella* vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.

Comments - If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc) (max. 32000 chars) :

Vaccination shall be carried out in accordance with Article 3 of Regulation (EC) No 1177/2006.
Vaccination of breeding hens is not mandatory, but in the event that it is carried out 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 --five-- ++three types of Salmonella (SE, ST, SMT, SI)++(this text shall be removed and added because of updating) 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. 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.

17. 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 (max. 32000 chars) :

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, Fisheries and Food 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.

18. 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...)

(max. 32000 chars) :

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 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.
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.

B. General information

1. Structure and organisation of the **Competent Authorities** (from the central CA to the local CAs)

Short description and/or reference to a document presenting this description (max. 32000 chars) :

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 General Subdirectorate for Animal Health and Hygiene of the Ministry of Agriculture, Fisheries 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. 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. **Legal basis** for the implementation of the programme

(max. 32000 chars) :

The measures included in this monitoring programme for application when Salmonella is detected

comply with the requirements of parts C and E of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council, and are implemented in accordance with Commission Regulation (EC) No 200/2010, including requirements for detection tests (type of samples, frequency of sampling, preparation of samples, laboratories, methods of analysis and notification of results).

3. 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).

(max. 32000 chars) :

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 was as shown below, with the most prevalent target serotypes being S. monophasic, Typhimurium and SV, followed by SE, ST and SI (a file containing the evolution of prevalence is enclosed):

4. System for the registration of holdings and identification of flocks

(max. 32000 chars) :

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)

5. System to monitor the implementation of the programme.

(max. 32000 chars) :

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 own checks and inspection of own-check laboratories (document enclosed):
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 of the laboratories in its territory within two years.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year : 2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Breeding flocks of Gallus gallus	5 000
Serotyping	Breeding flocks of Gallus gallus	100
Antimicrobial detection test	Breeding flocks of Gallus gallus	50
Test for verification of the efficacy of disinfection	Breeding flocks of Gallus gallus	10

1.2 Targets on official sampling of flocks for year : 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)	1 020	1 720
No of flocks in the programme	1 020	1 720
No of flocks planned to be checked (b)	5	1 700
No of flock visits to take official samples (c)	5	2 500
No of official samples taken	35	5 010
Target serovars (d)	SE+ ST + SH +SI + SV	SE+ ST + SH +SI + SV
Possible No of flocks infected by target serovars	3	8
Possible No of flocks to be depopulated	3	8
Total No of birds to be slaughtered/culled	20 000	80 000
Total No of eggs to be destroyed	Text	423 000
Total No of eggs to be heat treated	Text	770 000

Breeding flocks of Gallus gallus

(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 serveral 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

2 Targets on vaccination

2.1 Targets on vaccination for year : **2023**

Type of the test (description)	Target on vaccination
Number of flocks in the Salmonella programme	1 720
Number of flocks expected to be vaccinated	1 600
Number of birds expected to be vaccinated	14 500 000
Number of doses expected to be administered	50 000 000

D.1. Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2023

1. Testing of official samples

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Breeders: Bacteriological detection test	5 000	27.24	136,200	yes	75	102 150	X
Testing	Breeders: Serotyping	100	55.68	5568	yes	75	4 176	X
Testing	Breeders: Antimicrobial detection test	50	26.88	1344	yes	75	1 008	X
Testing	Breeders: Test for verification of the efficacy of disinfection	10	44.86	448.6	yes	75	336,45	X

2. Vaccination (if you ask cofinancing for purchase of vaccins, you should also fill in A.16 and E.1.d)

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Vaccination	Breeders: Purchase of vaccine doses	50 000 000	0.05	2,500,000	yes	75	1 875 000	X

3. Slaughter and destruction (without any salaries)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Breeders: Heat treated hatching eggs	770 000		0	no	75	0	X
Compensation	Breeders: Hatching eggs destroyed	423 000		0	no	75	0	X
Compensation	Breeders: Animals culled or slaughtered	100 000	8	800,000	yes	75	600 000	X

4.Cleaning and disinfection

Breeding flocks of Gallus gallus

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	In case of full flock depopulation			0	no	75	0	X

5.Other essential costs

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				Add a new row				

6. Cost of official sampling

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Sampling	Breeders: Official sampling visit	2 500	13.91	34775	yes	75	26 081,25	X

Total with Union funding request (€):	3,478,335.6	including	2,608,751.7
Total without Union funding request (€):	0		= requested EU contribution in €

E. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

The official samples are taken by official veterinarians. The cost of sampling is covered by the administrative authorities, in this case the Autonomous Communities.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

The official samples are analysed in the official laboratories of the Autonomous Communities. The cost of the analyses is covered by the Autonomous Community. The national reference laboratory (NRL, Algete) also carries out serotyping analysis of official samples. To a lesser extent, it also performs isolation and identification analyses. These analyses are paid for by the NRL.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

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, slaughter in the case of positive flocks is not compulsory and therefore is not compensated.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

The vaccination of breeding hens is voluntary. The private veterinarians working for a Livestock Health Association provide and perform the vaccination for the birds of the holding of the farmer that contract the services of that association.
The administrative authorities may finance the vaccination based on regional grants for the Livestock Health Associations. Regional veterinary services will reimburse these associations after checking the corresponding documents (invoices of purchase, nº of animals vaccinated, nº of doses used, date of vaccination, etc).

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/ service? Who pays?

Installations are always cleaned and disinfected after the sheds have been emptied. Before repopulating the sheds, cleaning and disinfection must be checked, taking environmental samples. These activities are the responsibility of the food business operators, who pay for them. On some occasions, the competent authority of the ACs also takes samples to check the effectiveness of cleaning and disinfection, in which case the administrative authorities cover the cost.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public funds.

☒*yes*

☐*no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo toma muestras ATC 052019.pdf	AnexotomamuestrasATC052019.pdf	256 kb
		Anexo toma muestras CO 052019.pdf	AnexotomamuestrasCO052019.pdf	261 kb
		Biosecurity breeders.pdf	Biosecuritybreeders.pdf	39 kb
		DIAGRAMA COMITE RASVE.doc	DIAGRAMACOMITERASVE.doc	224 kb
		Diagrama gestión aves matadero.docx	Diagramagestinavesmatadero.doc	271 kb
		PLAN CONTROL OFICIAL DE ATC.doc	PLANCONTROLOFICIALDEATC.doc	317 kb
		PLAN INSPECCIONES LAB ATC.docx	PLANINSPECCIONESLABATC.doc	66 kb
		Protocolo test confirmatorios.SNCP 2021.docx	ProtocolotestconfirmatoriosSNCP2021.doc	50 kb
		SNCP Evolution of prevalence and serotypes Salmonella_Spain_2021.docx	SNCPEvolutionofprevalenceandserotypesSalmonella_Spain_2021.doc	176 kb

		Modelo encuesta epidemiológica positivos Salmonella 2021.pdf	ModeloencuestaepidemiolgicapositivosSalmonella2021.pdf	132 kb
			Total size of attachments :	1793 kb

submitted for obtaining EU financial contribution

Annex II: Control programme – Reduction of prevalence of Salmonella serotypes in certain poultry populations

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Salmonella

Animal population Laying flocks of Gallus gallus

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Soledad Collado Cortés	Phone	0034 91 347 15 94
Email	scollado@mapa.es	Your job type within the CA :	Head of Service of Zoonoses

Submission Date

30/11/2022 14:39:32

Submission Number

1669815574991-18925

A. Technical information

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.

As a consequence, the following measures will be implemented during the whole period of the programme:

1. Aim of the programme

It is to implement all relevant measures in order to reduce the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium (including the serotypes with the antigenic formula I,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.

Comments(max. 32000 chars) :

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.

2. The programme will be implemented on the **whole territory** of the MS.

☒*yes* ☐*no*

If No, please explain :

3. Flocks subject to the programme

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 :

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)

	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	1 460		1 460	10
Adult flocks	3 115	3 115	3 115	900

Number of holdings with more than 1,000 laying hens	850
Number of flocks in these holdings	3 200

NB : All cells shall be filled in with the best estimation available.

Comments (max. 32000 chars) :

4. Notification of the 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 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 this programme.

The competent authorities of the livestock service and Public Health will between them ensure due reporting of positive results.

5. Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.

☒ *yes* ☐ *no*

if no, please explain. If yes, please describe the biosecurity measures that shall be applied, quote the document describing them (if any) (max. 32000 chars) :

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.

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 attached guideline protocol shall be observed in order to check and assess the biosecurity measures at holdings for laying hens. (Layer biosecurity survey)

6. Minimum sampling requirements for food business operators (FBO):

Samples at the initiative of the FBOs will be taken and analysed to test for the target *Salmonella* serovars respecting the following minimum sampling requirements:

a. Rearing flocks: day-old chicks, two weeks before moving to laying phase or laying unit

b. Adults laying 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)

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.

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.

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 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 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.

7. **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 is 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 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 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, en 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".

8. 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 or the suspicion of the presence of SE or ST (including monophasic ST I,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 that 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 off 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 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.

9. 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 is amended as a part of the Action Plan aproved 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 slaugtherhouse operator; in other words, the slaughterhouse operator must be informed if the result of the last analysis (or the results of 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 off 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, attached is 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.

10. 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. 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.

11. 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 6579-2002/Amd1:2007. `*Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. -- Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage*'.

    Serotyping is performed following the Kaufman-White-Le Minor scheme.

☒*yes* ☐*no*

If no please explain.

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 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 reportingDecision 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.

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.

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).

12. 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 :

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.

13. Please describe the **official controls at feed level** (including sampling).

Comments (max. 32000 chars) :

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

Regions.
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.

14. Official controls at holding, flock and hatchery 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.

(max. 32000 chars) :

Guides to Good Hygiene Practices 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.

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 328/2003, 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 food-borne 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 Typhimurium 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 give a description of what is done 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.

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:
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.

Similar to breeders programme, there is a national protocol with the minimum criteria for authorizing a confirmatory sampling requested by the FBO, that includes terms of type of production, epidemiological health situation and health history of the farm (for Salmonella spp and for target serovars). Furthermore, minimum guarantees of biosecurity measures are considered. Additionnal information can be found in the protocol that is attached to the programme.

1	2	3	4
For routine samples taken at the holding	No of flocks positive to SE / ST	Out of the flocks in column 2, No of cases where official confirmatory samples[3] were taken	Out of the cases in column 3, No of cases where confirmatory samples were negative
FBO samples[1]	33	6	4
Official samples[2]	57	2	1

[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?) (max. 32000 chars):

In 2021, 8 flocks were sampled for confirmatory tests.
In 5 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.

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, sampletaking) to check the correct implementation of this provision**.** For samples please describe the samples taken, the analytical method used, the result of the tests**.**

Comments - Describe also if any other measures are implemented*(max. 32000 chars) :*

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 dectect 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.

15. Salmonella vaccination

- ☐ Voluntary
- ☒ Compulsory
- ☐ Forbidden

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) (max. 32000 chars) :

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.

16. 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 also how improper implementation of biosecurity measures can affect the payment of compensation (max. 32000 chars) :

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, Fisheries and Food, 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.

17. Please describe the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (No of samples, No of tests, samples taken, etc).

(max. 32000 chars) :

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 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.
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.

B. General information

1. Structure and organisation of the **Competent Authorities** (from the central CA to the local CAs)

Short description and/or reference to a document presenting this description (max. 32000 chars) :

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. 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. **Legal basis** for the implementation of the programme

(max. 32000 chars) :

The measures included in this control programme meet the requirements laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council, and are implemented pursuant to

Commission Regulation (EU) No 517/2011 of 25 May 2011, including the requirements for the detection tests (type of samples, sampling frequency, preparation of samples, laboratories, methods of analysis and notification of results).

3. 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).

(max. 32000 chars) :

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)

4. System for the registration of holdings and identification of flocks

(max. 32000 chars) :

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)

5. System to monitor the implementation of the programme.

(max. 32000 chars) :

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 (document enclosed):

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 holdings 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.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year : 2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Laying flocks of Gallus gallus	1 870
Serotyping	Laying flocks of Gallus gallus	280
Antimicrobial detection test	Laying flocks of Gallus gallus	30
Test for verification of the efficacy of disinfection	Laying flocks of Gallus gallus	50

1.2 Targets on official sampling of flocks for year : 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)	1 460	3 115
No of flocks in the programme	1 460	3 115
No of flocks planned to be checked (b)	10	900
No of flock visits to take official samples (c)	10	925
No of official samples taken	50	2 750
Target serovars (d)	SE + ST	SE + ST
Possible No of flocks infected by target serovars	2	55
Possible No of flocks to be depopulated	2	45
Total No of birds to be slaughtered/culled	150 000	450 000
Total No of eggs to be destroyed	Text	70 000
Total No of eggs to be heat treated	Text	17 500 000

Laying flocks of Gallus gallus

(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 serveral 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

2 Targets on vaccination

2.1 Targets on vaccination for year : **2023**

Type of the test (description)	Target on vaccination
Number of flocks in the Salmonella programme	3 115
Number of flocks expected to be vaccinated	3 115
Number of birds expected to be vaccinated	73 750 000
Number of doses expected to be administered	215 400 000

D.1. Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2023

1. Testing of official samples

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Layers: Bacteriological detection test	1 870	27.24	50938.8	yes	75	38 204,1	X
Testing	Layers: Serotyping	280	55.68	15590.4	yes	75	11 692,8	X
Testing	Layers: Antimicrobial detection test	30	26.88	806.4	yes	75	604,8	X
Testing	Layers: Test for verification of the efficacy of disinfection	50	44.86	2243	yes	75	1 682,25	X

2. Vaccination (if you ask cofinancing for purchase of vaccins, you should also fill in A.15 and E.1.d)

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Vaccination	Layers: Purchase of vaccine doses	215 400 000	0.05	10,770,000	yes	75	8 077 500	X

3. Slaughter and destruction (without any salaries)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Layers: Table eggs destroyed	70 000		0	no	75	0	X
Compensation	Layers: Animals culled or slaughtered	600 000	3.5	2,100,000	yes	75	1 575 000	X

4.Cleaning and disinfection

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

Laying flocks of Gallus gallus

Cleaning and disinfection	In case of full flock depopulation			0	no	75	0	X

5.Other essential costs

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				Add a new row				

6. Cost of official sampling

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Sampling	Layers: Official sampling visit	925	13.91	12866.75	yes	75	9 650,06	X

Total with Union funding request (€):	12,952,445.35	including	9,714,334.01
Total without Union funding request (€):	0		= requested EU contribution in €

E. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

The official samples are taken by official veterinarians. The cost of sampling is covered by the administrative authorities, in this case the Autonomous Communities.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

The official samples are analysed in the official laboratories of the Autonomous Communities. The cost of the analyses is covered by the Autonomous Community. The national reference laboratory (NRL, Algete) also carries out serotyping analysis of official samples. To a lesser extent, it also performs isolation and identification analyses. These analyses are paid for by the NRL.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

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, slaughter in the case of positive flocks is not compulsory and therefore is not compensated.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

The vaccination of laying hens is compulsory. The private veterinarians working for a Livestock Health Association provide and perform the vaccination for the birds of the holding of the farmer that contract the services of that association.
The administrative authorities may finance the vaccination based on regional grants for the Livestock Health Associations. Regional veterinary services will reimburse these associations after checking the corresponding documents (invoices of purchase, nº of animals vaccinated, nº of doses used, date of vaccination, etc).

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/ service? Who pays?

Installations are always cleaned and disinfected after the sheds have been emptied. Before repopulating the sheds, cleaning and disinfection must be checked, taking environmental samples. These activities are the responsibility of the food business operators, who pay for them. On some occasions, the competent authority of the ACs also takes samples to check the effectiveness of cleaning and disinfection, in which case the administrative authorities cover the cost.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public funds.

☒*yes*

☐*no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo toma muestras ATC 052019.pdf	AnexotomamuestrasATC052019.pdf	256 kb
		SNCP Evolution of prevalence and serotypes Salmonella_Spain_2021.docx	SNCPEvolutionofprevalenceandserotypesSalmonella_Spain_2021.doc	176 kb
		Anexo toma muestras CO 052019.pdf	AnexotomamuestrasCO052019.pdf	261 kb
		biosecurity layers.pdf	biosecuritylayers.pdf	30 kb
		DIAGRAMA COMITE RASVE.doc	DIAGRAMACOMITERASVE.doc	224 kb
		Diagrama gestión aves matadero.docx	Diagramagestinavesmatadero.doc	271 kb
		Modelo encuesta epidemiológica positivos Salmonella 2021.pdf	ModeloencuestaepidemiolgicapositivosSalmonella2021.pdf	132 kb
		PLAN CONTROL OFICIAL DE ATC.doc	PLANCONTROLOFICIALDEATC.doc	317 kb
		PLAN INSPECCIONES LAB ATC.docx	PLANINSPECCIONESLABATC.doc	66 kb

		Protocolo test confirmatorios.SNCP 2021.docx	ProtocolotestconfirmatoriosSNCP2021.doc	50 kb
		ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
			Total size of attachments :	2071 kb

submitted for obtaining EU financial contribution

Annex II: Control programme – Reduction of prevalence of Salmonella serotypes in certain poultry populations

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Salmonella

Animal population Broiler flocks of Gallus gallus

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Soledad Collado	Phone	0034 91 347 15 94
Email	scollado@mapa.es	Your job type within the CA :	Head of Service of Zoonoses

Submission Date

30/11/2022 15:04:04

Submission Number

1669817046699-18929

A. Technical information

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,
- 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.

As a consequence, the following measures will be implemented during the whole period of the programme:

1. 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 national 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:-, in broilers will be to reduce the maximum percentage of broiler flocks which test positive for these serotypes to 1% or less.
Definition of positive:
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 in the flock.
Positive flocks of broilers will 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.

Measures where a positive case is detected:

If Salmonella spp. is detected, the samples must be serotyped by the National Reference Laboratory or by an authorised Autonomous Community official or own-checks laboratory. If either of the two serotypes (S. Enteritidis or S. Typhimurium, including the monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:,) is detected in any of the samples, the competent authorities for animal health or the food operators will take the appropriate measures, involving at least the following, in accordance with Regulation (EC) No 2160/2003:

1. In all broiler flocks in which a positive result was obtained, an in-depth epidemiological investigation will 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. 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 rigorous check of the biosafety measures applied to all flocks on the holding will be performed in accordance with the guideline protocol for checking biosafety measures on broiler holdings. Checks will also be carried out on the correct performance of the own checks for these flocks.

3. No live birds may be moved into or off 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.

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 (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 Wednesday 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

5. 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 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, it shall apply the measures described in point 14 of this programme.

6. The premises will 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 biosafety 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.

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 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, 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) in charge of the animals , or anybody who can be considered as a riks,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 will 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.
Thorough checks on the biosafety measures for all flocks on the holding in accordance with the procedure for checking biosafety measures on broiler holdings.

2. Geographical coverage of the programme

The programme will be implemented on the **whole territory** of the MS.

☒ *yes* ☐ *no*

If no, please explain.

3. Flocks subject to the programme

The programme covers all flocks of broilers. It does not apply to flocks for private domestic use.

Comments (max. 32000 chars) :

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)

	Number of holdings
Total number of holdings with broilers in the MS	4 650
Total number of houses in these holdings	40 000
Number of holdings with more than 5,000 broilers	4 500
NB : All cells shall be filled in with the best estimation available.	

4. Notification of the 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 FBO and the laboratory performing the analyses.

☒ *yes* ☐ *no*

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 this programme: The competent authority of the livestock and public health service will keep both appropriately informed of the positive results.

5. Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.

☒*yes* ☐*no*

If no, please explain. - If yes, describe the biosecurity measures that shall be applied, quote the document describing them (if any) and attach a copy.

A biosafety survey will be carried out at the same time as the collection of samples as part of the official checks. The biosafety measures will be verified once a year, observing the protocol for checking biosafety measures at least on all holdings of broiler poultry on which the official control is performed in accordance with this programme. Checks on these measures will take place at the same time as the official sampling in the flock. The data gathered in such exercises must be recorded using the computer application in the Biosafety section, whether or not official samples were collected. If, in the course of an inspection, significant shortcomings in the biosafety measures are detected, this will be made known to the holder by means of an official notice, drawn up in at least triplicate and addressed to the holder or 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 must adopt a proportionate and progressive approach in his work to enforce biosafety 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. Other measures or sanctions may also be applied to the flock, or to the whole holding: depending on the seriousness of the shortcoming detected, they may range from placing the holding under quarantine to withdrawing the health authorisation for its operation. The guideline protocol attached will be observed in order to check and assess the biosafety measures on broiler holdings.

6. Minimum sampling requirements for food business operators (FBO):

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 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

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.
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 - 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 - 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.

7. 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: 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"

8. 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 is amended as a part of the Action Plan aproved 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 slaugtherhouse 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 off 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, attached is 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.

9. **Laboratories** in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 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. 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.

10. 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 6579-2002/Amd1:2007. `*Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. -- Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage*'.

    Serotyping is performed following the Kaufman-White-Le Minor scheme.

☒*yes* ☐*no*

If no please explain.

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 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.

For samples taken on behalf of the FBO alternative methods may be used if validated in accordance with the most recent version of EN/ISO16140 may be used.

☒*yes* ☐*no*

If no please explain.

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).

11. 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 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 within 48 hours of receipt and within 96 hours of sampling

12. Please describe the **official controls at feed level** (including sampling).

Comments (max. 32000 chars) :

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 Regions.
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.

13. 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.

(max. 32000 chars) :

Good Hygiene Practice Guides 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.
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 offical 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 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 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 give a description of what is done 2) who is taking the official samples *(max. 32000 chars)* :

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, and 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**.**

(max. 32000 chars) :

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 dectect 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.

14. Please describe the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (No of samples, tests, samples taken, etc.)

(max. 32000 chars) :

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 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.
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.

B. General information

1. Structure and organisation of the **Competent Authorities** (from the central CA to the local CAs)

Short description and/or reference to a document presenting this description (max. 32000 chars) :

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. 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. **Legal basis** for the implementation of the programme

(max. 32000 chars) :

The measures included in this control programme when Salmonella is detected comply with the requirements set out in Section E of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council, and are implemented in accordance with Commission Regulation (EC) No

200/2012, including the requirements for the detection tests (type of samples, sampling frequency, preparation of samples, laboratories, analysis methods and notification of results

3. 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).

(max. 32000 chars) :

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. monophasic Typhimurium, followed by S. Typhimurium, the more prevalent serotypes under control.

4. System for the registration of holdings and identification of flocks

(max. 32000 chars) :

Measures and applicable legislation as regards the registration of holdings:
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.

Measures and applicable legislation as regards the registration of flocks 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.

5. System to monitor the implementation of the programme.

(max. 32000 chars) :

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 (document inserted). 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.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year : 2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Broiler flocks of Gallus gallus	525
Serotyping	Broiler flocks of Gallus gallus	75
Antimicrobial detection test	Broiler flocks of Gallus gallus	5
Test for verification of the efficacy of disinfection	Broiler flocks of Gallus gallus	25

1.2 Targets on official sampling of flocks for year : 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)	0	40 000
No of flocks in the programme	0	40 000
No of flocks planned to be checked (b)	0	480
No of flock visits to take official samples (c)	0	500
No of official samples taken	0	525
Target serovars (d)	SE + ST	SE + ST
Possible No 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 serveral 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

D.1. Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2023

1. Testing of official samples

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Broilers: Bacteriological detection test	525	27.24	14301	yes	75	10 725,75	X
Testing	Broilers: Serotyping	75	55.68	4176	yes	75	3 132	X
Testing	Broilers: Antimicrobial detection test	5	26.88	134.4	yes	75	100,8	X
Testing	Broilers: Test for verification of the efficacy of disinfection	25	44.86	1121.5	yes	75	841,13	X

2. Vaccination

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				0	no		0	X

3. Slaughter and destruction (without any salaries)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

4.Cleaning and disinfection

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	In case of full flock depopulation			0	no	75	0	X

Broiler flocks of Gallus gallus

5.Other essential costs

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				Add a new row				

6. Cost of official sampling

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Sampling	Broilers: Official sampling visit	500	13.91	6955	yes	75	5 216,25	X

Total with Union funding request (€):	26687.9	including	20015.93
Total without Union funding request (€):	0		= requested EU contribution in €

E. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

The official samples are taken by official veterinarians. The cost of sampling is covered by the administrative authorities, in this case the Autonomous Communities.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

The official samples are analysed in the official laboratories of the Autonomous Communities. The cost of the analyses is covered by the Autonomous Community. The national reference laboratory (NRL, Algete) also carries out serotyping analysis of official samples. To a lesser extent, it also performs isolation and identification analyses. These analyses are paid for by the NRL.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

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, slaughter in the case of positive flocks is not compulsory and therefore is not compensated.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

The vaccination of broilers is not compulsory and is not carried out. The administrative authorities therefore do not finance it.

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/service? Who pays?

Installations are always cleaned and disinfected after the sheds have been emptied. Before repopulating the sheds, cleaning and disinfection must be checked, taking environmental samples. These activities are the responsibility of the food business operators, who pay for them. On some occasions, the competent authority of the ACs also takes samples to check the effectiveness of cleaning and disinfection, in which case the administrative authorities cover the cost.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public funds.

☒ *yes*

☐ *no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo toma muestras ATC 052019.pdf	AnexotomamuestrasATC052019.pdf	256 kb
		Anexo protección animal en sacrificio.docx	Anexoproteccinanimalensacrificio.doc	38 kb
		Anexo toma muestras CO 052019.pdf	AnexotomamuestrasCO052019.pdf	261 kb
		biosecurity broilers .pdf	biosecuritybroilers.pdf	35 kb
		DIAGRAMA COMITE RASVE.doc	DIAGRAMACOMITERASVE.doc	224 kb
		Diagrama gestión aves matadero.docx	Diagramagestinavesmatadero.doc	271 kb
		Modelo encuesta epidemiológica positivos Salmonella 2021.pdf	ModeloencuestaepidemiolgicapositivosSalmonella2021.pdf	132 kb
		PLAN CONTROL OFICIAL DE ATC.doc	PLANCONTROLOFICIALDEATC.doc	317 kb
		PLAN INSPECCIONES LAB ATC.docx	PLANINSPECCIONESLABATC.doc	66 kb

		SNCP Evolution of prevalence and serotypes Salmonella_Spain_2021.docx	SNCPEvolutionofprevalenceandserotypesSalmonella_Spain_2021.doc	176 kb
		ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
			Total size of attachments :	2065 kb

submitted for obtaining EU financial contribution

Annex II: Control programme – Reduction of prevalence of Salmonella serotypes in certain poultry populations

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Salmonella

Animal population Breeding flocks of Turkeys

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Soledad Collado Cortés	Phone	0034 91 347 15 94
Email	scollado@mapa.es	Your job type within the CA :	Head of Service of Zoonoses

Submission Date

30/11/2022 15:18:57

Submission Number

1669817940271-18931

A. Technical information

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 1190/2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and Typhimurium in flocks of turkeys,

- 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.

As a consequence, the following measures will be implemented during the whole period of the programme:

1. Aim of the programme

It is to implement all relevant measures in order to reduce the maximum annual percentage of flocks of breeding turkeys remaining positive to *Salmonella* Enteritidis (SE) and *Salmonella* Typhimurium (ST)(including the serotypes with the antigenic formula I,4,[5],12:i:-)('Union target') to 1% or less.
However, 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

The National Programme takes account of the specifications set out in Commission Regulation (EC) No 1190/2012 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council 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 fattening turkey flocks that continue to test positive for Salmonella Enteritidis and Salmonella Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less and the reduction of the maximum percentage of adult breeding turkey flocks that continue to test positive for Salmonella Enteritidis and Salmonella Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

However, 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.

DEFINITION OF 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 at any time, 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 serotypes (S. Enteritidis or S. Typhimurium, including the strains with the antigenic formula 1,4,[5],12:i:-) is detected in any of the samples taken from fattening 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 in an 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. 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 biosafety measures for all the flocks in the holding will be carried out in accordance with the guideline protocol for verifying biosafety measures on turkey holdings, and it will 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 will 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 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.

5. 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 shall 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 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 14 of this programme shall be performed.

6. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and if necessary insect removal processes. Restocking may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosafety 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.

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 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, when 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 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 in an 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 biosafety measures for all flocks on the holding in accordance with the procedure for checking biosafety measures on turkey holdings.

2. Geographical coverage of the programme

The programme will be implemented on the **whole territory** of the Member State**.**

☒*yes* ☐*no*

if no, please explain

3. Flocks subject to the programme

	Total number of flocks of breeding turkeys in the MS	Number of flocks with at least 250 adult breeding turkeys	Number of flocks where FBO sampling shall take plase	Number of flocks where official sampling will take place
Rearing flocks	80		80	2
Adult flocks	105	105	105	105
NB : All cells shall be filled in with the best estimation available.				

Comments (max. 32000 chars) :

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.

4. Notification of the 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 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 this programme.
The competent authority of the livestock service and Public Health shall, between them, ensure that there is sufficient information about the positive results.

5. Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.

☒*yes* ☐*no*

if no, please explain; if yes, describe the biosecurity measures that shall be applied, quote the document describing them (if any) and attach a copy (max. 32000 chars) :

Biosecurity measures shall be verified at least once a year, observing the protocol included in this programme for checking biosecurity measures, on all of the turkey holdings from which samples are collected as part of the official controls.

The data gathered in such exercises must be recorded using the computer application in the 'Biosecurity' section, whether or not official samples were collected.

If, in the course of an inspection, significant shortcomings in the biosecurity measures are detected, this shall be made known to the holder by means of an official notice, drawn up in at least triplicate and addressed to the holder or 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 ensure compliance with 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. Other measures or sanctions may also be applied to the flock, or to the whole holding: depending on the seriousness of the shortcoming detected, they may range from placing the holding under quarantine to withdrawing the health authorisation for its operation.

The guideline protocol to be observed when checking and evaluating biosecurity measures on turkey holdings is attached.

6. Minimum sampling requirements for food business operators (FBO):

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 egges intended for trade within the union). The last sampling session takes place withing three weeks before slaughter.

☒*yes* ☐*no*

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 aso 1)if additional FBO sampling going beyond EU minimum requirements is performed (to be described) 2) who is taking the official samples

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. 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.

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.

7. 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:
1º. 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

2º. Liver, caecum and yolk sac of 60 chicks (parts of the viscera may be removed and processed as a

single sample), or

3º. 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):

1º. 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 together 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

2º. 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.

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, 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"

8. Specific requirements laid down in Annex II.C of Regulation (EC) No 2160/2003 will be complied with where relevant (due to the presence of SE or ST (including monophasic ST 1,4,[5],12:i:-), all birds of infected reading or adult flocks are slaughtered or killed and destroyed, and all eggs are destroyed or heat treated):

☒ *yes* ☐ *no*

If no, please explain. If yes, indicate if birds are slaughtered or killed and destroyed and if eggs are destroyed or heat treated (max. 32000 chars) :

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. In the event of a positive result of SE or ST (including STM), all birds in the flock, including day-old chicks, must be slaughtered or destroyed in order to minimise the risk of spreading Salmonella. Slaughtering must be carried out in accordance with Community legislation on food hygiene. 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 of 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.

9. If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO (i.e. the farmer) 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 (max. 32000 chars) :

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 slaugtherhouse 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 off 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.
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, attached is 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 (max. 32000 chars) :

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: http://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/PROPOLLO.pdf
By way of example we enclose a diagram setting out the procedure for handling birds sent to a slaughterhouse.

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.

10. 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. 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.

11. 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 6579-2002/Amd1:2007. `*Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. -- Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage*'.

    Serotyping is performed following the Kaufman-White-Le Minor scheme.

☒*yes* ☐*no*

If no please explain.

Salmonella spp. shall be isolated in accordance with --Amendment 1 of -- 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 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.

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.

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).

12. 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.

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 within 48 hours of receipt and within 96 hours of sampling.

13. Please describe the **official controls at feed level** (including sampling).

Comments

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 Regions.
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.

14. 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**.**

(max. 32000 chars) :

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 328/2003 and Royal Decree 1084/2005, 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 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:

■ 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 Samonella 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. If yes, indicate 1)if additional official sampling going beyond EU minimum requirements is performed, give a description of what is done 2)who is taking the official samples (max. 32000 chars) :

Official samples must be taken by the qualified or authorised veterinarian or in some cases by sufficiently trained authorised personnel under veterinary supervision, and 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

Comments - Describe also if any other measures are implemented*(max. 32000 chars) :*

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:

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 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.

Similar to breeders programme of Gallus gallus, there is a national protocol with the minimum criteria for authorizing a confirmatory sampling requested by the FBO, that includes terms of type of production, epidemiological health situation and health history of the farm (for Salmonella spp and for target serovars). Furthermore, minimum guarantees of biosecurity measures are considered. Additionnal information can be found in the protocol that is attached to the programme.

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, sampletaking) 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.

(max. 32000 chars) :

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.
The examination shall consist of a test, using accredited techniques to dectect 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.

15. Salmonella vaccination

- [x] Voluntary
- [ ] Compulsory
- [ ] Forbidden

Use of *Salmonella* vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.

Comments - If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc) (max. 32000 chars) :

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.

16. 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 (max. 32000 chars)

The competent authority shall order the compulsory slaughter of breeding turkeys that tested positive for the Salmonella serotypes covered by the programme.

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.

17. Please describe the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (numbers of samples, number of tests, samples taken, etc...)

(max. 32000 chars) :

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 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.
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.

B. General information

1. Structure and organisation of the **Competent Authorities** (from the central CA to the local CAs)

Short description and/or reference to a document presenting this description (max. 32000 chars) :

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. 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. **Legal basis** for the implementation of the programme

(max. 32000 chars) :

The measures included in this programme relating to the detection of Salmonella comply with the requirements established in parts D and E of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council, and are developed in accordance with Commission Regulation (EU) No 1190/2012, including requirements for detection tests (type of samples, sampling frequency, preparation of the samples, laboratories, analysis methods and notification of results).

3. 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).

(max. 32000 chars) :

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.

4. System for the registration of holdings and identification of flocks

(max. 32000 chars) :

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)

5. System to monitor the implementation of the programme.

(max. 32000 chars) :

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.

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 to be inserted).

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 of the laboratories in its territory.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year : 2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Breeding flocks of Turkeys	230
Serotyping	Breeding flocks of Turkeys	15
Antimicrobial detection test	Breeding flocks of Turkeys	5
Test for verification of the efficacy of disinfection	Breeding flocks of Turkeys	15

1.2 Targets on official sampling of flocks for year : 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)	80	105
No of flocks in the programme	80	105
No of flocks planned to be checked (b)	2	105
No of flock visits to take official samples (c)	2	115
No of official samples taken	14	230
Target serovars (d)	SE + ST	SE + ST
Possible No of flocks infected by target serovars	1	1
Possible No of flocks to be depopulated	1	1
Total No of birds to be slaughtered/culled	10 000	1 500
Total No of eggs to be destroyed	Text	500
Total No of eggs to be heat treated	Text	10 000

Breeding flocks of Turkeys

(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 serveral 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

2 Targets on vaccination

2.1 Targets on vaccination for year : **2023**

Type of the 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	200 000
Number of doses expected to be administered	600 000

D.1. Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2023

1. Testing of official samples

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Breeding Turkeys: Bacteriological detection test	230	27.24	6265.2	yes	75	4 698,9	X
Testing	Breeding Turkeys: Serotyping	15	55.68	835.2	yes	75	626,4	X
Testing	Breeding Turkeys: Antimicrobial detection test	5	26.88	134.4	yes	75	100,8	X
Testing	Breeding Turkeys: Test for verification of the efficacy of disinfection	15	44.86	672.9	yes	75	504,68	X

2. Vaccination (if you ask cofinancing for purchase of vaccins, you should also fill in A.15 and E.1.d)

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Vaccination	Breeding Turkeys: Purchase of vaccine doses	600 000	0.03	18000	yes	75	13 500	X

3. Slaughter and destruction (without any salaries)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Breeding Turkeys: Heat treated hatching eggs	10 000		0	no	75	0	X
Compensation	Breeding Turkeys: Hatching eggs destroyed	500		0	no	75	0	X
Compensation	Breeding Turkeys: Animals culled or slaughtered	11 500	24	276,000	yes	75	207 000	X

4.Cleaning and disinfection

Breeding flocks of Turkeys

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	In case of full flock depopulation			0	no	75	0	X

5.Other essential costs

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				Add a new row				

6. Cost of official sampling

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Sampling	Breeding Turkeys: Official sampling visit	115	13.91	1599.65	yes	75	1 199,74	X

Total with Union funding request (€):	303,507.35	including	227,630.52
Total without Union funding request (€):	0		= requested EU contribution in €

E. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

The official samples are taken by official veterinarians. The cost of sampling is covered by the administrative authorities, in this case the Autonomous Communities.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

The official samples are analysed in the official laboratories of the Autonomous Communities. The cost of the analyses is covered by the Autonomous Community. The national reference laboratory (NRL, Algete) also carries out serotyping analysis of official samples. To a lesser extent, it also performs isolation and identification analyses. These analyses are paid for by the NRL.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

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.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

The vaccination of breeding turkeys is voluntary. The private veterinarians working for a Livestock Health Association provide and perform the vaccination for the birds of the holding of the farmer that contract the services of that association.
The administrative authorities may finance the vaccination based on regional grants for the Livestock Health Associations. Regional veterinary services will reimburse these associations after checking the corresponding documents (invoices of purchase, nº of animals vaccinated, nº of doses used, date of vaccination, etc).

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/service? Who pays?

Installations are always cleaned and disinfected after the sheds have been emptied. Before repopulating the sheds, cleaning and disinfection must be checked, taking environmental samples. These activities are the responsibility of the food business operators, who pay for them. On some occasions, the competent authority of the ACs also takes samples to check the effectiveness of cleaning and disinfection, in which case the administrative authorities cover the cost.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public funds.

☒*yes*

☐*no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo toma muestras ATC 052019.pdf	AnexotomamuestrasATC052019.pdf	256 kb
		SNCP Evolution of prevalence and serotypes Salmonella_Spain_2021.docx	SNCPEvolutionofprevalenceandserotypesSalmonella_Spain_2021.doc	176 kb
		Anexo protección animal en sacrificio.docx	Anexoproteccinanimalensacrificio.doc	38 kb
		Anexo toma muestras CO 052019.pdf	AnexotomamuestrasCO052019.pdf	261 kb
		Biosecurity breeding turkeys.pdf	Biosecuritybreedingturkeys.pdf	33 kb
		DIAGRAMA COMITE RASVE.doc	DIAGRAMACOMITERASVE.doc	224 kb
		Diagrama gestión aves matadero.docx	Diagramagestinavesmatadero.doc	271 kb
		Modelo encuesta epidemiológica positivos Salmonella 2021.pdf	ModeloencuestaepidemiolgicapositivosSalmonella2021.pdf	132 kb
		PLAN CONTROL OFICIAL DE ATC.doc	PLANCONTROLOFICIALDEATC.doc	317 kb

		PLAN INSPECCIONES LAB ATC.docx	PLANINSPECCIONESLABATC.doc	66 kb
		Protocolo test confirmatorios.SNCP 2021.docx	ProtocolotestconfirmatoriosSNCP2021.doc	50 kb
		ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
			Total size of attachments :	2113 kb

submitted for obtaining EU financial contribution

Annex II: Control programme – Reduction of prevalence of Salmonella serotypes in certain poultry populations

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

Privacy Statement

Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Salmonella

Animal population Fattening flocks of Turkeys

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Soledad Collado Cortés	Phone	0034 91 347 15 94
Email	scollado@mapa.es	Your job type within the CA :	Head of Service of Zoonoses

Submission Date

30/11/2022 15:25:43

Submission Number

1669818345703-18933

A. Technical information

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 1190/2012 concerning a Union target for the reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of turkeys,
- 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.

As a consequence, the following measures will be implemented during the whole period of the programme:

1. The **aim of the programme** is to implement all relevant measures in order to reduce the maximum annual percentage of flocks of *turkeys* 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. However, for the 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.

The National Programme takes account of the specifications set out in Commission Regulation (EC) No 1190/2012 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council 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 fattening turkey flocks that continue to test positive for Salmonella Enteritidis and Salmonella Typhimurium, including monophasic strains of Salmonella typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less and the reduction of the maximum percentage of adult breeding turkey flocks that continue to test positive for Salmonella Enteritidis and Salmonella Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

However, 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.

DEFINITION OF 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 at any time, 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 serotypes (S. Enteritidis or S. Typhimurium, including the strains with the antigenic formula 1,4,[5],12:i:-) is detected in any of the samples taken from fattening 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 in an 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. 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 biosafety measures for all the flocks in the holding will be carried out in accordance with the guideline protocol for verifying biosafety measures on turkey holdings, and it will 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 will 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 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.

5. 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 shall 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 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 14 of this programme shall be performed.

6. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and if necessary insect removal processes. Restocking may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosafety 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.

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 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, when 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 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 in an 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 biosafety measures for all flocks on the holding in accordance with the procedure for checking biosafety measures on turkey holdings.

2. Geographical coverage of the programme

The programme will be implemented on the **whole territory** of the MS**.**

☒*yes* ☐*no*

If no please explain.

3. Flocks subject to the programme

The programme covers all flocks of fattening turkeys**.** It does not apply to flocks for private domestic use**.**

☒*yes* ☐*no*

If no please explain.

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.

	Number of holdings
Total number of holdings with fattening turkeys in the MS	690
Total number of houses in these holdings	4 250
Number of holdings with more than 500 fattening turkeys	685

NB : All cells shall be filled in with the best estimation available.

4. Notification of the 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 FBO and the laboratory performing the analyses.

☒ *yes* ☐ *no*

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 48 hours after the laboratory and the owner of the holding receive the results of the analysis.

5. Biosecurity measures

FBOs have to implement measures to prevent the contamination of their flocks.

☒ *yes* ☐ *no*

If no, please explain also the biosecurity measures that shall be applied, quote the document describing them (if any) and attach a copy (or indicate the URL address)

Biosecurity measures will be verified at least once a year, observing the protocol included in this programme for checking biosafety measures, on all of the turkey holdings from which samples are collected as part of the official checks.

The data gathered in such exercises must be recorded using the computer application in the 'Biosafety' section, whether or not official samples were collected.

If, in the course of an inspection, significant shortcomings in the biosecurity measures are detected, this shall be made known to the holder by means of an official notice, drawn up in at least triplicate and addressed to the holder or 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. Other measures or sanctions may also be applied to the flock, or to the whole holding: depending on the seriousness of the shortcoming detected, they may range from placing the holding under quarantine to withdrawing the health authorisation for its operation.

The guideline protocol to be observed when checking and evaluating biosecurity measures on turkey holdings is attached.

6. Minimum sampling requirements for food business operators (FBO):

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 han 100 days or fall under organic turkey production according to Commisson 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.

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 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 Commison Regulation (EC) No 889/2008.

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.

7. 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.

Preparation of samples in the laboratory (official control and own checks).
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'

8. 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 is amended as a part of the Action Plan aproved 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 slaugtherhouse 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 off 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, attached is 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.

9. **Laboratories** in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 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. 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.

10. 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 200/2012 i.e. Amendment 1 of EN/ISO 6579-2002/Amdl:2007. *'Microbiology offood and animal feeding stuffs - Horizontal method for the detection of Salmonella spp. — Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage'.*
Serotyping is performed following the Kauffman-White-Le Minor scheme.
For samples taken on behalf of the FBO alternative methods may be used if validated in accordance with the most recent version of EN/IS016140.

☒*yes* ☐*no*

If no please explain.

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 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.

11. 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.

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 within 48 hours of receipt and within 96 hours of sampling.

12. Please describe the **official controls at feed level** (including sampling).

Comments (max. 32000 chars) :

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 Regions.
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.

13. 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.

(max. 32000 chars) :

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

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;

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, give a description of what is done 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, and 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. 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.

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.

(max. 32000 chars) :

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.
The examination shall consist of a test, using accredited techniques to dectect 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.

14. Please describe the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house. (no of samples, of tests, sample taken, etc)

(max. 32000 chars) :

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 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.
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.

B. General information

1. Structure and organisation of the **Competent Authorities** (from the central CA to the local CAs)

Short description and/or reference to a document presenting this description (max. 32000 chars) :

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. 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. **Legal basis** for the implementation of the programme

(max. 32000 chars) :

The measures included in this programme relating to the detection of Salmonella comply with the requirements established in parts D and E of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council, and are developed in accordance with Commission Regulation (EU) No 1190/2012, including requirements for detection tests (type of samples, sampling frequency, preparation of the samples, laboratories, analysis methods and notification of results).

3. 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).

(max. 32000 chars) :

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.

4. System for the registration of holdings and identification of flocks

(max. 32000 chars) :

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)

5. System to monitor the implementation of the programme.

(max. 32000 chars) :

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.

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 to be inserted).

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 of the laboratories in its territory.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year : 2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Fattening flocks of Turkeys	90
Serotyping	Fattening flocks of Turkeys	60
Antimicrobial detection test	Fattening flocks of Turkeys	5
Test for verification of the efficacy of disinfection	Fattening flocks of Turkeys	15

1.2 Targets on official sampling of flocks for year : 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)	0	4 250
No of flocks in the programme	0	4 250
No of flocks planned to be checked (b)	0	85
No of flock visits to take official samples (c)	0	88
No of official samples taken	0	90
Target serovars (d)	SE + ST	SE + ST
Possible No 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 serveral 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

D.1. Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2023

1. Testing of official samples

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Fattening Turkeys: Bacteriological detection test	90	27.24	2451.6	yes	75	1 838,7	X
Testing	Fattening Turkeys: Serotyping	60	55.68	3340.8	yes	75	2 505,6	X
Testing	Fattening Turkeys: Antimicrobial detection test	5	26.88	134.4	yes	75	100,8	X
Testing	Fattening Turkeys: Test for verification of the efficacy of disinfection	15	44.86	672.9	yes	75	504,68	X

2. Vaccination

Cost related to	Specification	Number of vaccine dosis	Average cost per dose in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				0	no		0	X

3. Slaughter and destruction (without any salaries)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	

4.Cleaning and disinfection

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Cleaning and disinfection	In case of full flock depopulation			0	no	75	0	X

Fattening flocks of Turkeys

5.Other essential costs

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				Add a new row				

6. Cost of official sampling

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Sampling	Fattening Turkeys: Official sampling visit	88	13.91	1224.08	yes	75	918,06	X

Total with Union funding request (€):	7823.78	including	5867.84
Total without Union funding request (€):	0		= requested EU contribution in €

E. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who perform the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

The official samples are taken by official veterinarians. The cost of sampling is covered by the administrative authorities, in this case the Autonomous Communities.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

The official samples are analysed in the official laboratories of the Autonomous Communities. The cost of the analyses is covered by the Autonomous Community. The national reference laboratory (NRL, Algete) also carries out serotyping analysis of official samples. To a lesser extent, it also performs isolation and identification analyses. These analyses are paid for by the NRL.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

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.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

The vaccination of broilers and fattening turkeys is not compulsory and is not carried out. The administrative authorities therefore do not finance it.

e) Implementing entities - **other essential measures**: who implement this measure? Who provide the equipment/service? Who pays?

Installations are always cleaned and disinfected after the sheds have been emptied. Before repopulating the sheds, cleaning and disinfection must be checked, taking environmental samples. These activities are the responsibility of the food business operators, who pay for them. On some occasions, the competent authority of the ACs also takes samples to check the effectiveness of cleaning and disinfection, in which case the administrative authorities cover the cost.

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public funds.

☒*yes*

☐*no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo toma muestras ATC 052019.pdf	AnexotomamuestrasATC052019.pdf	256 kb
		Anexo protección animal en sacrificio.docx	Anexoproteccinanimalensacrificio.doc	38 kb
		Anexo toma muestras CO 052019.pdf	AnexotomamuestrasCO052019.pdf	261 kb
		Biosecurity fatt turkeys.pdf	Biosecurityfattturkeys.pdf	33 kb
		DIAGRAMA COMITE RASVE.doc	DIAGRAMACOMITERASVE.doc	224 kb
		Diagrama gestión aves matadero.docx	Diagramagestinavesmatadero.doc	271 kb
		Modelo encuesta epidemiológica positivos Salmonella 2021.pdf	ModeloencuestaepidemiolgicapositivosSalmonella2021.pdf	132 kb
		PLAN CONTROL OFICIAL DE ATC.doc	PLANCONTROLOFICIALDEATC.doc	317 kb
		PLAN INSPECCIONES LAB ATC.docx	PLANINSPECCIONESLABATC.doc	66 kb

		SNCP Evolution of prevalence and serotypes Salmonella_Spain_2021.docx	SNCPEvolutionofprevalenceandserotypesSalmonella_Spain_2021.doc	176 kb
		ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
			Total size of attachments :	2063 kb

submitted for obtaining EU financial contribution

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

If encountering difficulties:

- concerning the information requested, please contact HADEA-VET-PROG@ec.europa.eu.
- on the technical point of view, please contact SANTE-BI@ec.europa.eu, include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

Protection of Your Personal Data:
For consultation about the processing and the protection of your personal data, please click to follow this link

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Instructions to complete the form:

1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.
Using the button "Add attachments" on the last page of the form.
2) Before submitting this form, please use the button "Verify form"(bottom right of each page).
If needed, complete your pdf document as indicated.
3) When you have finished completing this pdf document, save it on your computer.
4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.
Save this completed document on your computer for your record.
5) For simplification purposes you are invited to submit multi-annual programmes.
6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ESPANA

Disease Transmissible Spongiform Encephalopathies

This program is multi annual : no

Request of Community co-financing for year : 2023

1. Contact data

Name	Esther Prieto	Phone	0034913471444
Email	meprieto@mapa.es	Your job type within the CA :	Head of Service of Veterinary Programm

Submission Date

01/12/2022 15:18:45

Submission Number

1669904326662-18991

2. Description of the programme

Please give a short description of the programme (max. 32000 chars) :

n 1994, Spain began to apply measures to prevent, control and eradicate TSEs by monitoring meat meals in feed. Since 1997, in accordance with the criteria of the World Organisation for Animal Health (OIE), and in application of Community regulations, Spain has implemented control and monitoring programmes for transmissible spongiform encephalopathies based on passive monitoring.
As a result of the emergence of the first case of BSE in a bovine animal in Spain in the year 2000, and following publication of Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals, specific action became necessary, particularly programmes of active monitoring, control of substances used in animal feed, inspection of establishments for the processing of by-products and dead animals and controls on specified risk materials.
At EU level, Regulation (EC) 999/2001 as amended represents the cornerstone of the fight against TSEs, as it is a compilation of all mandatory EU measures in various fields (monitoring, eradication, feedingstuffs, Specified Risk Material, etc.) which hitherto came under various Community Decisions. The strict eradication measures taken to deal with outbreaks of scrapie were based on the theoretical possibility that these animals might be suffering from BSE. The situation has now changed, in that discriminatory diagnostic tests are now available that permit BSE to be distinguished from scrapie. In July 2005 the Commission proposed a new control strategy that was outlined in the 'Road Map' document with the aim of presenting the strategy to combat TSEs in the short, medium and long terms. Owing to a general improvement in the epidemiological situation in the EU and new scientific knowledge, in July 2010 the Commission published the 'New Road Map' aimed at looking into relaxing the measures relating to TSEs, provided that food security is ensured. This document sets out the key points that could change over the coming years. The surveillance and eradication components of this programme comply with Regulation (EC) No 999/2001 as amended, and it would accordingly be re-evaluated and redesigned if necessary to meet any new requirements.
This programme has a double objective:
- to ascertain the epidemiological situation in the population of cattle and small ruminants (sheep and goats) in relation to BSE and scrapie, and
- to detect these diseases and, if necessary, implement the appropriate control and eradication measures.

In 2021 and 2022 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.
Monitoring scheme for bovine
A.- ACTIVE SURVEILLANCE.
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.
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 (LCV).
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).

Monitoring in sheep and goats

A. Active surveillance:

Aimed at actively searching for the disease, by means of random and representative sampling of a certain number of animals, classified into different groups called "subpopulations".

The selection of the sample will be made in such a way as to avoid over-representation of any group in terms of origin, age, breed, type of production or any other characteristic. The sample shall be representative of each region and season, avoiding, whenever possible, multiple sampling in the same herd. Whenever possible, efforts should be made to test for TSEs in subsequent years on all officially registered farms with more than 100 head on which TSEs have never been detected.

The subpopulations to be sampled presented below have been adapted to the provisions of Decision 2014/288/EU and to those requested by the European Commission in Annex III, the model through

which the program is sent for approval and subsequent co-financing.

A.1.- Animals intended for human consumption older than 18 months, or whose gums have erupted two permanent incisors.
This includes 10,000 sheep and 10,000 goats. In this subpopulation, animals slaughtered within the framework of a livestock sanitation campaign, as contemplated in Royal Decree 2611/1996, may be included, without this group exceeding 10% of the minimum total established, as established in Annex I of this program.
In addition, a maximum of 50 % of its minimum sample of sheep or goats slaughtered for human consumption established, can be substituted by the analysis of dead sheep or goats older than eighteen months, at a ratio of 1:1.

A.2.- Animals not slaughtered for human consumption, older than 18 months, or whose gums have erupted two permanent incisors.
10,000 sheep and 10,000 goats are included, which in turn are divided into the following groups:
- dead on the farm.
- slaughtered, but not for human consumption or as part of a disease eradication campaign, regulated by Royal Decree 2611/1996.

A.3 Animals from holdings subject to control and eradication measures of Regulation 999/2001 (monitoring in holdings subject to control and eradication measures for TSEs).
In this point, the animals referred to in points 2.2.2 b and 2.2.2.c of Chapter B of Annex VII will be sampled.
This includes animals that are slaughtered for destruction or for human consumption in application of the eradication measures: option 1 (slaughter and destruction/human consumption of all animals) and option 2 (slaughter and destruction/human consumption of all susceptible animals).

A.3.a. - In the case that slaughter and destruction is chosen, sampling will be as follows:
In this case, an established minimum quantity6 (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the following table6.

Number of animals older than 18 months, or with a dentition of more than two permanent incisors, slaughtered for destruction in the herd. Minimum sample size
70 or less All eligible animals
80 68
90 73
100 78
120 86
140 92
160 97
180 101
200 105
250 112
300 117
350 121
400 124
450 127
500 or more 150

A.3.b.- In the case that slaughter and destination for human consumption is chosen, all the premises

established in Order PRE/1642/2013 must be fulfilled. All animals > 18 months destined for human consumption will be sampled.
Animals from holdings under control and eradication measures of Regulation 999/2001 (monitoring in holdings under control and eradication measures for TSEs).
In this point, the animals referred to in points 2.2.1 shall be sampled when the presence of BSE in the farm cannot be ruled out.
In this case, a minimum established quantity6 (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the table above (A.3.a).

A.4 Animals from holdings subjected to monitoring (analysis of sheep, for 2 years, after the application of the measures (animals referred to in Annex VII, chapter B, point 3.1: after applying options 1 and 2 and when BSE is not excluded).
After the application of the different eradication measures in the case of classical scrapie (point 4.7 of this program) the animals must undergo monitoring Animals from holdings under control and eradication measures of Regulation 999/2001 (monitoring in holdings under control and eradication measures for TSEs).
At this point, the animals referred to in points 2.2.1 shall be sampled when the presence of BSE in the farm cannot be ruled out.
In this case, a minimum established quantity (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the table above (A.3.a).

A.5 Animals from flocks subjected to monitoring (analysis of sheep, for 2 years, after the application of the measures (animals referred to in Annex VII, chapter B, point 3.1: after applying options 1 and 2 and when BSE is not excluded).
After the application of the different eradication measures in the case of classical scrapie (point 4.7 of this program) the animals must be subjected to an intensified surveillance (point 3, Chapter B Annex VII) of at least two years consisting of the analysis of:
- all animals > 18 months dead or slaughtered not for consumption;
- all animals > 18 months slaughtered for human consumption that were present on the farm when the case of classical scrapie was confirmed.

A.6.- Animals from infected flocks (option 3 or the exceptions contemplated in option 2), subjected to follow-up (ovine analysis, for 2 years and applying the measures of point 4.1.
Chapter B Annex VII).
The following must be sampled
- all animals > 18 months dead or slaughtered not for consumption;
- all animals > 18 months slaughtered for human consumption.
A.7.- All holdings that carry out intra-community trade must comply with the conditions established in Annex VIII, Chapter A, Section A of Regulation 999/2001.
The sampling will depend on the classification of the farms against classical scrapie (Controlled Risk or Insignificant Risk) and will focus on the analysis of all dead animals > 18 months in the qualified farms.
B. Passive surveillance.
Any animal that presents clinical symptoms compatible with scrapie will be sacrificed. The tissue will be sent to the LNR, as established in the "Manual for taking samples and sending them to the LNR".

3. *Description of the epidemiological situation of the disease*

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

Last year's No of cases	Total No	No of classical cases	No of atypical cases	No of undetermined cases
BSE case	2	0	2	0
Scrapie case (ovine)	190	184	6	0
Scrapie case (caprine)	45	43	2	0
Last case of		**date (classical case)**	**date (atypical case)**	**date (undetermined case)**
BSE		25/07/2014	17/08/2021	
Scrapie (ovine)		11/01/2022	18/01/2022	
Scrapie (caprine)		01/09/2021		

Comments (if any)

The epidemiological 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.

With regard to BSE, between confirmation of the first case of BSE in Spain in 2000 and 31 December 2021, a total of 801 outbreaks (index case) were detected (see the map in Annex I). 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 2002-2020 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). (See Annex I). 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 18.66 years in 2014 (see Annex I). The most recent cases detected in 2011 and 2012 in animals born in 2005

were cases of atypical BSE, which should not be taken into account 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 25 July 2014 (date of sampling) and the last case of atypical BSE was detected on 23 December 2020.
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 2002-2021 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 2003-2021 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 (OIE) 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.

As regards scrapie, there is no clear pattern in the development of the disease. The trend analysis shows a decline, but it is not significant for the whole period (2000-2021), only for the period 2008-2016. The software used to analyse time trends was WINPEPI software (Abramson, J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6).
In 2021, 18 outbreaks were declared (index case) (11 in sheep and 7 in goats), of which 10 outbreaks were classical strains and 8 were atypical (see the graph showing the number of outbreaks and the table characterising the outbreaks in Annex I).
In the period 2006-2021 (data shown in the table under point 3 Description of the epidemiological situation of the disease) 11 ovine outbreaks were detected (index cases), of which 5 were classical strains and 6 were atypical; and 7 caprine outbreaks were detected (index cases), of which 5 were classical strains and 2 were atypical.

4. Measures included in the programme

4.1 Designation of the central authority in charge of supervising and coordinating the departements responsible for implementing the programme

(max. 32000 chars) :

• The central authority responsible for the coordination and follow-up of the departments responsible for carrying out the programme: the Subdirectorate-General 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.
• 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.
• National Reference Laboratories: the following are recognised as National Reference Laboratories:
a) the 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) The 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.
• Authorised or recognised laboratories: the competent bodies 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.
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4.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

(max. 32000 chars) :

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• Authorised or recognised laboratories: the competent bodies 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.

4.3 System in place for the registration of holdings

(max. 32000 chars) :

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

4.4 System in place for the identification of animals

(max. 32000 chars) :

he identification system for bovine animals is regulated at EU level by Regulation 1760/2000 of 17 July 2000 establishing a system of identification and registration of bovine animals and at domestic level by Royal Decree 1980/1998 of 18 September 1998 establishing a system for identifying and registering bovine animals.
The identification system consists of the following elements:
- Ear tags: consisting of two plastic tags that are fixed to each of the ears and bear the same unique identification code that can identify each individual animal and the holding on which it was born.
- Computerised database: in Spain it is called SITRAN and it incorporates the General Register of

Livestock Holdings (REGA), the Individual Animal Identification Register (RIAA) and the Movements Register (REMO).
- Bovine Identification Document (DIB) which accompanies the animal on any movement.
- Holding logbook which may be manual or computerised and must be accessible to the competent authority for at least three years.

Royal Decree 685/2013 of 16 September 2013, repealing the provisions laid down for ovine and caprine species in Royal Decree 947/2005, establishes an identification and registration system for animals of ovine and caprine species pursuant to Regulation (EC) No 21/2004.
The identification system consists of the following elements:
- Means of identification: animals shall generally be identified by means of a yellow plastic tag placed in the animal's right ear and the introduction of a ruminal bolus. As an alternative, the competent authority may nevertheless authorise the replacement of the ruminal bolus:
---in ovine animals, with an electronic eartag;
---in caprine animals, with one of the following alternatives: an electronic eartag, an electronic tag in the pastern of the right hind leg or an injectable tag in the right metatarsal.
Both the eartag and the electronic identifier must bear the same identification code.
- Computerised database: in Spain it is called SITRAN and it incorporates the General Register of Livestock Holdings (REGA), the Individual Animal Identification Register (RIAA) and the Movements Register (REMO).
- Movement or transfer documents that contain data on the holding of origin, the destination holding and the movement.
- A holding register, which may be kept manually or electronically and must be accessible to the competent authority for a minimum of three years following the last entry
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

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars) :

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

4.6 Testing

4.6.1 Rapid tests in bovine animals

Targets for year **2023**

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests, including rapid tests used for confirmation
Healthy slaughtered bovine animals born in Ms listed in Annex to CD2009/719/EC	72	5	5
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	64 000	64 000
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	20	20
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	10	10
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		7	7

4.6.2 Rapid tests on small ruminants

The sampling rules applicable for the monitoring of ovine and caprine animals slaughtered or not for human consumption (described below as healthy slaughtered/dead animals) are in compliance with provisions of Annex III, II, 4 of Regulation (EC) No 999/2001, in particular:

- *Animals are over 18 months of age or have more than two permanent incisors,*
- *No over-representation of any group (origin, age, breed, production type, etc),*
- *Sampling representative of each region and season,*
- *Multiple sampling in the same flock avoided whenever possible,*
- *A system is in place to ensure that in successive sampling years, all officially registered holdings with more than 100 animals where TSE cases have never been detected are subject to TSE testing,*
- *A system is in place to check that animals are not being diverted from sampling (except derogation communicated to the Commission):*

☒ *yes* ☐ *no*

If no please explain.

4.6.2.1 Rapid tests on ovine animals

Estimated population of adult ewes and ewe lambs put to the ram. 12 277 962

Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered ovine animals (a)	10 000
Dead ovine animals (b)	10 000
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Ovine animals from holdings affected by classical scrapie	10 000
Ovine animals from holdins affected by atypical scrapie	0
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	5
Total number of tests	30 005

(a) Annex III, A, II, 2 of the TSE regulation
(b) Annex III, A, II, 3 of the TSE regulation
(c) Art 12 of the TSE regulation

4.6.2.2 Rapid tests on caprine animals

Estimated population of female goats and female kids mated . 2 130 342

Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered caprine animals (a)	10 000
Dead caprine animals (b)	10 000
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Caprine animals from holdings affected by classical scrapie	1 600

Caprine animals from holdins affected by atypical scrapie	
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	5
Total number of tests	**21 605**

(a) Annex III, A, II, 2 of the TSE regulation
(b) Annex III, A, II, 3 of the TSE regulation
(c) Art 12 of the TSE regulation

4.6.3 Confirmatory tests ***other than rapid tests*** as referred to in Annex X Chapter C of Regulation (EC) No 999/2001

Targets for year **2023**

	Estimated number of tests
Confirmatory tests in Bovine animals	4
Confirmatory tests in Ovine an Caprine animals	650

4.6.4 Discriminatory tests (Annex X.C point 3.1 (c) and 3.2 (c)(i) of Regulation (EC) No 999(2001)

Targets for year **2023**

	Estimated number of tests
Primary molecular testing on bovine animals	4
Primary molecular testing on ovine and caprine animals	280
Total	**284**

4.6.5 Genotyping of positive and randomly selected animals

Adult sheep population

☒ *More than 750,000 animals*
☐ *Less than or equal to 750,000 animals*

Targets for year **2023**

	Estimated number
Genotyping of TSE cases	300
Random genotyping	0

4.7 Eradication

4.7.1 Measures following confirmation of a TSE case in bovine animals

4.7.1.1 Description

(max. 32000 chars) :

If a TSE is confirmed, or in the event of a suspected case where the presence of a TSE cannot be ruled out after carrying out the relevant clinical, laboratory and/or ante-post mortem analyses, total or selective culling of the stocks identified below will be carried out:

a) all the other bovines on the holding on which the animal in which the disease has been confirmed is located.

b) when the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease.

c) all animals of the cohort of the animal in which the disease was confirmed.

However, where the culling of all the other bovines on the holding on which the animal in which the disease has been confirmed is concerned, the competent authority may exempt the following animals from slaughter:

- all animals brought onto the holding in question over the 12 months prior to the emergence of the case, provided that they came from another holding, as well as any of their progeny during that period.
- On those holdings which the affected animal entered in the previous twelve months, not all the bovine livestock on the holding will be culled. In this situation, the animals specified in paragraphs (b) and (c) of point 1 (total eradication culling) must be culled and completely destroyed, as well as any animals for which there is incomplete traceability and which cannot therefore be ruled out as belonging to these groups.

The competent authority may exempt from slaughter all the other bovines on the holding on which the animal in which the disease has been confirmed is located and proceed with eradication by selective slaughter.

In this case, provided identification and traceability are guaranteed by means of computer systems or birth records, the at-risk stocks defined by the World Organisation for Animal Health (the animals born on the holding during the twelve months before or after the birth of the affected animal and all descendants born in the last two years) will be slaughtered. Likewise, all those bovines whose identification and perfect traceability cannot be guaranteed by means of computer systems or birth records will be slaughtered.

Animals will be re-introduced onto the holding following authorisation from the competent bodies of the Autonomous Communities.

As an exception to the immediate total or selective slaughter of the cohort of positive animals, the Commission Implementing Decision of 15 March 2013 authorises the use of at-risk bovines in Spain until the end of their productive lives following confirmation of the presence of BSE. That exception may apply subject to prior authorisation from the Ministry of Agriculture, Food and Environment following analysis of whether the requirements set out in the Decision are met.

4.7.1.2 Summary table

Targets for year **2023**

	Estimated number
Bovine animals culled and destroyed	20

4.7.2 Measures following confirmation of a TSE case in ovine and caprine animals

4.7.2.1 Description

(max. 32000 chars) :

When a case of scrapie is confirmed different measures are taken (Annex VII to Regulation (EC) No 999/2001 as subsequently amended) according to the kind of scrapie diagnosed and the species concerned:
1 -Epidemiological survey;
2 –Eradication options
b.1) Classical scrapie:
Option 1: immediate culling and complete destruction (or immediate culling and human consumption).
Option 2: selective culling: immediate or deferred culling and destruction of susceptible animals (or immediate or deferred culling and human consumption of susceptible animals).
Option 3: No slaughter.
b.2) Atypical scrapie : no additional measures
3- Breeding programme for TSE resistance in ovines.

4.7.1 Inquiry to identify all animals at risk: the corresponding epidemiological survey is carried out to identify all the animals that are at risk. The aspects to be covered in such a survey are summarised in Annex III to this Programme and a model for carrying it out is attached.

This survey must identify:

a) all the ruminants other than sheep and goats from the holding on which the disease was confirmed;

b) the parents, when these can be identified and, in the case of females, the embryos, ova and progeny of the last generation;

c) all ovines and caprines from the holding on which the disease has been confirmed;

d) the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or exposed to the same feed or contamination source;

e) the movement of feedingstuffs or other potentially contaminated materials or any other means of transmission of the TSE agent;

4.7.2 Measures for the eradication of all the animals at risk (identified in accordance with point 4.7.1) and their products: as provided for in Regulation (EC) Nos 142/2011 and 1069/2009.

In cases of both typical and atypical scrapie it is mandatory to rule out BSE (primary molecular discriminatory tests carried out by the NRL in all cases that test positive for scrapie).

a) If the laboratory results provided for in Annex X, Chapter C, point 3.2 of Regulation (EC) No 999/2001 do not permit BSE to be ruled out: the animals, embryos and ova identified in the epidemiological survey (4.7.1 from b) to e)) will be immediately slaughtered and completely destroyed.

All the animals > 18 months of age slaughtered for destruction will be tested for TSEs. The milk and milk products derived from the animals to be destroyed and that were present on the holding from the date of confirmation that BSE cannot be ruled out will also be destroyed until all the animals have been destroyed.

After the slaughter and complete destruction, the holding will be subject to intensified surveillance for two years (see point b.1.4)

b) If BSE is ruled out in accordance with Annex X, Chapter C, point 3.2 of Regulation No 999/2001, the legislation allows for different options, depending on various factors such as the type of TSE, the animals' genotype, difficulties in restocking, etc.
b.1) CLASSICAL SCRAPIE:

When BSE and atypical scrapie are ruled out, there are three options for eradication (see diagram in Annex III).

Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding. The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2(a) of Annex VII to Regulation (EC) No 999/2001.

b.1.1) OPTION 1: Culling and complete destruction of all animals (point 2.2.2(b) of Annex VII to Regulation (EC) No 999/2001).

Option applicable to both sheep and goats with classical scrapie.

Culling and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry and referred to in points b) and c) of point 4.7.1 above.

Measures applicable:
a) Animals > 18 months of age that are slaughtered for destruction will be analysed in accordance with paragraph 5, Part II, Chapter A of Annex III to Regulation (EC) No 999/2001 point 4.6.1) (A.3 of this programme).

b) For ovines the prion protein genotype of at least 50 animals has to be determined.

c) Derogation from culling and complete destruction: pursuant to point 2.2.2.b.i of Annex VII to Regulation (EC) No 999/2001 and Order PRE 1642/2013, culling and complete destruction may be replaced by immediate slaughter for human consumption subject to the following conditions:
- the competent authority authorises the animals to leave the holding and the transfer document for the

animals indicates that they come from a holding on which a case of scrapie has been diagnosed.
- the animals are slaughtered in a slaughterhouse located on Spanish territory.
- all animals which are over 18 months of age or in which more than two permanent incisors have erupted through the gum are analysed to detect the presence of TSE.

d) Until the culling and complete destruction or total slaughter for human consumption are complete, the following measures are applicable on the holding:
- Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding.
- The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2 (a) of Annex VII to Regulation (EC) No 999/2001.
- Animals may only be moved for slaughter and destruction or slaughter for human consumption.

e) Once this option has been completed (the outbreak has been declared closed), the holding must be subject to intensified surveillance under the measures provided for at point b.1.4) (point 3 of Chapter 2 of Annex VII to Regulation (EC) No 999/2001).

b.1.2) OPTION 2: Culling and complete destruction of susceptible animals (selective slaughter by genotyping). (point 2.2.2(c) of Annex VIII to Regulation (EC) No 999/2001). Option applicable to both sheep and goats with classical scrapie.

Genetic resistance to classic scrapie has been demonstrated in sheep, and goats, so this option is applicable to both.

On mixed holdings, the slaughter of goats cohabiting with sheep or sheep cohabiting with goats (depending which specie is the index case) may be deferred, as detailed at d) and explained below.

Genotyping and identification of all animals on the holding must be undertaken prior to selective culling.

If it is decided to send animals for destruction or for human consumption it is not necessary to genotype them.

Animals with sensitive genotypes are subsequently culled, thus all animals, embryos and ova identified by the inquiry and referred to in points b) and c) of point 4.7.1 above are culled and destroyed, except:
- male ovines intended for breeding of the ARR/ARR genotype,
- breeding female ovines having at least one ARR allele and not having the VRQ allele and, when these are pregnant at the time of the survey, the lambs, if their genotype meets the above requirements.
- ovines with one ARR allele which are intended for slaughter.

Measures applicable:

a) Animals > 18 months of age that are slaughtered for destruction will be analysed in accordance with paragraph 5, Part II, Chapter A of Annex III to Regulation (EC) No 999/2001 (point 4.6.1, A.3 of this programme).

b) Exceptions to the immediate slaughter and complete destruction of susceptible animals:
- Pursuant to point 2.2.2.c.i of Annex VII to Regulation (EC) No 999/2001 and Order PRE 1642/2013 culling

and complete destruction may be replaced by immediate slaughter for human consumption subject to the following conditions:
- the competent authority authorises the animals to leave the holding and the transfer document for the animals indicates that they come from a holding on which a case of scrapie has been diagnosed.
- the animals are slaughtered in a slaughterhouse located on Spanish territory.
- all animals which are over 18 months of age or in which more than two permanent incisors have erupted through the gum are analysed to detect the presence of TSE.

c) Until the culling and complete destruction or total slaughter for human consumption are complete, the following measures are applicable on the holding:

Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding. The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2(a) of Annex VII to Regulation (EC) No 999/2001.

- The following animals > 18 months of age (except ARR/ARR males) will be tested for TSEs):
 -animals intended for human consumption which were present on the holding at the time when the index case was confirmed,
- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.
- Only ARR/ARR males and females with at least one ARR and no VRQ may be re-introduced onto the holding.
- Only the following may be used for breeding: rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ.
- The movement of animals is permitted only under the following conditions:
slaughter and destruction, goats with at least one ARR may be sent to the slaughterhouse for human consumption, females with at least one ARR and no VRQ may travel to holdings under restrictions (when taking option 1 or option 2);
to the slaughterhouse for human consumption subject to the conditions set out above;
without prejudice to the previous paragraph, lambs and kids may be moved to another holding solely for the purposes of fattening prior to slaughter, provided that the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter. At the end of the fattening period, and at the age of 12 months at the latest, they should go directly to a Spanish slaughterhouse.

d) Pursuant to point 2.2.2.c.ii and iii of Annex VII to Regulation (EC) No 999/2001, the obligatory immediate slaughter and destruction or slaughter for consumption of susceptible animals may be deferred:

d.1) by no more than three months when the date of confirmation of the index case (primary case) coincides or is close to the time of parturition provided that the sheep and goats and their young do not have contact with sheep and goats from other holdings (point 2.2.2.c.ii).

d.2) by no more than three years from the date of confirmation of the index case, in ovine and mixed flocks (ovines-caprines). The objective of this exception is to create a herd with resistant genotypes as it replaces itself, and the ultimate objective is therefore the slaughter of sensitive animals, increasing the frequency of ARR alleles and eliminating VRQ alleles (point 2.2.2.c.iii of Regulation (EC) No 999/2001).

The conditions for applying this exemption are the following:
---The frequency of resistant alleles in the herd is low and external restocking poses difficulties, including for economic reasons;
---immediate slaughter or castration of male animals that are not ARR/ARR;
---culling of females with VRQ;
---culling as soon as possible of females that do not have at least one ARR;
---The Competent Authority must guarantee that the number of animals slaughtered after these three years is not greater than the number of susceptible animals present on the holding when the index case was confirmed.
---If a holding applies this derogation it will be subject to the arrangements set out in point b.1.3 (a) to (h) until a decision is reached on the slaughter and destruction or slaughter for human consumption of susceptible animals.

e) Once this option 2 has been completed, whether by immediate or deferred application (the outbreak has been declared closed), the holding will be subject to intensified surveillance in the form of the measures set out at point b.1.4.

b.1.3) OPTION 3: No mandatory culling and complete destruction (point 2.2.2 (d) of Annex VIII to Regulation (EC) No 99/2001).

The competent authority may decide not to kill or destroy animals identified in an epidemiological survey (point 4.7.1 (b) and (c) above) when it is difficult to replace sheep of a given genotype (male ARR/ARR, female ARR/no VRQ), when the frequency of the ARR allele within the breed or holding is low, when it is deemed necessary in order to avoid inbreeding or based on reasoned consideration of all the epidemiological factors.

The prion protein genotype of at least 50 animals is to be determined within three months of the confirmation of the index case.

If the Member State permits this option to be applied to manage outbreaks of classical scrapie, the competent authority must keep a record, with reasons and criteria, of each case in which this option is invoked. If the Competent Authority decides to apply this option, this decision must be communicated to MAPA.

If further cases of classical scrapie occur on a holding on which this option was taken, the Competent Authority must re-evaluate the choice of this option. If this reassessment shows that Option 3 does not ensure proper control of the disease on that holding, the decision may be taken to apply options 1 or 2.

When it is decided to apply option 3 (no mandatory culling and complete destruction) or exception d.2 under option 2 (deferral of slaughter and destruction or slaughter for human consumption by no more than 3 years), the following intensified surveillance measures shall be applied immediately (pursuant to point 4, chapter B of Annex VII to Regulation (EC) No 999/2001):
- In the case of option 3: the measures described below shall be applied for two years from the date of confirmation of the last case of classical scrapie on the holding.

If an atypical scrapie case is diagnosed during this period of intensified surveillance, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

- In the event of exception d.2 of option 2: these measures shall apply until all the susceptible animals have been destroyed or all the susceptible animals have been slaughtered for human consumption

(within three years of the appearance of the index case).

a) Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding.

The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2 (a) of Annex VII to Regulation (EC) No 999/2001.

b) The following animals > 18 months of age (except ARR/ARR males) will be tested for TSEs:

- animals intended for human consumption

- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.

c) Only ARR/ARR males and females with at least one ARR and no VRQ may be re-introduced onto the holding.

However, in the case of the indigenous breeds at risk of extinction listed in Annex IV to Regulation 1974/2006, and when the frequency of the ARR allele is low on the holdings, the entry of males with at least one ARR and no VRQ and females with no VRQ allele may be authorised.

d) Only the following may be used for breeding: rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ may be used.

However, in the case of the indigenous breeds at risk of extinction listed in Annex IV to Regulation 1974/2006 and when the frequency of the ARR allele is low on the holdings, breeding rams with at least one ARR and no VRQ, semen from males with at least one ARR and no VRQ and embryos with no VRQ allele may be authorised.

e) The movement of animals is permitted only under the following conditions:
- slaughter and destruction;
- ARR/ARR animals may leave the holding for all purposes, including breeding, provided that the holding of destination is subject to the measures applicable in option 2 or option 3 (points B.1.2 and B.1.3) of this programme and points 2.2.2.c and 2.2.2.d of Regulation (EC) No 999/2001
- directly to slaughter in the slaughterhouse for human consumption:
- animals with at least 1 ARR,
- lambs and kids under 3 months of age and
- the animals listed in Section D.2 of option 2 (point b.1.2 of this programme and 2.2.2.c.iii of Regulation (EC) No 999/2001) and option 3 (point b.1.3 of this programme and 2.2.2.d of the Regulation) with the established sampling criteria.

f) Lambs and kids may be moved to another holding solely for the purposes of fattening prior to slaughter, provided that the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter. At the end of the fattening period, and at the age of 12 months at the latest, they should go directly to a Spanish slaughterhouse.

g) The Competent Authority shall ensure that the semen, embryos and ova do not leave the holding.

h) All ovine and caprine animals from the holding shall be denied access to common pasture during the period of parturition and rearing of young.

Access to common pasture outside the period of parturition and rearing of young shall be subject to the conditions set by the competent authority.

b.1.4) Intensified surveillance

This generally applies when any of the eradication options set out above apply, i.e. once:

- all the animals on the holding have been slaughtered and destroyed (point a: BSE cannot be ruled out in goats or sheep).
- all the animals have been culled and destroyed (option1) or all the animals previously testing negative for TSEs have been slaughtered for human consumption (exception of option 1).
- all the animals have been immediately culled and destroyed (option 2) or all the animals previously testing negative for TSEs have been slaughtered immediately for human consumption (exception of option 2).

If it is decided to implement these selective eradication measures deferred by a maximum of three years, this point will first be applied once this period is over and the eradication measures have been taken.

The measures described below will be applied until the ARR/ARR genotype is obtained in all ovine animals on the holding or for 2 years since the eradication measures of option 1 or option 2 were applied completely and providing no other case of classic scrapie has been diagnosed on the holding.

If an atypical scrapie case is diagnosed during this period of intensified surveillance, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

Intensified surveillance measures (in accordance with point 3, Chapter B, Annex VII of Regulation (EC) No 999/2001):

a) The holding must be subject to a protocol of intensified surveillance including the testing of all animals > 18 months (except ARR/ARR sheep):

- animals intended for human consumption which were present in the holding at the time when the index case was confirmed;

- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.

b) Entry of animals to the holding: only males with the ARR/ARR genotype, females with ARR and no VRQ and caprine animals may be reintroduced onto the holding after cleansing and disinfection of the accommodation.

c) For breeding: only rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ may be used.

d) The movement of animals from the holding will be subject to the following conditions: -- for destruction;

-- the following may be moved for any purpose, including breeding:

- ARR/ARR ovines,

- females with at least one ARR and no VRQ may be moved to other holdings subject to restrictions (holdings that are applying options 2 or 3)

- caprines may be moved to other holdings with restrictions (holdings on which options 2 or 3 are being applied).

-- the following may be moved directly for slaughter for human consumption:

- ovines with at least one ARR allele;

- caprines;

- lambs and kids under 3 months of age; -

all animals subject to the exceptions provided for at points b.1.1, (c) and b.1.2(b) of this programme

b.2) ATYPICAL SCRAPIE

When atypical scrapie is diagnosed in sheep or goats on a holding, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

When applying any of the eradication measures set out in this point 4.7.2, compliance with the requirements on the protection of animals, in accordance with Regulation (EC) No 1099/2009 of 24 September 2009 and Royal Decree 37/2014 of 24 January 2014 on the protection of animals at the time of slaughter, is mandatory.

With effect from 1 January 2013 Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of slaughter applies.

This Regulation provides that, in the event of depopulation, the competent authorities should act to safeguard the welfare of the animals involved and inform the European Commission and the public ex post of the measures taken.

By depopulation the above-mentioned legislation means not only action in the event of outbreaks of animal diseases, but also action when animals have to be killed for reasons such as public health, animal welfare or environmental reasons, always under the supervision of the competent authority.

When depopulation is to be undertaken for reasons of animal health and in accordance with this Manual, the document entitled 'Protection of animals at slaughter for depopulation for health reasons in accordance with Regulation (EC) No 1099/2009 of 24 September 2009' should be used in a complementary manner and at the same time. This can be found at:

https://www.mapa.gob.es/es/ganaderia/temas/produccion-y-mercadosganaderos/bienestanimal/en-la-granja/default.aspx1

The competent authorities of the Autonomous Communities will supplement the document on the

protection of animals with such information as is necessary. The document 'Protection of animals during slaughter for depopulation for health reasons in line with Regulation (EC) No 1099/2009 of 24 September 2009' forms part of this Manual, along with the standardised working procedures in the annexes thereto. Furthermore, it will be updated when there are changes in the rules that apply, when required by acquired experience or when it is necessary to update the information included therein (such as the procedures referring to the enterprises involved in the supply of material or the competent authority's relationship with the same).

4.7.2.2 Summary table

Targets for year **2023**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	30
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	4 000
Genotyping tests - monitoring and eradication measures	22 000

4.7.3 Breeding programme for resistance to TSEs in sheep

4.7.3.1 General description

Description of the programme according to the minimum requirements set out in Annex VII, Chapter B of Regulation (EC) No 999/2001

(max. 32000 chars) :

n the wake of the latest scientific opinions concerning the disease, various amendments to Regulation (EC) No 999/2001 of 22 May 2001 have been published. Accordingly, the decision to continue with ovine breeding programmes to select for resistance to TSEs is left to the Member States. Those programmes shall include a framework to recognise the TSE-resistant status of certain flocks.

In Spain, the Ministry of Agriculture, Fisheries and Food (MAPA), in cooperation with the Autonomous Communities and the breeders' associations, has decided to continue running the 'National Programme for Genetic Selection for Resistance to Transmissible Spongiform Encephalopathies (TSEs) in Sheep' (see description in Annex IV), while certain amendments have been made in light of the above-mentioned scientific opinions, the most relevant being the voluntary participation by the breeders' associations in the Genetic Selection Programme. Those amendments are reflected in Royal Decree 21/2013 of 18 January 2013, the current basis for the programme. Nevertheless, the main lines of action of this programme are still the following:

-- individual identification and study of genotypes for the PNRP gene,

-- information system for identifying and genotyping sheep (ARIES),

-- dissemination of improvements and level of resistance,

-- Algete Molecular Genetics Reference Laboratory,

-- selection programmes for resistance to TSEs.

In general, since 2003, a continuing trend has been observed of a rise in ARR at the expense of a decline in ARQ, which has resulted in ARR/ARR replacing ARR/ARQ as the most common genotype, which previously had replaced ARQ/ARQ. The intensity of selection seems to be accelerating somewhat, although the period considered does not meet the criteria previously used for mean generation interval, and significantly fewer samples were tested than in the two periods studied previously, so this trend needs to be confirmed later.

4.7.3.2 Summary table

Targets for year **2023**

	Estimated number
Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	80 000
Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	20 000
Total	100 000

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars) :

The economic forecast for the 2023 Programme was prepared in accordance with European Commission documents: Grant Agreement VP/2021-2022/ES/SI2.869406 . The possible updating of unit and eligible costs, the expected number of tests and slaughtered animals for 20203may be updated according to the changes made to this WG and in line with the disease's epidemiological situation in Spain.

BSE COSTS:

• Cost of diagnosis for the surveillance and control programme: cost of conducting rapid, confirmatory and discriminatory tests for detecting BSE per animal investigated.

• Costs of compensating livestock farmers for the compulsory culling of animals which test positive and animals subjected to preventive culling on the farm, or animals which the competent authority, in view of the epidemiological survey results, considers should be culled.

5.1.1.- Costs of implementing the follow-up programme.

The estimated number of rapid tests for the rapid detection of BSE for 2023 is calculated according to the Autonomous Communities' forecasts and the certified costs from 2021. The confirmatory tests carried out by the NRL are also included when confirmation is carried out using rapid tests.

☐ It is planned that the NRL will carry out confirmatory tests(€ 77.99), different from rapid tests.

☐ The spontaneous appearance of atypical strains means it is necessary to plan for the following: discriminatory tests for BSE carried out by the NRL, representing expenditure eligible for co-financing of unit cost €145.87/test; The estimated real expenditure eligible for co-financing for monitoring under the Monitoring Programme for BSE includes: rapid tests + confirmatory tests + discriminatory tests for BSE

5.1.2 - Costs of compensating livestock farmers for the compulsory culling of animals.

Several factors have to be taken into account to forecast the number of animals that are eligible in 2023:

- the certified costs from the Autonomous Communities for 2021;

- the epidemiological evolution of the disease along with the number of animals that have to be slaughtered as provided for in point 2(a) of Annex VII to Regulation (EC) No 999/2001;

- the trend towards the eradication of classical BSE at the same time as new atypical forms are discovered;

- the possibility open to Spain of deferring the slaughter of the cohorts of a positive animal until the end of their productive lives.

For 2023, it is estimated that between 0 and 20 animals will be slaughtered each year, given that no outbreaks of classical BSE are expected to be diagnosed. However, as a result of the appearance of atypical strains together with the application of Decision 2013/137/EU, it is estimated that 20 animals will be slaughtered and destroyed in 2023. The average compensation per slaughtered animal is estimated at €408,97, calculated by the average rate of compensation of 2017 (last available rate certified by the Autonmomous Communities) on the basis of the Royal Decree establishing the scales for compensation for animals under the national programmes for combating, controlling or eradicating bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis, bluetongue and transmissible spongiform encephalopathies.

BSE TOTAL COSTS:
The total cost calculated for the expenditure that is eligible for co-financing for the two lines of action :surveillance and eradication.

SCRAPIE COSTS:
Estimations have been calculated taking into account that there are several big holdings under TSE eradication measures and under intensified monitoring protocol.

The cost of the programme derives from three lines of action:

• Cost of diagnosis for the surveillance and control programme: cost of conducting rapid, confirmatory and discriminatory tests for detecting TSE in animals investigated and the cost of confirmatory and discrimination tests on scrapie positives.

• Cost of analysing the genotype of the PNRP gene: cost of conducting tests for analysing the genotype of the PNRP gene per animal investigated.

• Costs of compensating livestock farmers for the compulsory culling of animals which test positive and animals subjected to preventive culling on the farm, or animals which the competent authority, in view of the epidemiological survey results, considers should be culled.

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

1.- Diagnostic costs.

Estimations for rapid tests, confirmatory tests and discriminatory tests for the detection of TSE in small ruminants:

The estimated expenditure eligible for co-financing for surveillance, have been taking into account unit costs and eligible costs according to Grant Agreement VP/2021-2022/ES/SI2.869406.

The estimated real expenditure eligible for co-financing for monitoring under the Monitoring Programme for Scrapie contain rapid tests + confirmatory tests + discriminatory tests

2. Costs of analysing genotypes.
The estimated expenditure eligible for co-financing in line with Grant Agreement VP/2021-2022/ES/SI2.869406.

According to Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals, Spain remains exempt from the obligation to genotype a minimum sample (random genotyping), since the Spanish Breeding Programme does not meet the criteria laid down in Point 8, Part 1, Chapter C of Annex VII, which lays down the minimum requirements of a breeding programme for sheep resistant to TSEs.

The estimated real cost of genotyping includes positive animals, eradication measures and breeding programme).

3.- Costs of compensating livestock farmers for culling.

As mentioned above, based on the number of animals slaughtered as an eradication measure in 2021 and the average size of flock per outbreak, the number of animals to be slaughtered pursuant to point 2(b) in Annex VII to Regulation (EC) No 999/2001, i.e. in applying measures to eradicate scrapie, is estimated to be for 2023: 4000 categorised as slaughtered and intended for consumption and 40 as slaughtered and destroyed.

5.2 Detailed analysis of the cost of the programme

Costs of the planned activities for year : **2023**

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

1. Rapid tests in bovine animals (as referred to in point 4.6.1)

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Healthy slaughtered animals	5	12.77	63.85	yes	45	28,73	X
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Risk animals	64 000	12.77	817,280	yes	45	367 776	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Healthy slaughtered animals	20	12.77	255.4	yes	45	114,93	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Risk animals	10	12.77	127.7	yes	45	57,47	X
Testing	Rapid tests on suspect bovine animals	7	12.77	89.39	yes	45	40,23	X

2. Rapid tests in ovine and caprine animals (as referred to in point 4.6.2 and 4.6.3)

Cost related to	Specification	Total number of tests	Cost per test	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid Tests - ovine	30 005	12.77	383,163.85	yes	45	172 423,73	X
Testing	Rapid Tests - caprine	21 605	12.77	275,895.85	yes	45	124 153,13	X

3. Confirmatory testing (as referred to in point 4.6.4)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Confirmatory Tests in Bovines	4	77.99	311.96	yes	45	140,38	X
Testing	Confirmatory Tests in Ovines and Caprines	650	77.99	50693.5	yes	45	22 812,08	X

4. Discriminatory testing (as referred to in point 4.6.5)

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Primary molecular tests	284	145.87	41427.08	yes	45	18 642,19	X

5. Genotyping

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Genotyping test (standard) - monitoring and eradication measures	22 000	29.33	645,260	yes	45	290 367	X
Testing	Genotyping test (standard) - breeding programme	100 000	29.33	2,933,000	yes	45	1 319 850	X
Testing	Genotyping test - TSE cases	300	110.07	33021	yes	45	14 859,45	X
Testing	Genotyping test (standard) - random sample	0	29.33	0	yes	45	0	X

6. Compulsory culling/slaughter

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Bovine animals culled and destroyed	20	1000	20000	yes	45	9 000	X
Compensation	Ovine and caprine animals culled and destroyed	30	140	4200	yes	45	1 890	X
Compensation	Ovine and caprine animals - compulsory slaughter	4 000	100	400,000	yes	45	180 000	X

7. Chronic Wasting Disease

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				0	no		0	X

Total with Union funding request (€):	5,604,789.58	including	2,522,155.32
Total without Union funding request (€):	0		= requested EU contribution in €

5.3. Financial information

1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.
Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who performs the official sampling? Who pays?
(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

(max. 32000 chars) :

TSE sampling is carried out by official or authorised veterinarians. The cost is borne by the Autonomous Community, which subsequently receives financial support from the State (MAPA).

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

(max. 32000 chars) :

Samples are analysed (rapid tests) by the authorised regional laboratories in the different Autonomous Communities. Confirmation of suspect samples and strain discrimination is carried out in the National Reference Laboratory (Algete Central Veterinary Laboratory). The laboratory personnel is made up of official or authorised veterinarians and the costs are borne by the Autonomous Community or MAPA.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?
(e.g. compensation is paid by the central level of the state veterinary services,
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

(max. 32000 chars) :

The slaughter of animals for the purpose of eradication is carried out in authorised slaughterhouses by slaughterhouse staff under the supervision of official veterinarians. The Autonomous Community pays the compensation for compulsory culling of animals to the farmers and subsequently receives financial support from the State (MAPA).

d) Implementing entities - **vaccination (if applicable)** : who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

(max. 32000 chars) :

NA

e) Implementing entities - **other essential measures**: who implements this measure? Who provides the equipment/ service? Who pays?

(max. 32000 chars) :

NA

2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

☒ *yes*

☐ *no*

3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:

Attachments

IMPORTANT :

1) The more files you attach, the longer it takes to upload them .
2) This attachment files should have one of the format listed here : jpg, jpeg, tiff, tif, xls, xlsx, doc, docx, ppt, pptx, bmp, pna, pdf.
3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
*4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!*
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

		Attachment name	File will be saved as (only a-z and 0-9 and -_) :	File size
		Anexo I TSE FINAL REPORT 2021.pdf	AnexoITSEFINALREPORT2021.pdf	1210 kb
			Total size of attachments :	1210 kb

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 AI programme	WP2 Salmonella programme	WP3 TSE programme	
Forms of funding	Lump sum contribution	Lump sum contribution	Lump sum contribution	
	a	b	c	d = a + b + c
1 - MAPA	46 228.22	2 992 470.03	1 008 862.13	4 047 560.38

[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).

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).

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

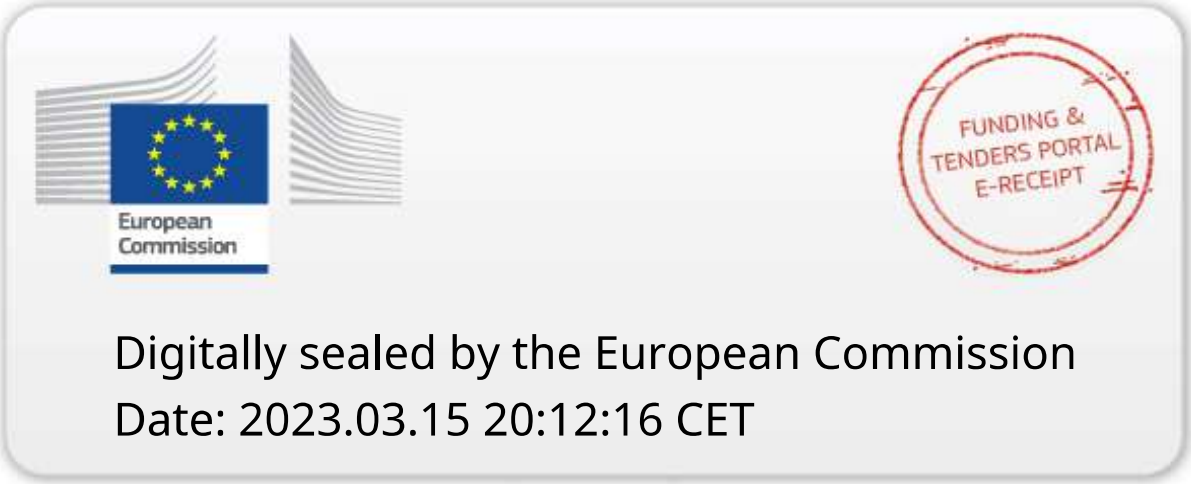
- the payment deadline for the first prefinancing is automatically suspended until the granting authority is informed about the approval for financing

- 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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