

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HADEA)

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

GRANT AGREEMENT

Project 101194988 — ES_VP 2025-2027

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)

Associate SWITh LUCUM SHIPREM. AFAS (2015) 1326722: -415/02/2025

Annex 1 Description of the action¹

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 <u>Portal Reference Documents</u>.

² Template published on Portal Reference Documents.

³ Template published on <u>Portal Reference Documents</u>.

TERMS AND CONDITIONS

TABLE OF CONTENTS

GRANT AGREEMENT	1
PREAMBLE	1
TERMS AND CONDITIONS	3
DATASHEET	8
CHAPTER 1 GENERAL	12
ARTICLE 1 — SUBJECT OF THE AGREEMENT	12
ARTICLE 2 — DEFINITIONS	12
CHAPTER 2 ACTION	13
ARTICLE 3 — ACTION	13
ARTICLE 4 — DURATION AND STARTING DATE	13
CHAPTER 3 GRANT	13
ARTICLE 5 — GRANT	13
5.1 Form of grant	13
5.2 Maximum grant amount	14
5.3 Funding rate	14
5.4 Estimated budget, budget categories and forms of funding	14
5.5 Budget flexibility	14
ARTICLE 6 — ELIGIBLE AND INELIGIBLE CONTRIBUTIONS	14
6.1 and 6.2 General and specific eligibility conditions	14
6.3 Ineligible contributions	15
6.4 Consequences of non-compliance	15
CHAPTER 4 GRANT IMPLEMENTATION	15
SECTION 1 CONSORTIUM: BENEFICIARIES, AFFILIATED ENTITIES AND OTHER PARTICIPANTS	
ARTICLE 7 — BENEFICIARIES	
ARTICLE 8 — AFFILIATED ENTITIES	17
ARTICLE 9 — OTHER PARTICIPANTS INVOLVED IN THE ACTION	17
9.1 Associated partners	17
9.2 Third parties giving in-kind contributions to the action	17
9.3 Subcontractors	
9.4 Recipients of financial support to third parties	18

ARTICI	LE 10 — PARTICIPANTS WITH SPECIAL STATUS	18
10.1	Non-EU participants	18
10.2	Participants which are international organisations	19
10.3	Pillar-assessed participants	19
SECTION 2	RULES FOR CARRYING OUT THE ACTION	21
ARTICI	LE 11 — PROPER IMPLEMENTATION OF THE ACTION	21
11.1	Obligation to properly implement the action	21
11.2	Consequences of non-compliance	21
ARTICI	LE 12 — CONFLICT OF INTERESTS	22
12.1	Conflict of interests	22
12.2	Consequences of non-compliance.	22
ARTICI	LE 13 — CONFIDENTIALITY AND SECURITY	22
13.1	Sensitive information	22
13.2	Classified information.	23
13.3	Consequences of non-compliance.	23
ARTICI	LE 14 — ETHICS AND VALUES	23
14.1	Ethics	23
14.2	Values	23
14.3	Consequences of non-compliance.	24
ARTICI	LE 15 — DATA PROTECTION	24
15.1	Data processing by the granting authority	24
15.2	Data processing by the beneficiaries	24
15.3	Consequences of non-compliance.	25
ARTICI	LE 16 — INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS – ACCESS RIGHTS AND RIGHTS OF USE	
16.1	Background and access rights to background.	25
16.2	Ownership of results	25
16.3	Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination and publicity purposes	25
16.4	Specific rules on IPR, results and background	26
16.5	Consequences of non-compliance.	26
ARTICI	LE 17 — COMMUNICATION, DISSEMINATION AND VISIBILITY	27
17.1	Communication — Dissemination — Promoting the action	27
17.2	Visibility — European flag and funding statement	27
17.3	Quality of information — Disclaimer	28
17.4	Specific communication, dissemination and visibility rules	28

17.5	Consequences of non-compliance	28
ARTICL	E 18 — SPECIFIC RULES FOR CARRYING OUT THE ACTION	28
18.1	Specific rules for carrying out the action	28
18.2	Consequences of non-compliance	28
SECTION 3	GRANT ADMINISTRATION	28
ARTICL	E 19 — GENERAL INFORMATION OBLIGATIONS	28
19.1	Information requests	28
19.2	Participant Register data updates	29
19.3	Information about events and circumstances which impact the action	29
19.4	Consequences of non-compliance	29
ARTICL	E 20 — RECORD-KEEPING	29
20.1	Keeping records and supporting documents	29
20.2	Consequences of non-compliance	30
ARTICL	E 21 — REPORTING	30
21.1	Continuous reporting	30
21.2	Periodic reporting: Technical reports and financial statements	30
21.3	Currency for financial statements and conversion into euros	31
21.4	Reporting language	31
21.5	Consequences of non-compliance	31
ARTICL	E 22 — PAYMENTS AND RECOVERIES — CALCULATION OF AMOUNTS DUE	31
22.1	Payments and payment arrangements	31
22.2	Recoveries	32
22.3	Amounts due	32
22.4	Enforced recovery	37
22.5	Consequences of non-compliance	37
ARTICL	E 23 — GUARANTEES	38
23.1	Prefinancing guarantee	38
23.2	Consequences of non-compliance	38
ARTICL	E 24 — CERTIFICATES	39
ARTICL	E 25 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS	39
25.1	Granting authority checks, reviews and audits	39
25.2	European Commission checks, reviews and audits in grants of other granting authorities	40
25.3	Access to records for assessing simplified forms of funding	40
25.4	OLAF, EPPO and ECA audits and investigations	40

25.5 Consequences of checks, reviews, audits and investigations — Extension of findings	41
25.6 Consequences of non-compliance	42
ARTICLE 26 — IMPACT EVALUATIONS	42
26.1 Impact evaluation	42
26.2 Consequences of non-compliance	43
CHAPTER 5 CONSEQUENCES OF NON-COMPLIANCE	43
SECTION 1 REJECTIONS AND GRANT REDUCTION	43
ARTICLE 27 — REJECTION OF CONTRIBUTIONS	43
27.1 Conditions	43
27.2 Procedure	43
27.3 Effects	43
ARTICLE 28 — GRANT REDUCTION	43
28.1 Conditions	44
28.2 Procedure	44
28.3 Effects	44
SECTION 2 SUSPENSION AND TERMINATION	44
ARTICLE 29 — PAYMENT DEADLINE SUSPENSION	44
29.1 Conditions	44
29.2 Procedure	45
ARTICLE 30 — PAYMENT SUSPENSION	45
30.1 Conditions	45
30.2 Procedure	45
ARTICLE 31 — GRANT AGREEMENT SUSPENSION	46
31.1 Consortium-requested GA suspension	46
31.2 EU-initiated GA suspension	47
ARTICLE 32 — GRANT AGREEMENT OR BENEFICIARY TERMINATION	48
32.1 Consortium-requested GA termination.	48
32.2 Consortium-requested beneficiary termination.	49
32.3 EU-initiated GA or beneficiary termination	50
SECTION 3 OTHER CONSEQUENCES: DAMAGES AND ADMINISTRATIVE SANCTIONS	53
ARTICLE 33 — DAMAGES	53
33.1 Liability of the granting authority	53
33.2 Liability of the beneficiaries	53
ARTICLE 34 — ADMINISTRATIVE SANCTIONS AND OTHER MEASURES	53
SECTION 4 FORCE MAJEURE	54

ARTICLE	35 — FORCE MAJEURE	54
CHAPTER 6 FIN	AL PROVISIONS	54
ARTICLE	36 — COMMUNICATION BETWEEN THE PARTIES	54
36.1	Forms and means of communication — Electronic management	54
36.2	Date of communication.	55
36.3	Addresses for communication.	55
ARTICLE	37 — INTERPRETATION OF THE AGREEMENT	55
ARTICLE	38 — CALCULATION OF PERIODS AND DEADLINES	55
ARTICLE	39 — AMENDMENTS	56
39.1	Conditions	56
39.2	Procedure	56
ARTICLE	40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES	56
40.1	Accession of the beneficiaries mentioned in the Preamble	56
40.2	Addition of new beneficiaries	57
ARTICLE	2 41 — TRANSFER OF THE AGREEMENT	57
ARTICLE	42 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE GRANTING AUTHORITY	57
ARTICLE	2 43 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES	57
43.1	Applicable law	57
43.2	Dispute settlement	58
ARTICLE	2.44 — ENTRY INTO FORCE	58

DATA SHEET

1. General data

Project summary:

Project summary

Spanish Veterinary Programmes 2025-27 for EU cofinancing This proposal covers the application for the following programmes: Avian Influenza, Salmonella infections in certain poultry populations (breeding flocks of Gallus gallus, broiler flocks of Gallus gallus, laying flocks of Gallus gallus, breeding flocks of turkeys and fattening flocks of turkeys), and bovine spongiform encephalopathies. Overall, the actions shall contribute to the general objectives of the Single Market Programme Regulation (EU) 2021/690, Article 3, 2, e, including by preventing, detecting and / or eradicating animal diseases. In addition, programmes will contribute to the achievements resulting from mthe EU long-term engagement and legal obligations for the Member States in the area of animal health. More specifically, and in relation to the diseases covered, efforts are focused on: - prevention, early detection, eradication (as appropriate) of disease outbreaks; - control of the prevalence of an animal disease or zoonosis below a sanitary acceptable level/ set arget, by implementing relevant measures, - mandatory measures under EU legislation. Detailes descriptions of specific actions are in Annex 1 - Description of the action (part B).

Keywords:

Vet programme

Project number: 101194988

Project name: Spanish Veterinary Programmes 2025-27 for EU cofinancing

Project acronym: ES VP 2025-2027

Call: SMP-FOOD-2025-VETPROG-LS-IBA

Topic: SMP-FOOD-2025-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 2025

Project end date: 31 December 2027

Project duration: 36 months

Consortium agreement: Yes

2. Participants

List of participants:

N°	Role	Short name	name Legal name		PIC	Max grant amount
1	COO	MAPA	MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACION	ES	905557857	3 069 669.39
	· · ·		Total			3 069 669.39

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)	
3 069 669.39	3 069 669.39	

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):

		Payments				
Reporting periods			Туре	Deadline	Туре	Deadline (time to pay)
RP No	Month from	Month to				
					Initial prefinancing	30 days from entry into force/10 days before starting date/ financial guarantee (if required) – whichever is the latest
1	1	23	Additional prefinancing report	60 days after end of reporting period	Additional prefinancing	60 days from receiving additional prefinancing report/ financial guarantee (if required) – whichever is the latest
2	24	36	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

Prefinancing payments and guarantees:

Prefinancing p	payment	Prefinancing guarantee			
Type Amount		Guarantee amount	Division per participant		
Prefinancing 1 (initial)	920 900.82	n/a	1 - MAPA	n/a	
Prefinancing 2 (additional)	920 900.82	n/a	1 - MAPA	n/a	

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): No

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

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

No-profit rule: n/a

Late payment interest: ECB + 3.5%

Bank account for payments:

ES4490000001200253107033 ESPBESMM

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)

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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 2018/1046⁴ 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 2017/1371⁵ and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995⁶, 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 2988/95⁷.
- 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 101194988 — ES_VP 2025-2027 ('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 grant⁸ 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' (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/EC¹¹
- 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 2015/444¹² 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 2018/1725¹³.

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 2016/679¹⁴).

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.

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

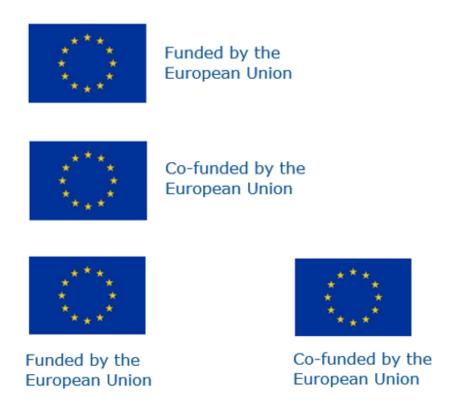
17.1 Communication — Dissemination — Promoting the action

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):



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 2015/2366¹⁵ 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, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

25.1.3 Audits

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

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

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

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

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

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

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

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

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

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

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

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

25.3 Access to records for assessing simplified forms of funding

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

25.4 OLAF, EPPO and ECA audits and investigations

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 883/2013¹⁶ and No 2185/96¹⁷
- the European Public Prosecutor's Office (EPPO) under Regulation 2017/1939
- the European Court of Auditors (ECA) under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 257 of EU Financial Regulation 2018/1046.

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

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

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

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

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

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

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

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

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

25.5.2 Extension from other grants

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

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

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

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

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

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

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

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

- (a) an invitation to submit observations on the list of grants affected by the findings
- (b) the request to submit revised financial statements for all grants affected
- (c) the correction rate for extrapolation, established on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected, if the beneficiary concerned:
 - (i) considers that the submission of revised financial statements is not possible or practicable or
 - (ii) does not submit revised financial statements.

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

- (a) an invitation to submit observations on the list of grants affected by the findings and
- (b) the **correction rate for extrapolation**, established on the basis of the systemic or recurrent errors and the principle of proportionality.

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

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

25.6 Consequences of non-compliance

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

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

ARTICLE 26 — IMPACT EVALUATIONS

26.1 Impact evaluation

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

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 2988/95¹⁸).

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 1182/71¹⁹, 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

Associated With Lucum Str Ref. Ares (2025) 1320722: -419/02/2025

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

For the granting authority



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:	101194988				
Project name:	Spanish Veterinary Programmes 2025-27 for EU cofinancing				
Project acronym:	ES_VP 2025-2027				
Call:	SMP-FOOD-2025-VETPROG-LS-IBA				
Topic:	SMP-FOOD-2025-VETPROGR-LS-IBA				
Type of action:	SMP-LS				
Service:	HADEA/A/02				
Project starting date:	fixed date: 1 January 2025				
Project duration:	36 months				

TABLE OF CONTENTS

Project summary	3
List of participants	3
List of work packages	4
Staff effort	6
List of deliverables	7
List of milestones (outputs/outcomes)	14
List of critical risks	15

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.

Spanish Veterinary Programmes 2025-27 for EU cofinancing

This proposal covers the application for the following programmes: Avian Influenza, Salmonella infections in certain poultry populations (breeding flocks of Gallus gallus, broiler flocks of Gallus gallus, laying flocks of Gallus gallus, breeding flocks of turkeys and fattening flocks of turkeys), and bovine spongiform encephalopathies.

Overall, the actions shall contribute to the general objectives of the Single Market Programme Regulation (EU) 2021/690, Article 3, 2, e, including by preventing, detecting and / or eradicating animal diseases.

In addition, programmes will contribute to the achievements resulting from mthe EU long-term engagement and legal obligations for the Member States in the area of animal health. More specifically, and in relation to the diseases covered, efforts are focused on:

- prevention, early detection, eradication (as appropriate) of disease outbreaks;
- control of the prevalence of an animal disease or zoonosis below a sanitary acceptable level/ set arget, by implementing relevant measures,
 - mandatory measures under EU legislation.

Detailes descriptions of specific actions are in Annex 1 - Description of the action (part B).

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

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

LIST OF WORK PACKAGES

Work packages

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

Work Package No	Work Package name	Lead Beneficiary	Effort (Person- Months)	Start Month	End Month	Deliverables
WP1	Influenza aviar	1 - MAPA	1.00	1	36	D1.1 – D1.1 D1.2 – D1.2 D1.3 – D1.3 D1.4 – D1.4 D1.5 – D1.5 D1.6 – D1.6
WP2	Bovine Spongiform Encephalopathy	1 - MAPA	1.00	1	36	D2.1 – D2.1 D2.2 – D2.2 D2.3 – D2.3 D2.4 – D2.4 D2.5 – D2.5 D2.6 – D2.6
WP3	Zoonotic Salmonella	1 - MAPA	1.00	1	36	D3.1 – D3.1 D3.2 – D3.2 D3.3 – D3.3 D3.4 – D3.4 D3.5 – D3.5 D3.6 – D3.6

Work package WP1 - Influenza aviar

Work Package Number	WP1	Lead Beneficiary	1 - MAPA
Work Package Name	Influenza aviar		
Start Month	1	End Month	36

Objectives

Surveillance of AI for early detection of incursion of HPAI strains in poultry and wild birds, monitoring of low pathogenic strains in poultry, monitoring and contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk, and annual demonstration of freedom of HPAI in poultry.

Description

Active and passive surveillance in poultry and wild birds.

Work package WP2 - Bovine Spongiform Encephalopathy

Work Package Number	WP2	Lead Beneficiary	1 - MAPA		
Work Package Name	Bovine Spongiform Encephalopathy				
Start Month	1	End Month	36		

Objectives

- to monitor the epidemiological situation in cattle population in relation to BSE, and
- to detect the presence of BSE disease and, when necessary, implement the appropriate control and eradication measures.

Description

Surveillance and monitoring of BSE for early detection of cases and mitigation of the risk associated to them by elimination of possitive animals form the producction chain.

Work package WP3 - Zoonotic Salmonella

Work Package Number	WP3	Lead Beneficiary	1 - MAPA
Work Package Name	Zoonotic Salmonella		
Start Month	1	End Month	36

Objectives

Reduction of the maximum percentage of breeding turkey, fattening turkey and broilers positive to Salmonella Enteritidis and Salmonella Typhimurium, including monophasic strains of Salmonella Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

Description

Surveillance and monitoring of zoonotic Slamonella in susceptible populations of turkey and broilers with he objective of confriming reduction of prevalence adapted to the requested target of less than 1%.

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	Туре	Dissemination Level	Due Date (month)
D1.1	D1.1	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	8
D1.2	D1.2	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	20
D1.3	D1.3	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	32
D1.4	D1.4	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	16
D1.5	D1.5	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	28
D1.6	D1.6	WP1	1 - MAPA	R — Document, report	SEN - Sensitive	36
D2.1	D2.1	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	8
D2.2	D2.2	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	16
D2.3	D2.3	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	20
D2.4	D2.4	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	28
D2.5	D2.5	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	32
D2.6	D2.6	WP2	1 - MAPA	R — Document, report	SEN - Sensitive	36
D3.1	D3.1	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	8
D3.2	D3.2	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	16
D3.3	D3.3	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	20

Deliverables

Grant Preparation (Deliverables screen) — *Enter the info.*

The labels used mean:

Public — fully open (automatically posted online)

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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	Туре	Dissemination Level	Due Date (month)
D3.4	D3.4	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	28
D3.5	D3.5	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	32
D3.6	D3.6	WP3	1 - MAPA	R — Document, report	SEN - Sensitive	36

Deliverable D1.1 – D1.1

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

Description	
Intermediate financial report year 2025 WP 1	

Deliverable D1.2 – D1.2

Deliverable Number	D1.2	Lead Beneficiary	1 - MAPA
Deliverable Name	D1.2		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	20	Work Package No	WP1

Description	
intermediate financial report year 2026 WP 1	

Deliverable D1.3 – D1.3

Deliverable Number	D1.3	Lead Beneficiary	1 - MAPA
Deliverable Name	D1.3		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	32	Work Package No	WP1

Description
intermediate financial report year 2027 WP 1

Deliverable D1.4 – D1.4

Deliverable Number	D1.4	Lead Beneficiary	1 - MAPA
Deliverable Name	D1.4		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	16	Work Package No	WP1

Description	
progress report year 2025	

Deliverable D1.5 – D1.5

Deliverable Number	D1.5	Lead Beneficiary	1 - MAPA
Deliverable Name	D1.5		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	28	Work Package No	WP1

Description	
progress report year 2026 WP 1	

Deliverable D1.6 – D1.6

Deliverable Number	D1.6	Lead Beneficiary	1 - MAPA
Deliverable Name	D1.6		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	36	Work Package No	WP1

Description
Final technical and financial report WP 1

Deliverable D2.1 – D2.1

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

Description	
D1 intermediate financial report year 2025	

Deliverable D2.2 – D2.2

Deliverable Number	D2.2	Lead Beneficiary	1 - MAPA
Deliverable Name	D2.2		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	16	Work Package No	WP2

Description	
D2 progress report year 2025	

Deliverable D2.3 – D2.3

Deliverable Number	D2.3	Lead Beneficiary	1 - MAPA
Deliverable Name	D2.3		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	20	Work Package No	WP2

Description	
D3 intermediate financial report year 2026	

Deliverable D2.4 – D2.4

Deliverable Number	D2.4	Lead Beneficiary	1 - MAPA
Deliverable Name	D2.4		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	28	Work Package No	WP2

Description	
D4 progress report year 2026	

Deliverable D2.5 – D2.5

Deliverable Number	D2.5	Lead Beneficiary	1 - MAPA
Deliverable Name	D2.5		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	32	Work Package No	WP2

Description
D5 intermediate financial report year 2027

Deliverable D2.6 – D2.6

Deliverable Number	D2.6	Lead Beneficiary	1 - MAPA
Deliverable Name	D2.6		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	36	Work Package No	WP2

Description	
D6 Final technical and financial report WP 2	

Deliverable D3.1 – D3.1

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

Description	
D1 intermediate financial report year 2025 WP 3	

Deliverable D3.2 – D3.2

Deliverable Number	D3.2	Lead Beneficiary	1 - MAPA		
Deliverable Name	D3.2				
Туре	R — Document, report	Dissemination Level	SEN - Sensitive		
Due Date (month)	16	Work Package No	WP3		

Description
D2 progress report year 2025 WP 3

Deliverable D3.3 – D3.3

Deliverable Number	D3.3	Lead Beneficiary	1 - MAPA
Deliverable Name	D3.3		
Туре	R — Document, report	Dissemination Level	SEN - Sensitive
Due Date (month)	20	Work Package No	WP3

Description
D3 intermediate financial report year 2026 WP 3

Deliverable D3.4 – D3.4

Deliverable Number	D3.4	Lead Beneficiary	1 - MAPA		
Deliverable Name	D3.4				
Туре	R — Document, report	Dissemination Level	SEN - Sensitive		
Due Date (month)	28	Work Package No	WP3		

Description	
D4 progress report year 2027 WP 3	

Deliverable D3.5 – D3.5

Deliverable Number	D3.5	Lead Beneficiary	1 - MAPA		
Deliverable Name	D3.5				
Туре	R — Document, report	Dissemination Level	SEN - Sensitive		
Due Date (month)	32	Work Package No	WP3		

Description	
D5 intermediate financial report year 2027 WP 3	

Deliverable D3.6 – D3.6

Deliverable Number	D3.6	Lead Beneficiary	1 - MAPA		
Deliverable Name	D3.6				
Туре	R — Document, report	Dissemination Level	SEN - Sensitive		
Due Date (month)	36	Work Package No	WP3		

Description	
D6 Final technical and financial report WP 3	

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	SIX-MONTHLY TECHNICAL REPORT 2025	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.	8
2	FINAL TECHNICAL REPORT 2025	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by at the end so that it is possible to see the evolution at that moment and to correct any deviation if necessary.	36
3	SIX-MONTHLY TECHNICAL REPORT 2026	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.	20
4	FINAL TECHNICAL REPORT 2026	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by at the end so that it is possible to see the evolution at that moment and to correct any deviation if necessary.	
5	SIX-MONTHLY TECHNICAL REPORT 2027	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.	32
6	FINAL TECHNICAL REPORT 2027	WP3, WP2, WP1	1 - MAPA	Technical monitoring data is collected by at the end so that it is possible to see the evolution at that moment and to correct any deviation if necessary.	

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	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system.		Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system.	WP3	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and specificity.		Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab.
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed.	WP3	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence	WP3	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated turkey meat.	WP3	Rigorous accomplishment of the control programme and of the next stages of the agrifood chain (hygiene process, slaughtering process). Rapid coordination and collaboration

Critical risks & risk management strategy

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

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
	Impact on public health, on food safety, on farmer's production.		between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and corrective actions established in the SNCP (in case the cause of contamination was at farm level).
7	Unexpected problem in certain region, that may not have enough human/financial resources because of other priorities such as disease circulation any Cat A disease.		Try to find financial and human support. If no possible, try to derive the affected sampling to the closest region or Autonomous Community to carry out the sampling to comply with national targets.
8	Lack of reporting of suspicions, inefficient passive surveillance. Low risk.	WP1	Continuous training and awareness campaigns aimed at the sector (farmers) and private veterinarians. Transparent and constant risk-communication, update epidemiological situation reports. Maintain regular meetings with the sector
9	Maintenance of disease in a certain area out of the high risk periods. High risk.	WP1	Immediately inform the Autonomous Regions so that surveillance can be increased in these periods not foreseen in the programme. Activate biosecurity measures of the national Order if needed.
10	Lack of reporting of suspects, inefficient passive surveillance.	WP2	Continuous training and awareness campaigns aimed at the stakeholders(farmers) and private veterinarians. Transparent and constant risk-communication, update epidemiological situation reports. Maintain regular meetings with the sector





Single Market Programme (SMP Food)

EU co-funded programme for the surveillance of Avian Influenza in animals for 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B)) Avian Influenza surveillance Programme

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	
Disease	AVIAN INFLUENZA
Species	Poultry ⊠ Wild birds ⊠ Other
Implementation Year	2025-2027

CONTACT PERSON on AI programme:

Name	Germán Cáceres Garrido
e-mail	gcaceres@mapa.es
Job type within the CA	Head of epidemiology Area (Ministry of Agriculture)

Avian Influenza Programme – 2025-2027

RELEVANCE

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

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

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

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

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

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

(maximum 200 characters)

1.2 Needs and specific objectives

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

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

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

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

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

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

- 3) Detection of HPAI in poultry species which generally do not show significant clinical signs The active surveillance component, includes the sampling in the following categories: ducks (fattening and breeders), geese (fattening and breeders), quails and poultry of the order Anseriformes species for supplying game, based on our risk-based surveillance system, especially in high-risk periods.
- 4) Detection of circulating low pathogenic avian influenza viruses (LPAIV): The active surveillance component, includes the sampling in laying hen, free range laying hens, turkeys for fattening and breeding and poultry of Galliformes species for supplying game. The sampling, when possible, shall apply to poultry establishments for which the competent authority has assessed the repeated occurrence of aggregations (either in time or space) in the past or in which the occurrence is more likely, based on our risk-based surveillance system and in high-risk periods.
- 5) Contribution to increased knowledge on HPAI and LPAIV posing a potential zoonotic risk: Within the Wildlife Surveillance Program, samples will be taken from wild carnivores (especially foxes and wolves) in those cases of mortality or presence of clinical signs compatible with HPAI, particularly in areas and periods where there is a risk of transmission of the disease because of circulation in wild birds.

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

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

(maximum 500 characters)

1.3 Complementarity with other actions — European added value

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

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

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

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

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

Additionally, the programme has been updated according to the inputs and results obtained from the risk analysis tool (Diflusion modelling tool), so that each year these resources can be optimised more and better. The modelling tool has been shared with countries that have shown interest about it.

(maximum 500 characters)

1.4 Target population and area of the implementation

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

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

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

Passive surveillance component

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

Active surveillance component

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

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

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

- (a) The species present on the establishment;
- (b) The production cycle and duration of production;
- (c) The presence of different poultry species;
- (d) The presence of poultry flocks of different ages;
- (e) The presence of long-lived poultry;
- (f) The practice of all-in-all-out;
- (g) The length of the waiting period between flocks; and
- (h) Biosecurity practices and poultry housing conditions.

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

- On the one hand, sampling shall be primarily directed, in the case of holdings with an openair production system, towards holdings located in municipalities included in the special risk areas and special surveillance zones established for each Autonomous Community in Annexes II and III of Order APA/782/2022 of 5 August amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza. Map 1 in annex IV shows the municipalities included in the 'special risk areas (Annex II) and the municipalities included in the 'special surveillance zones' (Annex III) of the mentioned Order.
- On the other hand, and complementarily, the selection of holdings shall be based on the outputs of the risk assessment tool/model, Diflusion, developed and used by MAPA in collaboration with the National Institute for Agricultural and Food Research and Technology in the MAPA-INIA 2019 Management Assignment. The number of holdings assigned to each Autonomous Community will be selected considering the level of regional risk, so that sampling will be more intense in the regions with higher risk compared to those with lower risk. Diflusion is based on a multi-criteria decision analysis tool -TOPSIS (Technique for Order Performance by Similarity to Ideal Solution). This tool allows the identification of livestock districts with a higher risk of HPAI introduction based on six parameters:

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

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

Vaccination

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

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

Target animals and animal population

Poultry

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

- Laying hens, free-range laying hens, breeding turkeys, fattening turkeys, poultry of Galliformes species for the supply of game birds to be released into the wild, for the detection of sub-clinical infections of Low Pathogenic Avian Influenza subtypes H5 and H7.
- Breeding ducks, breeding geese, fattening ducks, fattening geese and quail, for the detection of HPAI in poultry species that normally do not show significant clinical signs.

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

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

- ()
- b) Backyard poultry, only when the risk assessment justifies its inclusion.
- c) Others, only when justified by risk assessment.

Regarding the last data poultry population, the avian census in Spain is 311.48 million animals (in January 2024). According to SITRAN, most of this census, up to a total of 293.55 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 Castilla La Mancha, Castilla y León, Aragon, Catalonia and Galicia standing out regarding census.

For turkey production, the national census is 17.32 million heads, with Andalusia, Galicia 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 602.544 birds. There are two different productions, in the north (Navarre, Aragon and Catalonia) the production is mainly linked to the production of foie, while the production in the central area, which is also important, is more closely linked to the production of duck meat.

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

Wild birds

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

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

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

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

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

1.5 Epidemiological situation

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

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

POULTRY

During the years 2018- 2021, no outbreaks of highly pathogenic avian influenza were detected in poultry farms in Spain.

On January 18, 2022, the Central Veterinary Laboratory of Algete confirmed the detection of highly pathogenic avian influenza virus H5N1 in a fattening turkey farm located in the livestock region of Cantalejo, province of Segovia. Throughout the year 2022, a total of 37 outbreaks were reported in domestic poultry, 30 in Andalusia, 3 in Castilla y León, 2 in Castilla-La Mancha and 1 in Extremadura. In all the cases detected in 2022, the H5N1 subtype has been confirmed.

In 2023, just one outbreak was reported in February in the region of Garrigues, Lleida, identified with the H5N1 subtype in a turkey fattening farm.

During the year 2024, as of May 16, no outbreaks of HPAI have been reported in poultry farms in Spain.

In all outbreaks, the measures established in the Commission Delegated Regulation (EU) 2020/687 have been adopted, including the establishment of a protection and surveillance zone in each case and 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 in the farms, the destruction of all materials present that could carry the virus and their subsequent cleaning and disinfection.

As of March 11, 2023, the entire Spanish territory regained the status of a country free of notifiable avian influenza as established in the WOAH code.

WILD BIRDS

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

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

During 2022, a total of 149 outbreaks in wild birds and 3 in captive birds were reported. In total, at least 29 different species have been affected, the most represented being Atlantic gannets (35.84%), white storks (13.29%) and geese (12.14%). In terms of location, 14 Autonomous Communities have confirmed positives in the Central Veterinary Laboratory of Algete.

In 2023, a total of 52 outbreaks were reported, 7 in Aragon, 20 in Catalonia, 5 in the Basque Country, 1 in Cantabria, 3 in Valencia, 3 in Castilla y León, 2 in Castilla-La Mancha and 11 in Galicia.

In 2024, as of May 16, only one outbreak of HPAI has been reported in a wild bird (crane) in Toledo (Castilla La Mancha).

The cases were reported to the European Union and WOAH, and the following measures were implemented:

- Census of all commercial and non-commercial farms within a radius of 3 and 10 km.
- Clinical inspection of birds on all farms if considered.
- Evaluation of biosecurity measures applied in poultry farms if condidered.
- Intensification of surveillance in wild birds.
- Dissemination of information on the epidemiological situation.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

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

2.1.1 Disease surveillance

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

Describe case definition.

POULTRY ACTIVE SURVEILLANCE

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

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

- Prioritisation of poultry holdings located in municipalities included in special risk areas and special surveillance zones defined in Spain through Order APA/782/2022 of 5 August

amending Order APA/2442/2006 of 27 July establishing specific protection measures in relation to avian influenza;

- Prioritisation of holdings located in higher-risk livestock districts characterised through a risk analysis model based on the TOPSIS method
- Prioritisation based on the criteria included in Annex II of Commission Delegated Regulation (EU) 2020/689 of 17 December 2019.

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

The sampling procedure: The numbers of animals to be sampled in the poultry establishments will be defined to ensure 95 % probability of identifying at least one bird that tests positive for avian influenza where the prevalence of positive birds is \geq 30 %.

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

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

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

Sampling shall be carried out between 1 January 2025 and 31 December 2027. The sampling period shall be adapted to the seasonality of production. It is recommended the use of samples collected for other purposes, in order to increase the efficiency of the economic and human effort made. It may also be adapted to other types of periodicities identified at local level that may imply a higher risk. Consideration shall also be given to targeting sampling to the periods of highest risk of virus circulation, which are usually between October and April.

POULTRY PASSIVE SURVEILLANCE

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

- a) Clinical examination of the animals, necropsy and epidemiological survey.
- b) Collection of official samples and send them to the official laboratory
- c) Census of all animals including dead on the farm
- d) Communication to the owner of the conditions of immobilisation
- e) Official communication of the suspicion

Depending on the results of the tests carried out in the official labs, the steps laid down in the Manual for Avian Influenza shall be followed. Documents and sampling procedures are state

in the manual: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022 tcm30-437988.pdf

WILD

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

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

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

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

- (a) the disease agent responsible for HPAI, excluding vaccine strains, has been isolated in a sample from an animal or from a group of animals;
- (b) nucleic acid specific to the disease agent for HPAI, that is not a consequence of vaccination, has been identified in a sample from an animal or from a group of animals; or
- (c) positive result to an indirect diagnostic method, that is not a consequence of vaccination, has been obtained in a sample from a kept animal or from a group of kept animals showing clinical signs consistent with the disease or epidemiologically linked to a suspected or confirmed case.

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

- (a) an influenza A virus of H5 and H7 subtypes or any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1,2; or
- (b) an influenza A virus of H5 and H7 subtypes with a sequence of multiple basic amino acids present at the cleavage site of the haemagglutinin molecule (HAO) that is similar to that observed for other HPAI isolates.

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

OTHER SURVEILLANCE

Within the Wildlife Surveillance Program, samples will be taken from wild carnivores (especially foxes and wolves) in case of mortality or presence of clinical signs compatible with HPAI, particularly in areas and periods where there is a higher risk of transmission of the disease because of confirmation of circulation in wild birds.

In American mink farms, samples shall be taken in case of abnormal mortalities or presence of any respiratory, neurological or any other symptomatology that may be compatible with

HPAI, particularly in those areas and periods in which there is a higher risk of HPAI transmission because of confirmation of circulation in wild birds.

In domestic swine farms, an epidemiological investigation will be carried out in case of clinical or epidemiological suspicion of infection of these animals with HPAI virus, particularly in those areas and periods in which there is a higher risk of HPAI transmission because of confirmation of circulation in wild birds.

2.1.2 Laboratory testing

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

Mention testing laboratories and tests they perform.

Describe assurance of the quality of the results produced by these laboratories (it is sufficient to indicate laboratory quality assurance schemes in place).

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

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

- (a) The analysis of the samples shall be carried out by laboratories designated by the corresponding Autonomous Communities, working under the control of the National Reference Laboratory (NRL). The NRL shall provide the necessary technical support and reference materials to the official regional laboratories, and organize periodically Proficiency Test (PT) for the control and harmonization of ELISA and RT-PCR diagnostic methods. All the designated laboratories are accredited according ISO17025 or work under quality assurance system including participation in the PT organized by NRL. All the AIV diagnostic techniques employed by the NRL are accredited according ISO 17025
- (b) The analysis of samples shall comply with Annex II Delegated Regulation 689/2020.
- (c) Samples collected in the framework of the targeted surveillance plan for LPAI and supplementary surveillance for HPAI in poultry species not normally showing significant clinical signs shall be subjected to laboratory testing by serological (ELISA for antibodies detection against Influenza A virus) or virological (M gene RT-PCR) methods in the authorised laboratories.
- d) Samples from passive surveillance must be subjected to laboratory testing by virological methods (M gene RT-PCR) for the early detection of HPAI in poultry, captive and wild birds, and for the follow-up of seropositive results.
- (e) In case of ELISA or M gene RT-PCR positive results, samples must be sent to National Reference Laboratory to be analyzed by Hemaglutinin H5/H7 Inhibition test in the case of serum samples, or specific RT-PCRs (H5, H7, H9, N1, N5, N6 and N8) in the case of swab/tissue samples, using the procedures recommended by AIV EURL. In case of positive H5, H7 serological results, further samples (at least 20 serological and 20 virological tracheal and cloacal swaps samples or tissues from at least 5 sick or dead birds) shall be taken and submitted to the National Reference Laboratory for virological analysis by M gene and specific PCR (H5, H7, H9, N1, N5, N6 and N8), sequencing for pathotyping in case of H5 or H7 positive results and isolation in embryonated chicken eggs.

- (f) Pooling of dry swab samples up to 5, from the same epidemiological unit and anatomical site in domestic animals is considered, according to the criteria stablished by EURL.
- (g) 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

- (h) 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.
- (i) The NRL shall forward to the EU Reference Laboratory all avian influenza viruses of H5 or H7 subtypes or other influenza viruses that may pose a significant threat for health, so that a virus repository can be established to allow future developments of diagnostic techniques and molecular epidemiology follow-up.

Tests shall comply with the procedures detailed in the Diagnostic Manual for Avian Influenza (2006/437/EC) as provided for in Council Directive 2005/94/EC, adapted as appropriate should the EURL so decide. This document sets out the guidelines to carry out the collection of samples, tissue material to be examined, transport of samples, laboratory protocols, and criteria required to evaluate the results of laboratory tests for a proper diagnosis of Al. This document will continue to be technically valid also after the abrogation. Accordingly, virological tests shall include: M gene and H and N sub-type specific RT-PCRs, sequencing for pathotyping, and inoculation of embryonated chicken eggs.

Special care shall be taken when storing and transporting samples to prevent their deterioration: among other things, they should be refrigerated and sent to the laboratory immediately. Swabs could be sent dry or completely immersed in a phosphate-buffer medium (PBM) with antibiotics or, in the absence of this, in a physiological serum with antibiotics. If no PBM or physiological serum is available, a commercial medium can be used that is specifically designed to transport viruses, but under no circumstances, media designed for bacterial should be used. A commercial medium can be used that is specifically designed to transport viruses, try to avoid the use of inactivating media that prevent virus isolation in case of positive samples.

2.1.3 Measures in case of disease suspicion and confirmation

Describe measures to be implemented in case of disease suspicion and confirmation (detailed references to the provisions of relevant Union legislation to be implemented in case of disease suspicion and confirmation are sufficient).

Spanish Animal Health Law 8/2003, of April 24, establishes in Article 5 that any person, physical or legal, public or private, will be obliged to notify the competent authority, immediately and, in any case, in the manner and within the established deadlines, all the

sources of knowledge of diseases of an epizootic nature, as well as of any pathological process that causes the suspicion of being a notifiable disease. At national level, Royal Decree 779/2023 establishes the list of notifiable animal diseases and regulates their notification.

The disease is listed in COMMISSION IMPLEMENTING REGULATION (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system. Furthermore, pursuant to Article 7 of Order APA 2442/2006 of 27 July 2006, all persons, in particular veterinarians, wild bird protection organisations, hunting associations, etc. must immediately report any abnormal deaths, in particular those of waterfowl, to the relevant health authorities.

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

- a) Clinical examination of the animals, necropsy and epidemiological survey.
- b) Collection of official samples and send them to the official laboratory
- c) Census of all animals including dead on the farm
- d) Communication to the owner of the conditions of immobilisation
- e) Communication of the suspicion to higher levels

Depending on the results of the tests carried out in the official labs, the steps laid down in the Manual for Avian Influenza shall be followed. If the disease is confirmed in the NRL, it shall be reported immediately to the Sub-Directorate General for Animal Health and Hygiene and Traceability, which shall report the information urgently to the European Commission, and the following measures laid down in the EU Delegated Regulation 687/2020 are immediately adopted:

- Immobilization of the farm since moment of suspicion.
- Epidemiological investigation: movements out/in. Likely source, possible contact with wild birds, presence of lagoons with water wild birds close by.
- Census of animals and risk products located in the affected farms.
- Stamping out: Culling of animals in the affected farms.
- Disposal of animals, litter and bedding straw (Rendering plant Category I or burial) in the affected farms.
- Zoning: surveillance 10km and protection 3 km zones and movement restrictions. Inspection of holdings in the restriction zone.
- Preliminary and final cleaning and disinfection in the affected farms.

All the measures, in case of suspicion and confirmation of AI, are detailed in the specific Manual available in MAPA Website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/manualiaabril2022_tcm30-437988.pdf

2.1.4 Data collection, management and analysis

Describe surveillance data collection, management and analysis, including spatial analysis (mapping, if any) of activities under both active and passive surveillance (to contribute identify possible gaps in disease surveillance).

All results (serological and virological) obtained by the approved official regional laboratories and the NRL shall be sent to the Sub-Directorate General for Animal Health and Hygiene and Traceability on a six-monthly basis, using a communication module within RASVE application created for this purpose. From the Sub-Directorate General for Animal Health and Hygiene and Traceability, the reported data are analysed and verified. Once the information has been verified, a report is carried out that will collate the results of the program implemented during the last year.

These results are presented and analysed once a year in Rasve Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme.

The results of the program are also shared with the national sector associations in a specific meeting after the results are endorsed by the Rasve Committee (May of the following year).

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

According to the Spanish Legal framework, the Autonomous Communities are the competent authority for the implementation of the program, while the National Government has the competence to establish the bases and national coordination in animal health.

The Animal Health Services of each Autonomous Community are responsible then for implementation of the AI programme in their respective regions.

The NRL for Avian Influenza (Central Veterinary Laboratory in Algete), is under the Directorate General for agrifood production health and animal welfare; and the Sub-Directorate General for Animal Health and Hygiene and Traceability (also under the same DG) is the authority in charge of the supervision and coordination of the activities carried out by the Autonomous Communities.

In the case of wild birds, the Competent Authorities also require the collaboration of the natural environment and hunting authorities, which will receive the necessary information on the epidemiological situation of the disease, particularly in those cases that present a higher risk of introduction and spread of the avian influenza virus in Spain. The central competent natural environment and hunting authorities and the Autonomous Communities will in turn pass this information on to hunting and ornithology organisations and wild birds recue centres. Samples taken from dead or sick birds will be forwarded to the corresponding Animal Health Laboratories of the respective Autonomous Communities via the Official Veterinary Services or via the departments responsible for the natural environment, depending on the distribution of responsibilities in each Autonomous Community.

Avian influenza is included in the list of notifiable diseases according to Royal Decree 779/2023 and COMMISSION IMPLEMENTING REGULATION (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system, and under Article 5 of Law 8/2003, national Animal Health Act, all natural or legal persons, public or private — thus including official or private veterinarians, livestock farmers, hunters, environmental health officers, laboratories, etc. — must duly inform the competent authority of any suspicion of diseases contained in the list of notifiable diseases.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of the achievement of targets (activity¹ indicators) - please describe for different programme activities; mention frequency of such controls.

What enforcement mechanisms will be initiated in case of failure of reaching the planned targets / to ensure continuous improvement.

Describe the evaluation of the progress² indicators (quantitative or qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values).

¹ Example of activity indictors: number of holdings checked; number of animals samples; number of samples tested, etc.

² Example of progress indicators: number of samples tested under passive surveillance higher than the last year, indicating higher likelihood of early detection of possible introduction of disease (new disease outbreaks).

The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

National surveillance programme for each year is elaborated by central government (MAPA) in coordination with the 17 Autonomous Regions OVS.

Surveillance results are collated every six months (in July for the first semester, and in January for the second semester), that are analysed together with the CAs of the Autonomous Regions in the framework of the monthly animal health coordination meeting in the frame of the Rasve Committee.

In case targets are not met, there is an indicator, the number of samples or the number of holding to be taken/visited that if is not achieved, the reason is analysed, to try to find a solution (for example select and replace with inclusion of additional holdings, firstly at regional level). The number of holdings per category to prepare the programme for next year is decided one year in advance, and there could be some differences between the farms active when deciding and the farms active at the moment of sampling.

As mentioned, the overall results of the programmes are analysed with the CAs of the Autonomous Regions (in April/May) and with the affected sector once a year (in May/June).

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Unexpected problem in certain region, that may not have enough human/financial resources because of other priorities such as disease circulation any Cat A disease. Medium risk.	Try to find financial and human support. If no possible, try to derive the affected sampling to the closest region or Autonomous Community to carry out the sampling to comply with national targets.
2	Lack of reporting of suspicions, inefficient passive surveillance. Low risk.	Continuous training and awareness campaigns aimed at the sector (farmers) and private veterinarians.

		Transparent and constant risk- communication, update epidemiological situation reports. Maintain regular meetings with the sector
3	Maintenance of disease in a certain area out of the high risk periods. High risk.	Immediately inform the Autonomous Regions so that surveillance can be increased in these periods not foreseen in the programme. Activate biosecurity measures of the national Order if needed.

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

Name	Due date (in month)	Means of verification				
Six-monthly technical report	July 2025, 2026 and 2027	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.				
Six-monthly technical report	January 2026, 2027 and 2028	Technical monitoring data is collected by semesters so that it is possible to see the evolution at that moment, to plan the second semester, and to correct any deviation if necessary.				
Annual report meeting with the regional authorities	April/May 2026, 2027 and 2028	A report is presented and analysed once a year in Rasve Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme.				
Annual report meeting with the sector	May/June 2026, 2027 and 2028	A report is presented and analysed once a year with the sector in May/June of the following year, in order to identify the gaps detected and to try to fix them for the following programme.				

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view).

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: increased likelihood of early detection and response in case of disease occurrence, contributes decrease in preventable losses in animal production and loses due to trade restrictions.

The surveillance programme has a direct impact on the early detection of HPAI:

- Passive surveillance is identified as a key tool to detect HPAI in poultry, captive birds and wild birds.
- Active surveillance is established as a very good tool for the detection of HPAI in species that do not show clinical symptomatology.
- Active surveillance is established as a very good tool for the detection of LPAI.

Furthermore, as it has an impact on early detection, the economic impact is also considered very important for the CA and the sector, as the consequences of a lack of early detection could lead to a further spread of the virus in farms, and so a bigger and more complicated outbreak, which would consequently imply:

- Increase number of farms affected with increased birds to be culled and carcasses and risk-products disposed.
- Increased budget and personal needed for outbreak management
- Increased number of farms immobilised in Restriction Zones and increase farms subject to preventive empty of birds that are sent to the SH before slaughtering weight.
- Increased export problems and restrictions by thirds countries.
- Greater number of businesses and families affected for a longer period of time.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

(0)

Information in the EU on funding for both national programmes and emergencies is available at the following link:

https://www.mapa.gob.es/es/ganaderia/legislacion/legislacion sanidad animal.aspx

Likewise, all information on HPAI, epidemiological situation, surveillance programme, measures, etc., is available at the following link:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/influenza-aviar/influenza aviar.aspx

All relevant epidemiological information and events is constantly updated in the Website and also sent via mail to the CA of the regions, and stakeholders involved with an established list of contact emails of: Regional OVS; Other central Ministries units, Poultry production and hunter associations, Environmental police (SEPRONA))

Publication of event reports in the website (RASVE News):

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/default.aspx

Regularly updated report on avian influenza situation in the world with special emphasis on EU and Spain: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/informeia_tcm30-584890.pdf

Wild bird's surveillance guide included in the evet reports to enhance passive surveillance in wild populations: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/guiavigilanciasanitariafaunasilvestre tcm30-511596.PDF

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

It is considered necessary to maintain HPAI surveillance efforts, both passive and active, to ensure early detection of the disease.

HPAI is an endemic disease that persists in wild birds and usually occurs in episodes on a cyclical basis, so it is essential to maintain this surveillance programme on a long-term basis.

The resources needed will depend on the epidemiological situation of the disease in each season, as the sampling effort (especially in passive surveillance) is directly related to the disease circulation.

ANNEX

- I. Baseline population data and Targets for 2025-2027
- II. History of disease occurrence
- III. Implementation of applicable rules and regulation
- IV. Maps (as relevant)

I. Baseline population data and targets for 2025

Table 1a: Poultry holdings³ (except ducks, geese and farmed game birds (waterfowl eg. Mallards) to be sampled (insert as appropriate for the programme)

Laying hens

Region (NUTS-2) ⁴	Total number of holdings ⁵	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁶
SPAIN	736	60	20	1200	1200	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				150	30	PCR test
TOTAL				1350	1380	

³ Holdings or herds or flocks or establishments as appropriate.

⁴ Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested

⁵ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁶ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Free range laying hens

Region (NUTS-2) ⁷	Total number of holdings ⁸	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁹
SPAIN	703	60	10	600	600	ELISA test
SPAIN					60	HI-test (H5)
SPAIN					30	HI-test (H7)
SPAIN				100	20	PCR test
TOTAL				700	710	

⁷ 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

⁸ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Turkey breeders

Region (NUTS-2) ¹⁰	Total number of holdings ¹¹	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ¹²
SPAIN	10	10	10	100	100	ELISA test
SPAIN					30	HI-test (H5)
SPAIN					15	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				130	151	

¹⁰ 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

¹¹ Total number of holdings of one category of poultry in concerned NUTS 2 region.

¹² Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening turkeys

Region (NUTS-2) ¹³	Total number of holdings ¹⁴	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ¹⁵
SPAIN	663	60	10	600	600	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				250	50	PCR test
SPAIN					3	Virus isolation test
TOTAL				850	803	

¹³ 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

¹⁴ Total number of holdings of one category of poultry in concerned NUTS 2 region.

¹⁵ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Farmed game birds (gallinaceous)

Region (NUTS-2) ¹⁶	Total number of holdings ¹⁷	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ¹⁸
SPAIN	286	60	10	600	600	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				250	50	PCR test
TOTAL				850	950	

¹⁶ 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

¹⁷ Total number of holdings of one category of poultry in concerned NUTS 2 region.

¹⁸ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Other please specify here: quails

Region (NUTS-2) ¹⁹	Total number of holdings ²⁰	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ²¹
SPAIN	101	80	20	1600	1600	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				400	80	PCR test
TOTAL				2000	2280	

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)

¹⁹ 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

²⁰ Total number of holdings of one category of poultry in concerned NUTS 2 region.

²¹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Chicken breeders

No representation

Farmed game (waterfowl)

No representation

Ratites

No representation

Broilers (only when at risk)

No representation

Backyard flocks

No representation

Totals	Total number of tests	Total number of samples
Total poultry 2025	6.274	5.880

Table 1b: DUCKS, GEESE AND FARMED GAME BIRDS (WATERFOWL eg. MALLARD) HOLDING²² to be sampled (insert as appropriate for the programme)

Duck breeders

Region (NUTS-2) ²³	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 ²⁴
SPAIN	6	6	20	120	120	ELISA test
SPAIN				0	50	HI-test (H5)
SPAIN				0	25	HI-test (H7)
SPAIN				60	12	PCR test
TOTAL				180	207	

²² Holdings or herds or flocks or establishments as appropriate.

²³ 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

²⁴ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening ducks

Region (NUTS-2) ²⁵	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 ²⁶
SPAIN	46	46	20	920	920	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				300	60	PCR test
SPAIN					2	Virus isolation test
TOTAL				1220	1582	

²⁵ 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

²⁶ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Geese breeders

Region (NUTS-2) ²⁷	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 ²⁸
SPAIN	6	6	20	120	120	ELISA test
SPAIN					50	HI-test (H5)
SPAIN					25	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				150	201	

²⁷ 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 ²⁸ Please choose between: **ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test**

Fattening geese

Region (NUTS-2) ²⁹	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 ³⁰
SPAIN	13	13	20	260	260	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				150	30	PCR test
TOTAL				410	593	

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)

Farmed game (waterfowl eg. Mallards)

No representation

Other please specify here _____

²⁹ 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

³⁰ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Totals	Total number of tests	Total number of samples
Total ducks and geese and farmed game birds 2025	2.580	1.960

TOTALS for Poultry (Table 1a) & Ducks and Geese (Table 1b) and farmed game birds for year: 2025

Poultry & Ducks/Geese/farmed game birds	Total number of tests
Grand Total	8.854
Grand Total ELISA	6.120
Grant Total agar	0
Grand Total HI tests (H5)	1.590
Grant Total HI tests (H7)	795
Grant Total Virus Isolation test	5
Grant Total PCR test	344
Grant Total Sampling	7.840

Table 1c: WILD BIRDS focussed on target species

Targets for year: 2025

Region (NUTS-2) ³¹	Total number of wild birds to be sampled	Estimated total number of wild birds to be sampled for passive surveillance	Type of test ³²	Number of tests
SPAIN	3.000	3.000	PCR	6.000
SPAIN			VIRUS ISOLATION TEST	100
TOTAL	3.000	3.000		6.100

	Total number of tests
Total number of tests	6.100
Total Virus isolation tests	100
Total PCR tests	6.000

³¹ 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.

³² Please choose between: Virus isolation test, PCR test, Other please specify here

Total Other tests	0
Total number of wild birds to be sampled for passive surveillance	3.000

II. History of disease outbreaks

Table 2: Poultry and wild birds' outbreaks

Outbreaks								
Year	Poultry (N	Iº holdings)	Wild birds (Nº birds)					
	Checked	cked Positive		Positive				
2024	No data available until 05.2024	0	No data available until 05.2024	1 (until 05.2024)				
2023	543	1	2.748	52				
2022	695	37	3.040	149				
2021	735	0	1.225	2				
2020	668	0	711	1				

III. Implementation of applicable rules and regulation

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE DETECTION AND ELIMINATION OF THE DISEASE)

EU countries

Implementation of applicable regulations - please tick the box as appropriate. In case of deviations, please describe / justify.

•				• • • •
1.	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, pp. 1-208)	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):
2.	Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, pp. 64-139).	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):
3.	Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system (OJ L 412, 8.12.2020, pp. 1-28).	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):
4.	Commission Implementing Regulation (EU) 2020/690 of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established (OJ L 174, 3.6.2020, pp. 341-344)	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):
5.	Commission Delegated Regulation (EU) 2020/689 on 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the	Yes ⊠	No □	Description of deviation/Justification (when relevant):

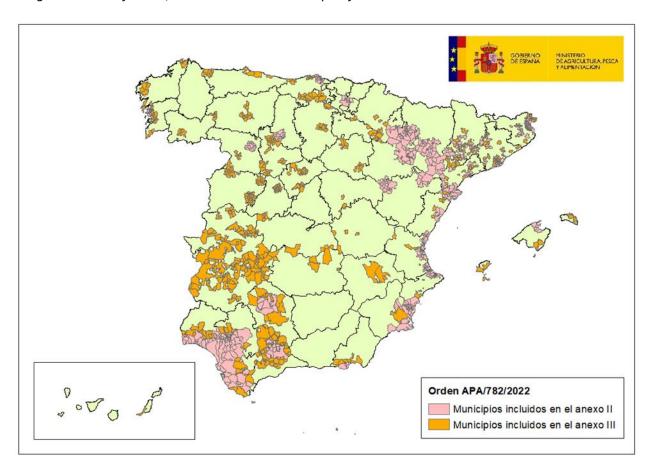
Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211–340)

IV. Maps (as relevant) Nº of holdings per types or categories and Autonomous Community. May 2024 -for 2025 IA Program

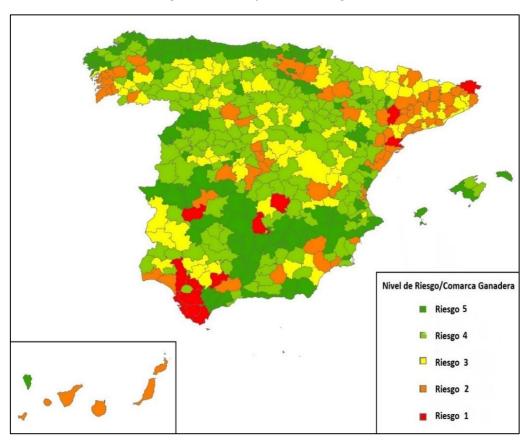
CCAA	Layin hens	Free range laying hens	Fattening turkeys	Breeding turkeys	Farm gallinaceous (game birds)	Quails	Fattening ducks	Breeding ducks	Fattening geese	Breeding geese
Andalucía	63	80	327	4	56	4	1	0	2	0
Aragón	34	26	24	0	6	9	1	0	0	0
Asturias	11	6	0	0	0	0	0	0	0	0
Baleares	3	40	0	0	2	0	0	0	0	0
Canarias	127	38	0	0	3	4	0	0	0	0
Cantabria	7	14	0	0	1	1	0	0	0	0
Castilla La Mancha	176	70	7	0	52	3	2	0	0	0
Castilla y León	65	92	29	0	38	18	6	2	3	6
Cataluña	106	114	105	6	36	49	13	1	2	0
Extremadura	5	21	26	0	41	6	0	0	2	0
Galicia	24	64	58	0	5	2	1	0	3	0
Madrid	8	5	0	0	8	1	0	0	1	0
Murcia	15	8	17	0	8	0	0	0	0	0
Navarra	9	17	0	0	10	2	20	2	0	0
País Vasco	17	71	0	0	3	2	1	1	0	0

La Rioja	8	2	0	0	4	0	0	0	0	0
Valencia	58	35	70	0	13	0	1	0	0	0
Ceuta										
Melilla										
TOTAL	736	703	663	10	286	101	46	6	13	6

Zones at special risk, updated in 2022 through Orden APA/782/2022, that modified Order APA/2442/2006, from 27th of July, that provides specific protection measures against avian influenza, and it is shown in the map as follows:



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



I. Baseline population data and targets for 2026

Table 1a: Poultry holdings³³ (except ducks, geese and farmed game birds (waterfowl eg. Mallards) to be sampled (insert as appropriate for the programme)

Laying hens

Region (NUTS-2) ³⁴	Total number of holdings ³⁵	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ³⁶
SPAIN	736	60	20	1200	1200	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				150	30	PCR test
TOTAL				1350	1380	

³³ Holdings or herds or flocks or establishments as appropriate.

³⁴ 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

³⁵ Total number of holdings of one category of poultry in concerned NUTS 2 region.

³⁶ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Free range laying hens

Region (NUTS-2) ³⁷	Total number of holdings ³⁸	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ³⁹
SPAIN	703	60	10	600	600	ELISA test
SPAIN					60	HI-test (H5)
SPAIN					30	HI-test (H7)
SPAIN				100	20	PCR test
TOTAL				700	710	

³⁷ 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

³⁸ Total number of holdings of one category of poultry in concerned NUTS 2 region.

³⁹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Turkey breeders

Region (NUTS-2) ⁴⁰	Total number of holdings ⁴¹	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁴²
SPAIN	10	10	10	100	100	ELISA test
SPAIN					30	HI-test (H5)
SPAIN					15	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				130	151	

⁴⁰ 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

⁴¹ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁴² Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening turkeys

Region (NUTS-2) ⁴³	Total number of holdings ⁴⁴	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁴⁵
SPAIN	663	60	10	600	600	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				250	50	PCR test
SPAIN					3	Virus isolation test
TOTAL				850	803	

⁴³ 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

⁴⁴ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁴⁵ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Farmed game birds (gallinaceous)

Region (NUTS-2) ⁴⁶	Total number of holdings ⁴⁷	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁴⁸
SPAIN	286	60	10	600	600	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				250	50	PCR test
TOTAL				850	950	

⁴⁶ 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

⁴⁷ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁴⁸ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Other please specify here: quails

Region (NUTS-2) ⁴⁹	Total number of holdings ⁵⁰	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁵¹
SPAIN	101	80	20	1600	1600	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				400	80	PCR test
TOTAL				2000	2280	

⁴⁹ 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

⁵⁰ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁵¹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Chicken breeders

No representation

Farmed game (waterfowl)

No representation

Ratites

No representation

Broilers (only when at risk)

No representation

Backyard flocks

No representation

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)

Totals Total number of tests		Total number of samples		
Total poultry 2026	6.274	5.880		

Table 1b: DUCKS, GEESE AND FARMED GAME BIRDS (WATERFOWL eg. MALLARD) HOLDING⁵² to be sampled (insert as appropriate for the programme)

Duck breeders

Region (NUTS-2) ⁵³	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 ⁵⁴
SPAIN	6	6	20	120	120	ELISA test
SPAIN				0	50	HI-test (H5)
SPAIN				0	25	HI-test (H7)
SPAIN				60	12	PCR test
TOTAL				180	207	

⁵² Holdings or herds or flocks or establishments as appropriate.

⁵³ 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

⁵⁴ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening ducks

Region (NUTS-2) ⁵⁵	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 ⁵⁶
SPAIN	46	46	20	920	920	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				300	60	PCR test
SPAIN					2	Virus isolation test
TOTAL				1220	1582	

⁵⁵ 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

⁵⁶ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Geese breeders

Region (NUTS-2) ⁵⁷	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 ⁵⁸
SPAIN	6	6	20	120	120	ELISA test
SPAIN					50	HI-test (H5)
SPAIN					25	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				150	201	

⁵⁷ 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

⁵⁸ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening geese

Region (NUTS-2) ⁵⁹	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 ⁶⁰
SPAIN	13	13	20	260	260	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				150	30	PCR test
SPAIN					3	Virus isolation test
TOTAL				410	593	

Farmed game (waterfowl eg. Mallards)

No representation

Other please specify here _____

⁵⁹ 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

⁶⁰ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

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)

Totals	Total number of tests	Total number of samples
Total ducks and geese and farmed game birds 2026	2.580	1.960

TOTALS for Poultry (Table 1a) & Ducks and Geese (Table 1b) and farmed game birds for year: 2026

Poultry & Ducks/Geese/farmed game birds	Total number of tests
Grand Total	8.854
Grand Total ELISA	6.120
Grant Total agar	0
Grand Total HI tests (H5)	1.590
Grant Total HI tests (H7)	795
Grant Total Virus Isolation test	5

Grant Total PCR test	344
Grant Total Sampling	7.840

Table 1c: WILD BIRDS focussed on target species

Targets for year: 2026

Region (NUTS-2) ⁶¹	Total number of wild birds to be sampled	Estimated total number of wild birds to be sampled for passive surveillance	Type of test ⁶²	Number of tests
SPAIN	3.000	3.000	PCR	6.000
SPAIN			VIRUS ISOLATION TEST	100
TOTAL	3.000	3.000		6.100

	Total number of tests
Total number of tests	6.100

⁶¹ 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.

⁶² Please choose between: Virus isolation test, PCR test, Other please specify here

Total Virus isolation tests	100
Total PCR tests	6.000
Total Other tests	0
Total number of wild birds to be sampled for passive surveillance	3.000

II. History of disease outbreaks

Table 2: Poultry and wild birds' outbreaks

	Outbreaks										
Year	Poultry (N	Iº holdings)	Wild birds (Nº birds)								
	Checked	Positive	Examined	Positive							
2024	No data available until 05.2024	0	No data available until 05.2024	1 (until 05.2024)							
2023	543	1	2.748	52							
2022	695	37	3.040	149							

2021	735	0	1.225	2
2020	668	0	711	1

III. Implementation of applicable rules and regulation

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE DETECTION AND ELIMINATION OF THE DISEASE)

EU countries

Implementation of applicable regulations - please tick the box as appropriate. In case of deviations, please describe / justify.

6.	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, pp. 1-208)	Yes ⊠ No □	Description of deviation/Justification (when relevant):
7.	Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, pp. 64-139).	Yes ⊠ No □	Description of deviation/Justification (when relevant):
8.	Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system (OJ L 412, 8.12.2020, pp. 1-28).	Yes ⊠ No □	Description of deviation/Justification (when relevant):
9.	Commission Implementing Regulation (EU) 2020/690 of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union	Yes ⊠ No □	Description of deviation/Justification (when relevant):

	surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established (OJ L 174, 3.6.2020, pp. 341-344)		
10.	Commission Delegated Regulation (EU) 2020/689 on 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211–340)	No 🗆	Description of deviation/Justification (when relevant):

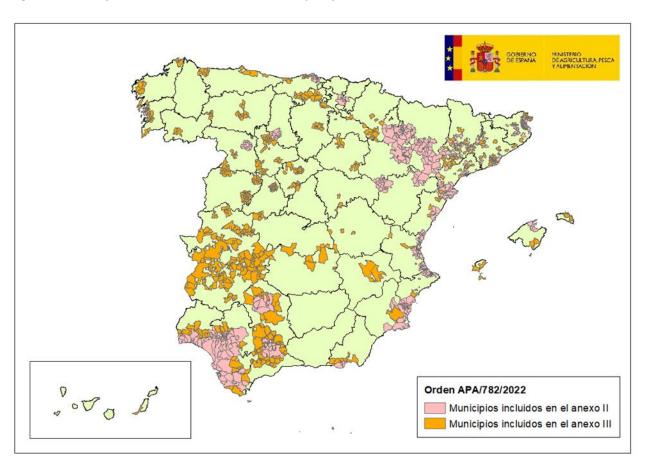
IV. Maps (as relevant)

Nº of holdings per types or categories and Autonomous Community. May 2024 -for 2026 IA Program

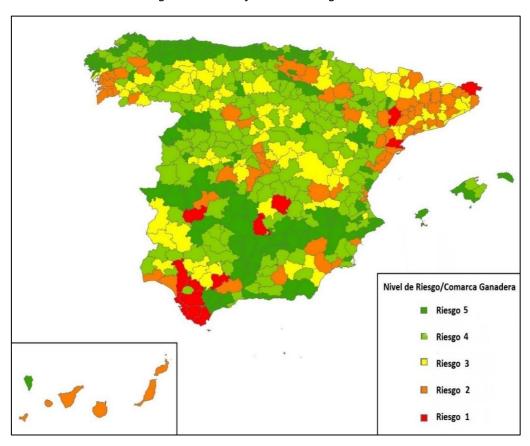
CCAA	Layin hens	Free range laying hens	Fattening turkeys	Breeding turkeys	Farm gallinaceous (game birds)	Quails	Fattening ducks	Breeding ducks	Fattening geese	Breeding geese
Andalucía	63	80	327	4	56	4	1	0	2	0
Aragón	34	26	24	0	6	9	1	0	0	0
Asturias	11	6	0	0	0	0	0	0	0	0
Baleares	3	40	0	0	2	0	0	0	0	0
Canarias	127	38	0	0	3	4	0	0	0	0
Cantabria	7	14	0	0	1	1	0	0	0	0
Castilla La Mancha	176	70	7	0	52	3	2	0	0	0
Castilla y León	65	92	29	0	38	18	6	2	3	6
Cataluña	106	114	105	6	36	49	13	1	2	0
Extremadura	5	21	26	0	41	6	0	0	2	0

Galicia	24	64	58	0	5	2	1	0	3	0
Madrid	8	5	0	0	8	1	0	0	1	0
Murcia	15	8	17	0	8	0	0	0	0	0
Navarra	9	17	0	0	10	2	20	2	0	0
País Vasco	17	71	0	0	3	2	1	1	0	0
La Rioja	8	2	0	0	4	0	0	0	0	0
Valencia	58	35	70	0	13	0	1	0	0	0
Ceuta										
Melilla										
TOTAL	736	703	663	10	286	101	46	6	13	6

ones at special risk, updated in 2022 through Orden APA/782/2022, that modified Order APA/2442/2006, from 27th of July, that provides specific protection measures against avian influenza, and it is shown in the map as follows:



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



I. Baseline population data and targets for 2027

Table 1a: Poultry holdings⁶³ (except ducks, geese and farmed game birds (waterfowl eg. Mallards) to be sampled (insert as appropriate for the programme)

Laying hens

Region (NUTS-2) ⁶⁴	Total number of holdings ⁶⁵	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁶⁶
SPAIN	736	60	20	1200	1200	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				150	30	PCR test
TOTAL				1350	1380	

⁶³ Holdings or herds or flocks or establishments as appropriate.

⁶⁴ 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

⁶⁵ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁶⁶ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Free range laying hens

Region (NUTS-2) ⁶⁷	Total number of holdings ⁶⁸	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁶⁹
SPAIN	703	60	10	600	600	ELISA test
SPAIN					60	HI-test (H5)
SPAIN					30	HI-test (H7)
SPAIN				100	20	PCR test
TOTAL				700	710	

⁶⁷ 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

⁶⁸ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁶⁹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Turkey breeders

Region (NUTS-2) ⁷⁰	Total number of holdings ⁷¹	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁷²
SPAIN	10	10	10	100	100	ELISA test
SPAIN					30	HI-test (H5)
SPAIN					15	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				130	151	

⁷⁰ 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

⁷¹ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁷² Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening turkeys

Region (NUTS-2) ⁷³	Total number of holdings ⁷⁴	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁷⁵
SPAIN	663	60	10	600	600	ELISA test
SPAIN					100	HI-test (H5)
SPAIN					50	HI-test (H7)
SPAIN				250	50	PCR test
SPAIN					3	Virus isolation test
TOTAL				850	803	

⁷³ 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

⁷⁴ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁷⁵ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Farmed game birds (gallinaceous)

Region (NUTS-2) ⁷⁶	Total number of holdings ⁷⁷	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁷⁸
SPAIN	286	60	10	600	600	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				250	50	PCR test
TOTAL				850	950	

⁷⁶ 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

⁷⁷ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁷⁸ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Other please specify here: quails

Region (NUTS-2) ⁷⁹	Total number of holdings ⁸⁰	Total number of holdings to be sampled	Number of samples per holding	Total number of samples	Total number of tests	Method of laboratory analysis ⁸¹
SPAIN	101	80	20	1600	1600	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				400	80	PCR test
TOTAL				2000	2280	

⁷⁹ 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

⁸⁰ Total number of holdings of one category of poultry in concerned NUTS 2 region.

⁸¹ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Chicken breeders

No representation

Farmed game (waterfowl)

No representation

Ratites

No representation

Broilers (only when at risk)

No representation

Backyard flocks

No representation

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)

Totals Total number of tests		Total number of samples		
Total poultry 2027	6.274	5.880		

Table 1b: DUCKS, GEESE AND FARMED GAME BIRDS (WATERFOWL eg. MALLARD) HOLDING⁸² to be sampled (insert as appropriate for the programme)

Duck breeders

Region (NUTS-2) ⁸³	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 ⁸⁴
SPAIN	6	6	20	120	120	ELISA test
SPAIN				0	50	HI-test (H5)
SPAIN				0	25	HI-test (H7)
SPAIN				60	12	PCR test
TOTAL				180	207	

⁸² Holdings or herds or flocks or establishments as appropriate.

⁸³ 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

⁸⁴ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening ducks

Region (NUTS-2) ⁸⁵	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 ⁸⁶
SPAIN	46	46	20	920	920	ELISA test
SPAIN					400	HI-test (H5)
SPAIN					200	HI-test (H7)
SPAIN				300	60	PCR test
SPAIN					2	Virus isolation test
TOTAL				1220	1582	

⁸⁵ 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 ⁸⁶ Please choose between: **ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test**

Geese breeders

Region (NUTS-2) ⁸⁷	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 ⁸⁸
SPAIN	6	6	20	120	120	ELISA test
SPAIN					50	HI-test (H5)
SPAIN					25	HI-test (H7)
SPAIN				30	6	PCR test
TOTAL				150	201	

⁸⁷ 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

⁸⁸ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Fattening geese

Region (NUTS-2) ⁸⁹	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 ⁹⁰
SPAIN	13	13	20	260	260	ELISA test
SPAIN					200	HI-test (H5)
SPAIN					100	HI-test (H7)
SPAIN				150	30	PCR test
SPAIN					3	Virus isolation test
TOTAL				410	593	

Farmed game (waterfowl eg. Mallards)

No representation

⁸⁹ 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

⁹⁰ Please choose between: ELISA test, agar gel immune diffusion test, HI-test (H5), HI-test (H7), Virus isolation test, PCR test

Other please specify here	
---------------------------	--

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)

Totals	Total number of tests	Total number of samples
Total ducks and geese and farmed game birds 2027	2.580	1.960

TOTALS for Poultry (Table 1a) & Ducks and Geese (Table 1b) and farmed game birds for year: 2027

Poultry & Ducks/Geese/farmed game birds	Total number of tests
Grand Total	8.854
Grand Total ELISA	6.120
Grant Total agar	0
Grand Total HI tests (H5)	1.590
Grant Total HI tests (H7)	795

Grant Total Virus Isolation test	5
Grant Total PCR test	344
Grant Total Sampling	7.840

Table 1c: WILD BIRDS focussed on target species

Targets for year: 2027

Region (NUTS-2) ⁹¹	Total number of wild birds to be sampled	Estimated total number of wild birds to be sampled for passive surveillance	Type of test ⁹²	Number of tests
SPAIN	3.000	3.000	PCR	6.000
SPAIN			VIRUS ISOLATION TEST	100
TOTAL	3.000	3.000		6.100

	Total number of tests
Total number of tests	6.100

⁹¹ 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.

⁹² Please choose between: Virus isolation test, PCR test, Other please specify here

Total Virus isolation tests	100
Total PCR tests	6.000
Total Other tests	0
Total number of wild birds to be sampled for passive surveillance	3.000

II. History of disease outbreaks

Table 2: Poultry and wild birds' outbreaks

	Outbreaks						
Year	Poultry (Nº holdings)		Wild birds (Nº birds)				
	Checked	Positive	Examined	Positive			
2024	No data available until 05.2024	0	No data available until 05.2024	1 (until 05.2024)			
2023	543	1	2.748	52			
2022	695	37	3.040	149			

2021	735	0	1.225	2
2020	668	0	711	1

III. Implementation of applicable rules and regulation

(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE DETECTION AND ELIMINATION OF THE DISEASE)

EU countries

Implementation of applicable regulations - please tick the box as appropriate. In case of deviations, please describe / justify.

11.	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, pp. 1-208)	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):
12.	Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, pp. 64-139).		No □	Description of deviation/Justification (when relevant):
13.	Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system (OJ L 412, 8.12.2020, pp. 1-28).	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):

14.	Commission Implementing Regulation (EU) 2020/690 of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to Union surveillance programmes, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established (OJ L 174, 3.6.2020, pp. 341-344)	Yes ⊠	No □	Description of deviation/Justification (when relevant):
15.	Commission Delegated Regulation (EU) 2020/689 on 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211–340)	Yes ⊠	No 🗆	Description of deviation/Justification (when relevant):

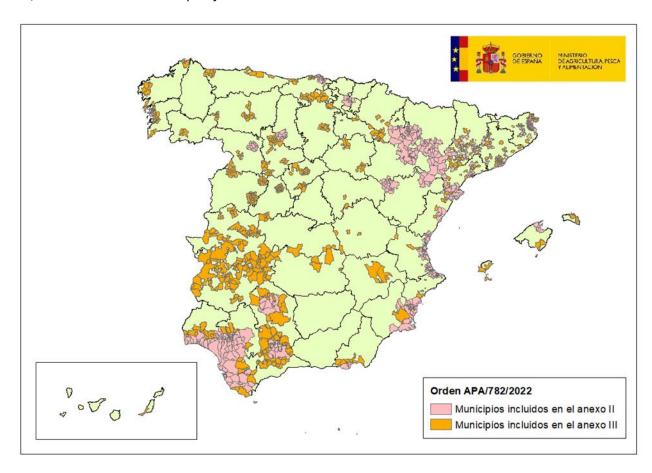
IV. Maps (as relevant)

Nº of holdings per types or categories and Autonomous Community. May 2024 -for 2027 IA Program

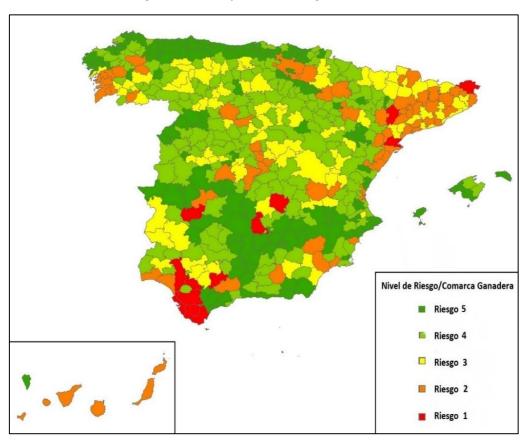
CCAA	Layin hens	Free range laying hens	Fattening turkeys	Breeding turkeys	Farm gallinaceous (game birds)	Quails	Fattening ducks	Breeding ducks	Fattening geese	Breeding geese
Andalucía	63	80	327	4	56	4	1	0	2	0
Aragón	34	26	24	0	6	9	1	0	0	0
Asturias	11	6	0	0	0	0	0	0	0	0
Baleares	3	40	0	0	2	0	0	0	0	0
Canarias	127	38	0	0	3	4	0	0	0	0
Cantabria	7	14	0	0	1	1	0	0	0	0
Castilla La Mancha	176	70	7	0	52	3	2	0	0	0
Castilla y León	65	92	29	0	38	18	6	2	3	6

Cataluña	106	114	105	6	36	49	13	1	2	0
Extremadura	5	21	26	0	41	6	0	0	2	0
Galicia	24	64	58	0	5	2	1	0	3	0
Madrid	8	5	0	0	8	1	0	0	1	0
Murcia	15	8	17	0	8	0	0	0	0	0
Navarra	9	17	0	0	10	2	20	2	0	0
País Vasco	17	71	0	0	3	2	1	1	0	0
La Rioja	8	2	0	0	4	0	0	0	0	0
Valencia	58	35	70	0	13	0	1	0	0	0
Ceuta										
Melilla										
TOTAL	736	703	663	10	286	101	46	6	13	6

Zones at special risk, updated in 2022 through Orden APA/782/2022, that modified Order APA/2442/2006, from 27th of July, that provides specific protection measures against avian influenza, and it is shown in the map as follows:



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







Single Market Programme (SMP Food)

EU co-funded BSE programme for years 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Bovine Spongiform Encephalopathy Programme Surveillance, Control and Eradication programme

Countries seeking an EU financial contribution for the implementation of national programmes for eradication, control and/or surveillance of animal diseases and zoonosis shall submit this Form (Annex 1 - Description of the action (part B)) completely filled in, by the 31 May of the year preceding its implementation (Part 2.1 of Annex I to the Single Market Programme Regulation). Applicant shall provide information on each question contained in the Form. The information filled in the Form, shall be clear, concise, consistent and complete.

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	BOVINE SPONGIFORM ENCEPHALOPATHY
Animal population/Species	Bovine animals
Implementation Year	2025-2027

CONTACT PERSON on BSE programme:

Name	ESTHER PRIETO CABALLERO
e-mail	meprieto@mapa.es
Job type within the CA	HEAD OF SERVICE OF VETERINARY PROGRAMES

Bovine Spongiform Encephalopathy Programme 2025-2027

1.RELEVANCE

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

the EU legislation will be implemented during its entire period of approval, in particular:
- Regulation (EC) No 999/2001 of 22 May 2001 (latest consolidated version 1 January 2023) laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalonathies

By submitting this programme, the Member State (MS) attests that the relevant provisions of

Spongii	orni checphalopatines		
Yes ⊠	No □		
If no, pl	ease explain:		
			(
			(maximum 200 characters)

1.2 Needs and specific objectives

Please give a short description of the programme

This programme has a dual objective:

- to monitor the epidemiological situation in cattle population in relation to BSE, and
- to detect the presence of BSE disease and, when necessary, implement the appropriate control and eradication measures.

For the period 2025-2027 the specific objective for the BSE programme is to continue to comply with requirements in order to maintain Spain's classification as a country with negligible BSE risk status, achieved in 2016.

(maximum 500 characters)

1.3 Complementarity with other actions — European added value

Explain how the project builds on the results of past activities carried out in the field. Illustrate the European dimension of the activities: MS follow different testing scheme for bovine animals coming from MSs not listed or from third countries, does MS implement other mitigate measures to minimize the risk, react promptly following suspicion and/or confirmation, etc.

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

Reference can be made that the programme implements Regulation (EC) No 999/2001

The surveillance programme has been updated and modified, according to the regulatory requirements.

Bovine Spongiform Encephalopathy (BSE) is a TSE disease of cattle. BSE was first diagnosed in the UK in 1986 and reached epidemic.

The Commission introduced the first EU legislation on BSE in July 1989. By the middle of 1990, basic EU legislation on BSE was in place. Today, Regulation (EC) No 999/2001 ("the TSE Regulation") forms the legal basis for almost all legislative actions on TSEs. It gathers together all BSE measures adopted over the years into a framework consolidating and updating them in line with scientific evidence and international standards.

The main provisions of the TSE Regulation can be summarised as follows: Monitoring, Feed ban, Removal of Specified Risk Material (SRM) BSE status Classification: negligible risk, controlled risk and undetermined risk. Control and Eradication of TSEs. Placing on the market, export and import.

Monitoring conducted in Spain, provided for in Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals, has been changing on several occasions to adapt it to new scientific knowledge on the subject and to Community rules. This approach of gradual changes to the monitoring programme has made it possible to steadily raise the age of cattle for compulsory sampling. This explains the slight but continuous reduction in the number of BSE tests carried out, which was particularly marked in 2014, following the decision to stop sampling healthy cattle slaughtered for human consumption.

The main changes to relax the rules on BSE monitoring in Spain were introduced on 4 June 2009, following publication of the amendment to the Spanish Royal Decree to bring it into line with Decision 2008/908/EU (repealed by Decision 2009/719/EC) authorising certain Member States to revise their annual BSE monitoring programmes, including Spain.

Since then, the successive amendments to Decision 2009/719/EC have been transposed into Spanish law to continue raising the age of cattle for compulsory sampling.

The most recent amendment was adopted by the Commission Implementing Decision of 4 February 2013 (Decision 2013/76/EC), authorising certain Member States to stop active BSE monitoring in healthy animals slaughtered in slaughterhouses. This and other measures to relax the rules are set out in Order PRE/1550/2013, which has been in force in Spain since 14 August 2013.

SPAIN, as the other MS, must carry out an annual monitoring programme for TSEs based on active surveillance and passive surveillance. The monitoring programme provides a reliable insight into the prevalence and evolution of TSEs in the MS and at the same time ensures that no BSE cases are being slaughtered for human consumption.

The active surveillance covers testing of two categories of bovine animals:

The results of this surveillance programme are useful for other countries. Spain as MS carries out **an annual report** on the monitoring and testing for the presence of TSEs to provide an overview of the monitoring results and epidemiology of TSEs, which assists the development of policy for the protection of human and animal health. In this report, it can be observed the trend analysis for the time series 2002-2022 which shows that the decline is significant for the

whole series. Mantel test for trend p< 0,001 (Abramson, J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6.

(maximum 500 characters)

1.4 Target population and Area of the implementation

This programme will be implemented on bovine animals. Please specify groups: healthy/risk/age groups.

Please specify age limit for testing of suspect bovine animals.

The categories of bovine animals to be submitted for BSE testing are defined in the TSE Regulation and are based on a combination of age (age limits have been changed over time) and surveillance target groups:

- 1. Risk animals: 48 months animals from Member States (MS) authorised to review their programme and 24 months when coming from MS not authorised to review their programme. We include 3 categories:
 - a. Emergency slaughter.
 - b. Animals with clinical signs ante-mortem.
 - c. Fallen stock.

2. Other categories:

- a. Healthy slaughtered: Born before 2001 and coming from herds with BSE positive cases.
 - b. Animals clinically suspected of being infected with BSE: no age limit.
 - c. Animals culled under BSE eradication measures: no age limit.

	(maximum 500 characters)
Fill in Table 1) in the Annex to this Form.	
Does the programme apply to the whole territory of the country?	
Yes x No □	
If no, please explain:	
	(maximum 500 characters)

1.5 Notification of BSE cases

Please explain the procedure in place as regards the notification of the disease – reference to the national legal basis.

Please confirm that confirmed cases of BSE are reported to the EC and other MSs in accordance with Regulation 999/2001.

BSE disease is officially declared in accordance with Royal Decree 526/2014 that states the list of notifiable animal diseases and lays down the rules for reporting them.

Furthermore, this notification must be made via RASVE (a computer application), as laid down by the RASVE Committees and the specific working groups for the coordination and following-up of the Programme for Surveillance and Control of TSEs.

The owners or persons in charge of the animals and the veterinary official who attends the holding must, on the emergence of any of the clinical symptoms consistent with BSE, notify the Autonomous Community in order to implement the measures detailed in the section below on 'suspicion of disease'.

For each confirmed primary case (outbreak), the competent authority for animal health responsible for notification of the outbreak will send MAPA as soon as possible, and in any event within one month of confirmation of the outbreak, the following additional epidemiological information:

- Clinical symptoms (if any, and if it is a suspected case), e.g. decline in milk production, ataxia, weight loss, changes in behaviour, etc.
- vaccine type (meat/milk);
- indicate whether the positive case was confirmed on the holding or herd of birth (yes/no);
- herd type (meat/milk/mixed production purpose);
- Feed system during the first year of life, e.g., feed concentrate, mixed, grass, etc.
- If the cohort ate the same feed as the positive case: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- If there was an age cohort: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- If there was offspring: indicate whether samples were taken, the number of samples and the number of positive and negative results.
- Father data (if available): indicate whether samples were taken, the number of samples and the number of positive and negative results.
- Mother data (if available): indicate whether samples were taken, the number of samples and the number of positive and negative results.

This information is sent in accordance with Chapter B of Annex III to Regulation 999/2001, since each year the EFSA asks Member States that have declared positive BSE cases for this information, so that it can be included in the summary report on TSE trends and sources in the EU.

1.6. Measures following the suspicion and confirmation of a BSE case

Give a short description of the procedure – reference to the national legal basis.

Whenever TSE is suspected in a holding, the competent authority must be notified, and the holding must be put under official control including moving restrictions until the final testing results are available. If TSE is confirmed, the entire body of the animal concerned must be disposed of. An inquiry to identify all animals at risk of having TSE must be carried out. For BSE, all animals at risk must be culled and disposed of as well as the products derived from them.

()

National legal basis for measures following suspicion and confirmation: Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals.

SUSPECTED DISEASE.

An animal suspected of being caused by a TSE shall be considered as any live, sacrificed, or dead animal that presents or has presented neurological or behavioral abnormalities or a progressive deterioration of the general condition attributable to a disorder of the central nervous system, with respect to which No other diagnosis can be made on the basis of clinical examination, response to treatment, post-mortem examination, or ante- or post-mortem laboratory analysis. Any bovine subjected to a rapid diagnostic test for BSE with a positive result shall also be considered as suspected of being affected by BSE.

- The competent bodies of the Autonomous Communities, in the event of notification of suspicion, as well as in cases in which they have data that suggests the possible existence of the disease, will adopt the following measures:
- Verification visit by the Official Veterinary Services.
- Immediate isolation of suspected animals and immobilization of animals present on the affected farm.
- If the competent bodies of the Autonomous Communities could not rule out the existence of the disease, they will proceed to:
- Sacrifice of the suspected animal. If it has been suspected due to clinical symptoms, I send the tissues to the National Reference Laboratory (LNR) for analysis, as detailed in the Sample Collection Manual and its referral to the LNR.
- Sampling (in all other cases). In the event of death of the animal on the farm itself, samples will be taken in situ, or in places authorized for this purpose, provided that the optimal conditions for obtaining the sample are guaranteed in both cases.
- All parts of the body of the suspected animal, including the skin, will be kept under official surveillance in the manner determined by the competent bodies of the Autonomous Communities, until the diagnosis has been proven or until they have been hygienically destroyed by incineration. or other authorized method.

If the analytical results rule out the existence of the disease, the competent bodies of the Autonomous Communities will lift the isolation and immobilization measures of the farm.

When the suspicion occurs in the slaughterhouse during the ante-mortem inspection, action will be taken at the farm of origin of the animal following the guidelines defined above.

CONFIRMATION of a BSE case:

When the disease is confirmed by the National Reference Laboratory for TSEs (Algete NRL), the General Subdirectorate for Animal Health and Hygiene and Traceability will notify the competent authority of the CCAA in order to make the official declaration of the disease outside and proceed to carry out the epidemiological investigation and apply the focus eradication measures.

1 Official declaration of the disease.

It is carried out in accordance with point 1.5. of this document.

2 Epizootiology investigation.

When a BSE is diagnosed, an investigation will be carried out that should identify the following points:

- a) All other ruminants present on the farm where the animal in which the disease has been confirmed is kept.
- b) In cases in which the disease has been confirmed in a female, all her descendants, who have been born in the two previous years or after the clinical appearance of the disease.
- c) All animals of the same age group as the animal in which the disease has been confirmed. For these purposes, age group shall be understood as all bovines on the farm during the twelve months before or after the birth of the affected bovine and in the same herd as the latter, or that during their first twelve months of life were raised in some moment with an affected bovine and that it will be able to consume the same feed that the affected animal consumed during its first twelve months of life.

When possible, it will require:

- d) The possible origin of the disease.
- e) Other animals on the farm of the animal in which the disease has been confirmed or on other farms, which may have improved results due to the agent causing the TSE, due to having received the same thoughts or having been exposed to the same source of pollution.
- f) The circulation of possibly contaminated feed, other materials or any other means of transmission that may have transmitted the TSE agent to or from the farm in question.

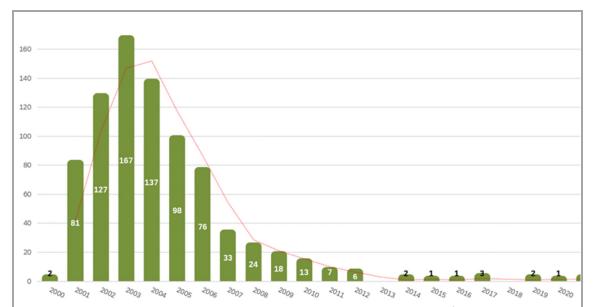
1.7 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of BSE cases.

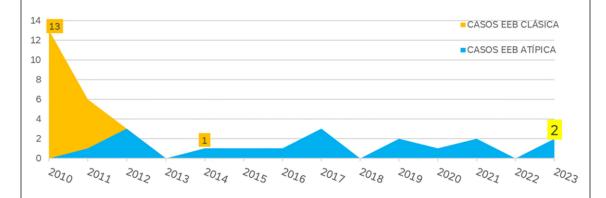
Total number of cases in the MS so far:

Number of cases during the last year	Total N	N of classical cases	N of atypical cases	N of undetermined cases
BSE	2	0	2	0

		, ,	Undetermined
BSE	25/07/2014	16/01/2024	
		(sample taken	
		24/12/2023)	



Since confirmation of the first case of BSE in Spain in 2000 to the date 23rd of may 2024, a total of **804** outbreaks (index case) were detected. Last case of classical BSE was detected in 2014. Since then , all outbreaks were atypical cases. (see graph 2)



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 2002-2023 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 like that of its appearance (a peak followed by a gradual reduction). The greatest proportion of the cases detected corresponds to animals born during the period 1995-1998, and the maximum number of positive animals were born in 1997.

We thus detect a period of seven years between the maximum births of cases testing positive for BSE (1997) and the year when the greatest number of cases of BSE were detected (2003).

Analysis of the average age of the cases detected shows that this has risen since surveillance began, from an average of 6,4 years of age to 15.9 years of age (the average in 2016) with a peak average age of 22,6 years in 2023. The most recent cases detected in 2023 and 2021 in

animals born in 2000 and 2008 were cases of atypical BSE, which should not be considered in the joint assessment of the average age of positive animals since their condition is not linked to the consumption of contaminated feed. In the risk analysis conducted to demonstrate the efficacy of the control measures, entering data that are not linked to those measures might skew the results obtained. However, given that the emergence of these cases in the EU is relatively recent and the European Commission has not set out guidelines for the independent notification of atypical strains, in Spain these positives are included in the assessment of the evolution of the disease until all the Member States reach a consensus on how they should be notified.



The last case of classical BSE was detected on 25th July 2014 (date of sampling) and the last case of atypical BSE was detected on 24th of December 2023) (date of sampling).

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 2002-2023 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 2003-2023 period remained low and constant and was concentrated in animals of advanced years. Bearing in mind that these results are similar in the other Member States studied, the data obtained reinforce the hypothesis that atypical BSE is a spontaneous, sporadic disease.
- In light of the favourable development of the epidemiological indicators, Spain asked the World Organisation for Animal Health (WOAH) to recognise it as a country with negligible BSE risk status. Our request was granted in May 2016 and that status will be maintained provided that the requirements giving rise to the request continue to be met.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

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

2.1.1 Targets monitoring and culling measures after detection of cases on bovine animals

Targets have been set up for

- the rapid testing on bovine animals based by age and risk group (Table 2 of the Annex)
- confirmatory testing other than rapid tests (Table 3 of the Annex)
- discriminatory tests (Table 4 of the Annex)
- culling/destroying bovine animals following suspicion and/or confirmation of a BSE case (Table 5 of the Annex)

If no, please describe.

Rapid testing targets:

	target surveillance group	ME authorised to review their program	ME no authorised to review their program ⁽¹⁾ + third countries ⁽²⁾	
၂၂	Emergency slaughter			
RISK ANIMAL	Antemorten sintomatology (different from BSE)	> 48 months	> 24 months	
	Fallen stock/ Not Slaughter for Human consumption			
OTHERS	Slaughter for Human consumption	Born before 2001 and coming from herds with BSE positive cases	> 30 months	
E	BSE Suspectos	no age limit	no age limit	
	Animals culled under BSE eradication measures	no age mint		

(1): Romania and Bulgary

(2) born or not in Great Britain and imported from Great Britain since 01/01/2021 are included

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.

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).

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B.2.- All animals of groups A1 and A2 specified above, whose sample has been positive or doubtful to rapid tests in authorized laboratories.

At all times, the animals described as TSE suspects will be submitted to control by means of methods and protocols of confirmation, established in the OIE Manual, in the National Reference Laboratory for TSEs (LCV).

confirmatory testing other than rapid tests: In case the result of the rapid tests performed is positive or doubtful, the sample will be referred for analysis by confirmatory testing to the National Reference Laboratory for TSEs (NRL).

- discriminatory tests: whenever a case of positive case is obtained, it will be necessary to
 discrimination of BSE strain that affects them, culling/destroying bovine animals
 following suspicion and/or confirmation of a BSE case
- culling/destroying bovine animals following suspicion and/or confirmation of a BSE case (Table 5 of the Annex)

In the case of confirming a BSE, or in the case of suspicion in which the presence of a TSE cannot be ruled out after carrying out the appropriate clinical, laboratory and/or ante-post mortem analyses, a sacrifice will be carried out. of total or selective eradication of the populations indicated below:

- a) All other bovines present on the farm where the animal in which the disease has been confirmed is kept.
- b) In cases in which the disease has been confirmed in a female, all her descendants, who have been born in the two previous years or after the clinical appearance of the disease.
- c) All animals of the same age group as the animal in which the disease has been confirmed.

However, with respect to the slaughter of all bovines present on the holding where the animal in which the disease has been confirmed is found, the competent authority may exempt the following animals from slaughter:

- i. All those who have joined the holding in question in the last twelve months prior to the appearance of the case, provided they came from another holding, as well as their possible offspring in said period.
- ii. In those farms in which the affected animal had entered the same during the last twelve months, the total slaughter of the bovine cattle present on the farm will not be carried out. In this case, the slaughter and complete destruction of at least the bovines indicated in sections b) and c) of point 1 must be carried out, as well as those animals that, since there is no perfect traceability, cannot be ruled out. their membership in these groups.

The competent authority may exempt from slaughter all bovines present on the farm where the animal in which the disease has been confirmed is kept, proceeding to eradicate it by selective slaughter.

In this case, and provided that identification and traceability is guaranteed through computer systems or birth records, the risk populations defined by the World Organization for Animal Health (the age group defined in Regulation 999 as well as all the offspring born in the last two

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years) will be slaughtered. Likewise, all those bovines in which perfect traceability cannot be guaranteed through computer systems or birth records will be slaughtered.

The reintroduction of animals on the farm will be carried out with prior authorization from the competent bodies of the Autonomous Communities.

Exception to sacrifice: Both for the immediate total and selective slaughter of the cohort of positive animals, the use in Spain of vulnerable bovines is authorized until the end of their productive life after official confirmation of the presence of BSE. Said exception may be applied with prior authorization from the Ministry of Agriculture, Fisheries and Food after analyzing whether the requirements contained in the Commission Implementing Decision of 15 March 2013 authorising the use of at-risk bovine animals until the end of their productive livesare met.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs) Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Central authority in charge of supervising and coordinating the departments responsible for implementing the programme.

• The **central authority** responsible for the coordination and follow-up of the departments responsible for carrying out the programme: the General Subdirection for Animal Health and Hygiene and Traceability (Ministry of Agriculture, Fisheries and Food — MAPA) is responsible for coordinating the programme and for informing the Commission concerning the development of this disease.

The 'National Committee for the Veterinary Health Alert System', set up under Royal Decree 1440/2001 of 21 December 2001 establishing the veterinary health alert system, is responsible for studying and proposing measures to eradicate diseases and monitoring the development of the epidemiological situation for diseases subject to eradication programmes. The committee is a collegiate body on which all the authorities responsible for coordinating and executing the measures planned in this Programme are represented.

• National Reference Laboratories: the following are recognised as National Reference Laboratories:

- a) Algete (Madrid): Central Veterinary Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for the diagnosis of Bovine Spongiform
- b) Food and Agriculture Arbitration Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for testing for the presence of animal products or remains, including meat and bone meal, in substances intended for feeding to production animals.

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

- Competent authorities at regional level: the Veterinary Services for Animal Health and Production, and for Public Health and Quality Control of Food and Agriculture in the Autonomous Communities, are responsible for implementing the Programme and compiling, evaluating and computerising the data obtained in their territory and sending it to the central authorities.
- Authorised or recognised laboratories: the competent authorities in the Autonomous Communities will designate laboratories located within their areas of jurisdiction to be responsible for the analytical monitoring of encephalopathies, including rapid post-mortem tests and the diagnostic techniques defined in the OIE's Diagnostics Manual and checks on the substances intended to feed production livestock. These laboratories may be public or private.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity¹ indicators) - please describe for different programme activities.

- e.g. all clinically suspect animals tested

Encephalopathy (BSE).

- tools applied to check/confirm that all bovine animals are tested based on the age group (relevant only for some MSs) (no bovine animals skipped the testing)

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

All rapid test positive results obtained by the approved official regional laboratories are contrasted and confirmed by the NRL. The NRL verifies the results of laboratory tests by performing comparative tests and harmonising methodological procedures and organisation and implement in-laboratory and inter-laboratory controls to the approved official regional laboratories participate in interlaboratory testing to validate their techniques, coordinated by the NRL.

On quarterly basis, the SGSHT monitors all data recorded in RASVE contrasting with all analysis realized by NRL (Algete) to supervise not only the accuracy of the data but also that monitoring by each Autonomous Community has been performed.

These results are presented and analysed once a year in RASVE Committee in April/May of the following year, in which the 17 Autonomous Communities and MAPA are involved, in order to identify the gaps detected and to try to fix them for the following programme. The results of the program are also shared with the national stakeholders' associations in a specific meeting after the results are endorsed by the RASVE Committee.

2.3.1 System for the registration of holdings

Give a short description of the system for the registration of holdings and identification of holdings. Please describe briefly the national procedure and reference to Reg 2016/429

Article 38(1) of Law 8/2003 of 24 April 2003 on animal health states that all livestock holdings must be registered in the Autonomous Community where they are located and that the basic information on those holdings is to be included in a national information register.

On that basis, Royal Decree 479/2004 of 26 March 2004 setting up and regulating the General Register of Livestock Holdings (REGA) was approved. It is a multi-species register containing data provided by each of the Autonomous Communities on all farms in Spain.

REGA is part of the Integrated Animal Traceability System (SITRAN) together with the Movements Register (REMO) and the Individual Animal Identification Register (RIIA), the legal basis for which is Royal Decree 728/2007 of 13 June 2007 setting up and regulating the General Register of Livestock Movements and the General Individual Animal Identification Register.

SITRAN is a heterogeneous and distributed database that feeds the records in the various Autonomous Communities into a centralised register, through specifically developed information exchange mechanisms.

Apart from Spanish legislation (in force) to mention EU legislation that supports it:

Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY
 AND DISPLACEMENT

Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

2.3.2 System for the identification of animals

Give a short description of the system for the identification of bovine animals

Royal Decree 1980/1998, of September 18, establishes a system of identification and registration of bovine animals, the elements that make up the identification system of this species are collected and consist of 2 ear tags with the same code (ear tags), a bovine identification document (DIB), a record book of the farm where the animal is located and a computerized database. In Spain, this database is called SITRAN, which is made up of the General Registry of Livestock Farms (REGA), the Individual Animal Identification Registry (RIIA) and the Movement Registry (REMO).

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Apart from Spanish legislation (in force) to mention EU legislation that supports it:

- Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT
- Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.

Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

2.3.3 Laboratory diagnosis

Describe laboratory protocol for testing on BSE (specify laboratory scheme for testing of different bovine categories - e.g. No of rapid tests used; specify laboratory protocol for confirmation of the disease)

TESTS TO BE CARRIED OUT FOR THE DIAGNOSIS OF BSE IN BOVINE SPECIES

1 RAPID DIAGNOSTIC TESTS

Those authorized for the bovine species in point 4 of Chapter C of Annex X of Regulation 999/2001 and its subsequent amendments are:

- ✓ dual functionality immunoassay (sandwich method) for the detection of PrPRes (short assay protocol), analyzed after a denaturation phase and a concentration phase (Bio-Rad TeSeE SAP Rapid test),
- ✓ immunoassay using a chemical polymer for selective capture of PrPSc and a monoclonal screening requirement directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA and HerdChek BSE-Scrapie Antigen (Idexx Laboratories)),
- ✓ Dual function immunoassays using two different monoclonal assays directed against two epitopes present in highly expanded bovine PrPSc (Roboscreen Beta Prion BSE EIA Test Kit),

2 CONFIRMATION TESTS.

All animals from surveillance groups whose result have been doubtful or positive, as well as all animals clinically suspected of being infected by BSE shall be immediately subjected to confirmation methods and protocols.

The confirmation methods will also be those authorized in Regulation 1148/2014, in accordance with the technical guidelines established in the WOHA Manual on diagnostic tests and vaccines, in its latest edition: immunohistochemistry, SAF immunotransfer or an alternative authorized by the WOHA, observation of the characteristic fibrils by electron microscopy, histopathological examination or combination of rapid diagnostic tests.

When the result of the histopathological examination is doubtful or negative, the tissues will be examined by one of the other confirmatory methods.

The samples for confirmation will be sent to the National Reference Laboratory (NRL) for TSEs (Central Veterinary Laboratory) where the techniques considered necessary to confirm or rule

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out the disease will be carried out. If the result of these confirmation methods is negative, the animal will be considered negative.

When the result of said analyzes is positive, the animal will be considered positive to BSE.

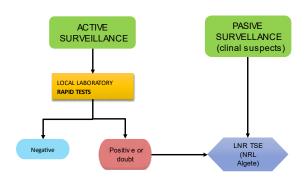
In the case of positive animals, it will be necessary to discriminate the BSE strain that affects them, classifying them as: Classic type BSE, Low type BSE (L) or High type BSE (H). This discrimination will be carried out at the NRL for TSEs (LCV), as a laboratory authorized by the EU Reference Laboratory (LR-UE), following the methods approved for this purpose.

Confirmation of suspected cases by rapid tests:

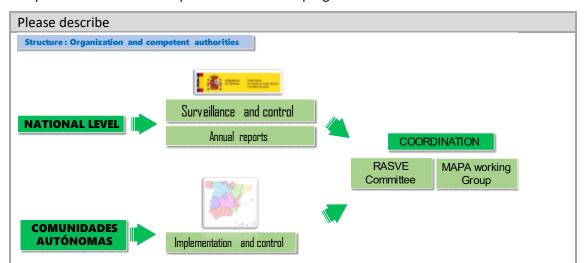
Rapid diagnostic tests may be used as a confirmatory method of BSE following the following guidelines issued by the Community Reference Laboratory (LR-UE):

- The confirmation is carried out in a National Reference Laboratory for TSE.
- One of the two rapid diagnostic tests have to be immunoblotting.
- The second rapid diagnostic test used:
 - o Include a negative control tissue and a BSE sample as a positive control tissue.
 - Is of a different type than the test used for primary screening.
- Whether the first rapid diagnostic test is immunoblotting, the result must be documented and submitted to the NRL.
- When the result of the primary screening is not confirmed by the subsequent diagnostic test, the sample must be subjected to another examination by one of the confirmation methods. In case of performing a histopathological examination and the result is negative or inconclusive or when the material has autolyzed, the tissues will be analyzed by one of the other confirmation methods.

The following flow chart shows the sample flow scheme to the NRL for TSEs:



2.3.4 System to monitor the implementation of the programme.



The Spanish State, represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and eradication program.

Spain submits all data and results obtained directly as eXtensible Markup Language (XML) files by using their own system for the automatic upload of data into the EFSA Data Collection Framework (DCF. The electronically submitted data is extracted from the RASVE database and further processed and validated to summarize the information.

The Autonomous Communities are responsible for the direct implementation and control of monitoring of the activities to be carried out under the programme. Data obtained is recorded in RASVE by the Autonomous Communities.

The information is thus subject to double review:

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On a quarterly basis, the Competent Authorities of the Autonomous Communities will record the following reports, collected in the **RASVE computer application** according to the following structure:

- **A)** Bovine monthly epidemiological surveillance: number of analyzes and positives found in the month of sampling. The deadline for completing the recording of these data will be 5 weeks after the end of the quarter in question. Information will be included in the following fields or subpopulations of animals:
- Bovine object of sacrifice for human consumption, that come from third countries or EU countries not authorized to review their BSE program, as well as for healthy bovines slaughtered for human consumption born before January 1st, 2001, and coming from holdings in which a case of BSE has been diagnosed.
- Emergency slaughter bovines.
- Cattle with clinical signs of some pathology in the ante-mortem inspection at the slaughterhouse (other than TSEs).
- Cattle slaughtered as a BSE eradication measure in application of Reg. 999/2001.
- Bovine slaughtered not for consumption and/or fallen stock.
- Suspected cattle: correspond to animals detected with clinical symptoms compatible with BSE.
- In relation to the animals slaughtered in campaigns to eradicate other diseases, they will be included in the subpopulation that corresponds to them based on the final destination of the carcasses of mentioned animals.

According to the European Commission guidelines derived from the conclusions of the Commission's TSE expert group, the analysis carried out on a bovine from Spain with a positive result in another MS will be recorded in the monthly epidemiological surveillance (with the criteria of sampling month) of the CCAA of origin, as long as it is shown that said AC is epidemiologically responsible.

B) Positive eradication cattle: all positive cases from eradication measures will be characterized. They will be recorded in the month corresponding to their sampling, and with the corresponding information after confirmation by the LNR.

The General Subdirectorate for Animal Health and Hygiene and Traceability (SGSHT)must be notified in writing of any incident related to the execution of epidemiological surveillance: among others, possible problems and incidents that may arise when sampling animals from a specific subpopulation.

With quarterly frequency, the SGSHT reviews all data recorded by Autonomous communities confronting data with results from NRL Algete.

On an annual basis, the SGSHT will request from the Autonomous Communities the additional epidemiological information required by EFSA for the preparation of the Annual Report on TSEs in the European Union, as established in Chapter B of Annex III of Regulation 999/2001.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
	Decrease of EU funding for 2025- 27. High risk	None
	Lack of reporting of suspects, inefficient passive surveillance. Low risk.	Continuous training and awareness campaigns aimed at the stakeholders(farmers) and private veterinarians.
		Transparent and constant risk-communication, update epidemiological situation reports. Maintain regular meetings with the sector

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

Name	Due date (in month)	Means of verification
Initiation of sampling and testing_1	8	Documentation on sampling and testing checks
Completion of sampling and testing_2	12	Documentation of the completion of the activities

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible example: eradication in general/or particular area

i.e. reference can be made that the programme implements Regulation (EC) No 999/2001

General benefits of BSE program are avoiding direct and indirect economic costs due to market losses and public investment.

Considering its **economic impact**, we classify under two aspects:

• Direct:

o Death and loss of production of affected animals. (short effect)

o Veterinary control and eradication measures on affected farms and affected natural spaces: sacrifices and expenses on sanitary programs. in the stage of eradication of the programme this aspect is nowadays limited. But we cannot forget the number of animals that were killed and disposed at the beginning of the control of this disease. (long – term effect)

Indirect

o Derived from trade restrictions imposed on affected countries. Not only that, in Spain, although last case of Classical BSE was on 2014 and we get the status of negigible risk that we maintain since 2016, but the declaration of atypical BSE cases also entails that some third countries impose export restrictions or do not open commercial trade with the country. (long – term effect)

On the other hand, from the point of view of **public health**, many epizootics are zoonoses that affect human health. Therefore, this is obvious in the case of this disease, that had in the early 2000 a big impact in public opinion. (Short effect)

Main target group in both (economic and public health aspects) are stakeholders, specifically farmers, and economic impact is the main one. But also, public administration (economic impact of policies and control programs for animal health but also for public health).

Moreover, we cannot forget environmental impact: Lost wildlife of endangered species can occur. CWD in wildlife has been diagnosed in the north of Europe. (long – term effect)

3.2 Communication, dissemination, and visibility

Communication, dissemination, and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

Communication and dissemination EU public:

Training programs

In order to raise awareness in sector as well as prompt notification of any suspected disease, it is necessary that veterinarians, farmers and other related professionals are well informed of the epidemiological situation, of the economic consequences for the sector, as well as of the possible options in the application of control and eradication measures financed by EU funding.

Meetings and information sessions

To raise the awareness and collaboration of these professionals, the CCAAs will organize meetings and information sessions. In this sense, all available information will be sent regularly for dissemination, ensuring an adequate flow of information in both directions on any incident related to this disease.

MAPA will collaborate with the Autonomous Communities by participating in Conferences whose objective will be the training of trainers. These conferences must be organized by the CCAAs and communicated to the MAPA sufficiently in advance.

Visibility

All information about BSE eradication program, including EU funding, is published in the web page of MAPA (https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/encefalopatias-espongiformes-transmisibles/EETs.aspx) which is regularly updated.

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

Sustainability and continuation:

Project should continue, especially the part of testing. This will be ensured and needs the sustain in long term by public funding. It is very important to get the support of farmers, not only in testing animals but also, and most important, in culling compensations measures. This always encourages farmers to communicate suspicion of diseases and collaborate in eradication measures.

Long-term impact: it is very important continuation of this program, specially testing of risk animals, in order to establish and maintain export agreements with third countries regarding meat and meat products of bovine as far as live animals for breeding. This programme grants a secure that adequate surveillance is carried out in order to maintain negligible risk of BSE granted by WOHA.

- I. Baseline population data
- II. Targets for 2025-2027
- III. Legal basis for the implementation of the programme
- IV. Maps (as relevant)

I. Baseline population data

Table 1 for year 2025: Bovine categories subject to the programme

	Number
Estimated population of bovine animals	6.429.973
Estimated population of bovine animals above (2) (4) years old	Bovines older than 24 months
	3.274.266
	Bovines older than 24 months and younger than 48 months
	984.380
	Bovines older than 48 months
	2.244.058

All cells shall be filled in with the best estimation available. The above data refer to 01/01/2024; **Source of the data**: SITRAN (Spanish Integrated Animal Traceability System) REPORT 2024

Table 1 for year 2026: Bovine categories subject to the programme

	Number
Estimated population of bovine animals	6.429.973
Estimated population of bovine animals above (2) (4) years old	Bovines older than 24 months
	3.274.266
	Bovines older than 24 months and younger than 48 months
	984.380

Bovines older than 48 months	
2.244.058	

All cells shall be filled in with the best estimation available. The above data refer to 01/01/2024; **Source of the data**: SITRAN (Spanish Integrated Animal Traceability System) REPORT 2024

Table 1 for year 2027: Bovine categories subject to the programme

	Number
Estimated population of bovine animals	6.429.973
Estimated population of bovine animals above (2) (4) years old	Bovines older than 24 months
, , , , , , , , , , , , , , , , , , ,	3.274.266
	Bovines older than 24 months and younger than 48 months
	984.380
	Bovines older than 48 months
	2.244.058

All cells shall be filled in with the best estimation available. The above data refer to 01/01/2024; **Source of the data**: SITRAN (Spanish Integrated Animal Traceability System) REPORT 2024

Baseline population and targets for 2025-2027

Table 2 for 2025: Targets on rapid tests on bovine animals

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests	Estimated number of rapid tests used for confirmation
Healthy slaughtered bovine animals born in MS listed in Annex to CD2009/719/EC	72	5	5	1
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	63000	63000	5
Healthy slaughtered bovine animals NOT born in MS listed in Annex to CD 2009/719/EC	30	20	20	2
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	10	10	1
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)	No limit age	5	5	1

Table 2 for 2026: Targets on rapid tests on bovine animals

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests	Estimated number of rapid tests used for confirmation
Healthy slaughtered bovine animals born in MS listed in Annex to CD2009/719/EC	72	5	5	1
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	63000	63000	5
Healthy slaughtered bovine animals NOT born in MS listed in Annex to CD 2009/719/EC	30	20	20	2
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	10	10	1
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)	No limit age	5	5	1

Table 2 for 2027: Targets on rapid tests on bovine animals

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests	Estimated number of rapid tests used for confirmation
Healthy slaughtered bovine animals born in MS listed in Annex to CD2009/719/EC	72	5	5	1
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	63000	63000	5
Healthy slaughtered bovine animals NOT born in MS listed in Annex to CD 2009/719/EC	30	20	20	2
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	10	10	1
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)	No limit age	5	5	1

Table 3 for 2025: Targets on confirmatory tests other than rapid tests as referred in Annex X Chapter C of Regulation (EC) No 999/2001

	Estimated number of tests
Confirmatory tests in Bovine animals	5

Table 3 for 2026: Targets on confirmatory tests other than rapid tests as referred in Annex X Chapter C of Regulation (EC) No 999/2001

	Estimated number of tests
Confirmatory tests in Bovine animals	5

Table 3 for 2027: Targets on confirmatory tests other than rapid tests as referred in Annex X Chapter C of Regulation (EC) No 999/2001

	Estimated number of tests
Confirmatory tests in Bovine animals	5

Table 4 for 2025: Targets on discriminatory tests (Annex X.C point 3.1 (c) and 3.2 Chapter (c) (i) of Regulation (EC) No 999/2001

	Estimated number of tests
Primary molecular testing on Bovine animals	4

Table 4 for 2026: Targets on discriminatory tests (Annex X.C point 3.1 (c) and 3.2 Chapter (c) (i) of Regulation (EC) No 999/2001

	Estimated number of tests
Primary molecular testing on Bovine animals	4

Table 4 for 2027: Targets on discriminatory tests (Annex X.C point 3.1 (c) and 3.2 Chapter (c) (i) of Regulation (EC) No 999/2001

	Estimated number of tests
Primary molecular testing on Bovine animals	4

Table 5 for 2025: Targets on culling/destroying bovine animals following suspicion and or confirmation of a BSE case

	Estimated number of culled/destroyed animals
Bovine animals culled and destroyed following suspicion	1
Bovine animals culled and destroyed following confirmation	6

Table 5 for 2026: Targets on culling/destroying bovine animals following suspicion and or confirmation of a BSE case

	Estimated number of culled/destroyed animals
Bovine animals culled and destroyed following suspicion	1
Bovine animals culled and destroyed following confirmation	6

Table 5 for 2027: Targets on culling/destroying bovine animals following suspicion and or confirmation of a BSE case

	Estimated number of culled/destroyed animals
Bovine animals culled and destroyed following suspicion	1
Bovine animals culled and destroyed following confirmation	6

II. Legal basis for the implementation of the programme)

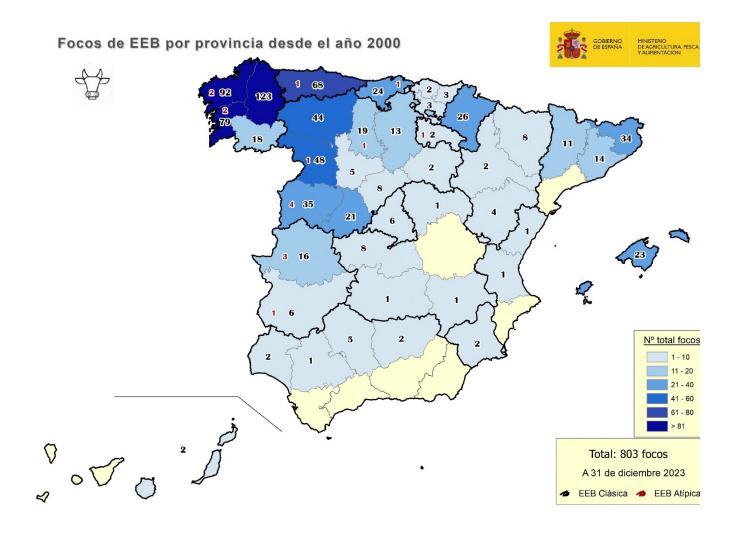
(TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

EU countries

• Regulation (EC) No 999/2001 of 22 May 2001 (latest consolidated version 1 January 2023) laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001R0999-20230101

III. Maps (as relevant)









Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for years 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Zoonotic Salmonella Programme Control programme – Reduction of prevalence of Salmonella serotypes in Breeding flocks of Gallus gallus 2025-2027

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	ZOONOTIC SALMONELLA
Animal population/Species	Breeding flocks Gallus gallus
Implementation Year	2025-2027

CONTACT PERSON on Zoonotic Salmonella programme:

Name	Cristina Caballero Fernández
e-mail	ccaballero@mapa.es
Job type within the CA	Head of Service of Zoonoses

Salmonella in Breeding flocks Gallus gallus Programme – 2025-2027

1.RELEVANCE

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

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

- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents
- Regulation (EU) No 200/2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

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1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Associated with document Ref. Ares(2025)132
Yes ⊠ No □
If no, please explain:
The objective of the National Programme is to control the presence of <i>S</i> . Enteritidis, <i>S</i> . Typhimurium, including monophasic strains of <i>Salmonella</i> Typhimurium with the antigenic formula 1,4,[5],12:i:-, <i>S</i> . Virchow, S. Infantis and <i>S</i> . Hadar in breeding flocks of <i>Gallus gallus</i> , 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 <i>Salmonella</i> 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 <i>Salmonella</i> serotypes have been detected in this flock during the production period or whether the sampling was carried out at the initiative of the food business operator or by the competent authority. However, if sampling during the production period is spread over two calendar years, the result of each year shall be reported separately. In the event that a positive result is detected, and the competent authority decided to perform a confirmatory analysis, the final valid result shall be the result of the said confirmatory analysis.
(maximum 500 words)

For a MS with less than 100 adult breeding flocks of Gallus gallus the target is to have no more than one such flock remaining positive for the relevant *Salmonella* serovars per year.

Yes □ No ⊠	
If no, please explain:	
Spain has more than 100 adult breeding flocks.	
	(maximum 500 words

1.3 Complementarity with other actions — European added value

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

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

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

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as *Salmonella*, through consequent EU legal provisions for the control and progressive reduction of the prevalence of *Salmonella*, supported on baseline studies with EFSA scientific assessment to establish the initial epidemiological situation of *Salmonella* in poultry and the different targets for prevalence reduction.

Therefore, the project is a continuation of previous programmes for the control of *Salmonella* submitted annually to the EU since the establishment of the prevalence reduction target, which was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be implemented in all Member States (MSs) with harmonised veterinary measures, in order to raise the level of public and animal health in the EU, while allowing the rational development of the livestock sector and providing a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme is based on a harmonised EU system, the results are comparable across MSs, and allows for spatial and temporal trend analysis at EU level.

It also has an international dimension, as it boosts the confidence not only of EU Member States and its consumers, but also of Third Countries, which can rely on a solid system that ensures the detection of *Salmonella* spp., studies trends and sources of infections in animal and human populations and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars of public health significance are detected. Thus, it helps to increase the confidence in EU products and to promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and the economy, bringing benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

This programme will be implemented on all breeding flocks of Gallus gallus
Yes ⊠ No □
If no, please explain on which flocks:
(maximum 500 words)

Fill in Table 1) in the Annex to this Form.
This programme will be implemented on the whole territory of the Member State
Yes ⊠ No □
If no, please explain:
It will be implemented in all holdings of <i>Gallus gallus</i> breeding hens (both adult breeding and rearing hens).
On breeding hen holdings where the producer directly supplies small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer, at least one FBO control should be done per year in all the flocks present in the farm at that moment. The competent authorities of the Autonomous Communities shall take any action required to ensure control and monitoring of salmonellosis with public health significance.
This programme will not be implemented at holdings that produce primary products for own consumption (for private domestic use).
Holdings to be covered by the programme must be authorised and registered by the competent authorities. For the purposes of the programme an <u>epidemiological unit</u> shall be considered to be a breeding <u>flock</u> , 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. In order to identify the flocks on a holding, the REGA code will be used, adding a capital letter corresponding to the shed (this letter must be written on the entrance door to the shed) and the date of entry of the birds into that shed, in the format mmyyyy. REGA + SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mmyyyy).
(maximum 500 words)
1.5 Notification of detection of target Salmonella serovars
A procedure is in place which guarantees that the detection of the presence of the relevant <i>Salmonella</i> 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 <i>Salmonella</i> serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.
Yes ⊠ No □
If yes, please describe the procedure briefly.
If no, please explain:

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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 FBO 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 SNCP in accordance with 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 FBO 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 the Programme.

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

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on *S*. Enteritidis and *S*. Typhimurium.

During 2004, the monitoring and data collection of *Gallus gallus* breeding flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of *Salmonella* and other specified food-borne zoonotic agents.

(0)

Since the beginning of the implementation of the *Salmonella* Control Programme in breeding hens until nowadays, the prevalence of *Salmonella* has dropped from 2,3% (2007) to 0,85% (2023), which corroborates the effectiveness of the programme (considering official and industry sampling and egg and meat production lines). Thus remaining within the EU target.

The most prevalent salmonellas with importance in public health in 2023 are *S*. Infantis and *S*. Enteritidis, followed by *S*. Typhimurium, *S*. monophasic Typhimurium, and *S*. Hadar.

The evolution of the prevalence of *Salmonella* target serovars in breeding flocks of *Gallus gallus* is shown in the graph of the evolution of the prevalence 2007-2023.

The production sector of breeding flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining an extremely high level of biosecurity measures before and after a positive result (as the introduction of birds and incubated eggs *Salmonella*-free, introduction of feed, keeping strict hygiene practices between flocks, correct training and awareness of all workers, limiting external visits, frequent rodent control, thoroughly cleaning and disinfection techniques and adequate verification analysis, adequate facilities maintenance, by-products and manure management, etc).

Furthermore, the mandatory slaughtering and destruction of the birds and eggs in case of a positive target serotype, with the consequent compensation of the costs, could be a technical and financial problem for both the farmer and the CA, depending on the number and the age of the birds.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

As mentioned in section 1.1. the MS attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval. This includes:

- that the appropriate measures are taken with regards to biosecurity, collection, transportation and storage of samples, and EU microbiological criteria in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*.
- if birds from flocks infected with SE or ST are slaughtered, the necessary measures are 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.
- -laboratory accreditation, analytical methods used for the detection of the target *Salmonella* serovars, antimicrobial controls and transportation of and storage of samples tasks are all performed according to the respective current EU legislation [accreditation requirement according to Art 37(4) of EU Regulation 2017/625].

Yes ⊠ No □

If no, please explain:

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (RD 637/2021, establishing rules for the management of poultry farms and National Animal Health Law 8/2003). These are complemented with a national guideline of good hygiene practices for the prevention and control of zoonotic *Salmonella* in breeders and a general national work guideline for the prevention and control of *Salmonella* in poultry.

When a slaughterhouse recieve a positive flock, it will be slaughter at the end of the day, to reduce cross contamination, and cleaning and disinfection will follow. Furthermore, slaghterhouses shall include in their sampling plans poultry carcasses from flocks with unknown or positive *Salmonella* status for SE and ST.

Samples shall be sent to the laboratories referred to in Regulation 2160/2003, within 24 hours after collection. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat 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.

Laboratory accreditation is governed by Regulation 2017/625 and microbiological criteria by Regulation 2073/2005.

The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the Salmonella serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not be taken in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

(maximum 200 words)

2.1.1 Minimum sampling requirements for food business operators

Samples at the initiative of the FBO must be taken and analysed to test for the target
Salmonella serovars respecting the following minimum sampling requirements:
a. Rearing flocks: day-old chicks, four-week-old birds, two weeks before moving to laying phase or laying unit
b. Adults breeding flocks: depending if the MS achieved the EU target for more than 2 years

Every second week during the laying period (at the holding and at the hatchery)

Every three weeks during the laying period at the holding. Sampling frequency remains at every 2nd week at the hatchery (derogation of point 2.1.1 of Annex to Regulation (EC) No 200/2010)

Indicate also who takes the FBO samples

Sampling shall be carried out in accordance with the minimum requirements laid down in Part B of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Zoonosis / Zoonotic agent *Salmonella* spp. with public health significance (ST, SE, SH, SV, SI)

Stages of production to be covered by sampling

Rearing:

- I. day-old chicks
- II. 4-week-old birds
- III. two weeks before transfer to the laying unit or the start of the laying phase

Adults:

II. Every 2 weeks during the laying phase

Environmental sampling should also be carried out to verify cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding *Salmonella*, as reflected in the program.

The owner of the holding shall be responsible for carrying out own checks (FBO controls), including sampling, in the form and under the conditions provided for by this programme. Sampling may be carried out by qualified staff from the laboratory which performs the analyses. The veterinarian responsible for the holding will ensure that the sampling protocol is in accordance with the conditions laid down in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

Since the Community target has been reached at national level for at least two consecutive calendar years in Spain, the frequency of sampling on the holding may be extended to every three weeks, at the discretion of the competent authority and in accordance with Commission Regulation (EC) 213/2009, amending Regulation (CE) 2160/2009. Each Autonomous Community is responsible for authorising the extension of the frequency of sampling in its territory.

AS:

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.

The data and information obtained from holdings where sampling is performed (Annex: SELF-CONTROL sampling) and the laboratory results shall be recorded in the application of the National programme for the control of Salmonella https://servicio.mapa.gob.es/

The results of the self-control samples (FBO samples) must be recorded in the self-control software application, together with the required accompanying data, within one month of obtaining the results of the laboratory analysis; the results must be obtained within 10-15 days of the sampling, on average, except in exceptional circumstances. All the data from the sampling sheet must be filled in correctly: if any information is missing the samples cannot be recorded in the application. All samples and data relating to sampled flocks that are not recorded in the Ministry applications (official monitoring and own checks) will not be valid within the framework of the SNCP. Notwithstanding the above, all positive results for *Salmonella* considered to have public health significance must be notified as specified in the SNCP.

2.1.2 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):

destroyed or heat treated. Please specify the options applied.
Yes 🗆 No 🗆
If no, please explain.
The minimum measures to be adopted when the presence of S. Enteritidis, S. Typhimurium,
including the monophasic variant of Salmonella Typhimurium with the antigenic formula

including the monophasic variant of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, *S.* Hadar, *S.* Virchow and/or *S.* Infantis is detected in a flock of birds are as follows (control and eradication measures after a positive to one or more of the 5 serotypes):

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection, in accordance with the epidemiological survey attached in the programme. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

If the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified and shall carry out the appropriate investigation in order to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

- 2. No live birds may be moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document made out by the competent authority stating at least the number of animals and the necessary information for identifying the holding and the transporter.
- 3. All birds, including day-old chicks, in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading Salmonella. Slaughter must be carried out in accordance with Community legislation on food hygiene. Products obtained from these birds may be placed on the market for human consumption only in compliance with Community legislation on food hygiene in force and with part E of Annex II to Regulation (EC) No 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.
- 4. Non-incubated eggs from the flock must be destroyed. However, such eggs may be used for human consumption if they are treated in a manner that guarantees the destruction of Salmonella in accordance with Community legislation on food hygiene and with the provisions of part D of Annex II to Regulation 2160/2003.
- 5. Where hatching eggs 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 this programme.

- 8. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.
- 9. The dates of slaughter or destruction of the flock, disinfection, collection of environmental samples and restocking must be notified to the competent authorities. All these processes must be duly recorded for possible consultation by the competent authorities and any depopulation, slaughter or destruction of the flock and restocking must take place under official supervision.

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- 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 the start of the laying stage.
- 11. If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anybody who can be considered as a risk to determine whether there are any *Salmonella* spp. carriers among them.
- If, however, a serotype not concerned by the control programme is identified, the following measures will be taken:
- 1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

In the event of recurrent positive results, if the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified in order to carry out the appropriate investigation to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

2. Thorough checking of biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on breeding hen holdings.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, Fish and Food (MAPA) is responsible for developing and coordinating this monitoring and control programme and for making any necessary amendments, particularly in the light of the data and results obtained; it shall liaise with the Commission, summarising the data and results obtained for communication to the Commission and reporting on the development of the disease. This Subdirectorate is the main responsible for the programme and for its coordination, through regular communications and meetings with regional authorities and with NRL and stakeholders.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the scope of the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and apply the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fish and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health for zoonoses. Its tasks include the following:

- a) Coordinating animal health actions across the different administrations.
- b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.
- c) Monitoring the development of the epidemiological situation regarding animal diseases at national, European and international level.
- d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc.), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subject to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc., and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an additional quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef tcm30-431061.pdf

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.6.

2.3.1. Official controls at holding, flock and hatchery levels

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as *Salmonella* control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of *Salmonella*. There are "Guides to Good Hygiene Practice for the prevention of zoonotic *Salmonella* in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Food and Environment. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves-bioseguridad.aspx

Holders of breeding hen establishments must have in place a code of good hygiene practices in order to meet the objective of this national *Salmonella* control programme and to ensure that health information is kept up-to-date. They must also keep the following records on holdings:

- a) A record of the type and origin of the feed supplied to the animals.
- b) A record of outbreaks 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 above mentioned 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.

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- 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 equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national Salmonella monitoring and control programmes (SNCP).

The detection methods used must be the same as for the other samples under the SNCP. The results for the same must be recorded using the MAPA computer application for FBO checks.

The samples must be recorded alongside the samples for the outgoing flock. The sampling sheet for own checks must be used when sending such samples to the laboratory. The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

- f) Adequate measures must be taken to prevent the transmission of *Salmonella* spp. through drinking water.
- g) The appropriate measures must be taken to prevent the presence of *Salmonella* spp. in raw materials and feedingstuffs. Specifically, the manufacturer or supplier of feed to the holding must guarantee that testing for *Salmonella* has been carried out and make express provision for such tests in the relevant HACCP system. The checks must include analysis of the corresponding samples, which will be made available to the health managers of the holdings receiving the feed. The veterinarian responsible for the holding may assist with the interpretation of the results of the analysis.
- h) Adequate training courses must be given to workers and appropriate health checks must be carried out to detect possible contamination of workers on the holding with any of the five Salmonella serotypes if the bacterium is detected in animals.
- i) Suitable health checks must be carried out to detect the possible source or sources of *Salmonella* contamination where the bacterium has been detected in animals or if this emerges from the epidemiological investigation.
- j) Appropriate vaccination programmes must be carried out where necessary.

k) Appropriate sampling and analyses are carried out to detect Salmonella spp. I) Adequate measures must be taken to ensure the traceability of eggs produced in accordance with the legislation in force. m) Adequate measures must be adopted if positive cases of salmonellosis involving any of the five Salmonella serotypes occur. n) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption. More information on biosecurity checks, the official protocol and the procedure in case of shortcomings, is explained in the program and the protocol is available on the website. b) Routine official sampling scheme when FBO sampling takes place at the hatchery: EU minimum requirements are implemented i.e. If the EU target is achieved for more than 2 years, the CA has decided to implement the derogation of point 2.1.2.3 of Annex to Regulation (EC) No 200/2010 and therefore the EU minimum requirement for official sampling is once a year at the hatchery and once a year on the holding during the laying phase. Yes □ No 🗵 If no, the EU minimum requirements for official sampling are implemented as follows: every 16 weeks at the hatchery twice during the laying phase at the holding (within four weeks at the beginning, within eight weeks before the end), and at the holding each time samples taken at the hatchery are positive for target serovar Yes □ No 🛛 If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples Samples are not taken at the hatcheries in Spain. c) Routine official sampling scheme when FBO sampling takes place at the holding: EU minimum requirements are implemented i.e.: If the EU target is achieved for more than 2 years, the CA has decided to implement the derogation of point 2.1.2.3 of Annex to Regulation (EC) No 200/2010 and therefore the EU minimum requirement for official sampling is twice during the laying phase at the holding. Yes ⊠ No □ If no, the EU minimum requirements for official sampling are implemented as follows: § Three times during the laying phase at the holding (within four weeks at the beginning, within eight weeks before the end and a third one in between)

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

Yes ⊠ No □

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Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by other sufficiently trained authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

A minimum of three separate official checks on all the flocks on all holdings with more than 250 birds must be carried out on three occasions during the production cycle:

- The first within four weeks of the transfer to the laying unit;
- The third towards the end of the laying phase, not earlier than eight weeks before the end of the production cycle;
- The second official analysis must be carried out during the productive period at an appropriate interval from the other two.

In addition, sampling by the competent authority shall take place whenever the competent authority considers it appropriate.

Given that the Community target has been reached at national level for at least two consecutive calendar years in Spain, the competent authority may replace the routine samplings by two samplings on the holding, on any two occasions with sufficient time between each other during the production cycle.

It falls to each Autonomous Community to decide whether or not to make use of this exemption. In Spain, most of the Autonomous Communities have decided to make use of it.

During sampling, all the data necessary to identify the sample and the flock from which it comes will be collected and will comprise at least the data set out in the sampling sheet for official checks.

Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check).

All data and information gathered on holdings on which official sampling has been performed (SEE THE SAMPLING SHEET FOR OFFICIAL CHECKS and the BIOSECURITY SURVEY) and the laboratory results shall be recorded in a dedicated computer application developed for the national programme for the control of Salmonella.

Official sampling protocol is the same as the protocol described for FBO samples (sampling in adult breeding flocks).

Other official samples

Whenever the competent authority deems it necessary, official samples of animal feed and drinking water and environmental samples may be taken to confirm the effectiveness of cleaning and disinfection measures.

If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anyone who can be considered as a risk, in order to determine whether there are any *Salmonella* spp. carriers among them.

d) EU conditions for confirmatory testing are complied with and confirmatory testing is not applied routinely

Yes ⊠ No □
e) 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
\square 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

Describe also if any other measures are implemented

☐ None of these measures

In exceptional cases, and with a view to ruling out false positives or false negatives for samples taken as part of official controls or self-controls, the competent authority may decide to carry out confirmatory analyses according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of *Salmonella* serotypes subject to control in poultry farms", available on the MAPA's website:

- i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected using fabric swabs of at least 900 cm² or replacing the dust samples by 2 extra samples of faeces or boot swabs; however, a sub-sample of 25 grams must be collected of each faecal material and dust sample for analysis; all samples must be analysed separately, or
- ii) bacteriological investigation of the caeca and oviducts of 300 birds, or
- bacteriological investigation of the shell and the content of 4 000 eggs from each flock, in pools of maximum 40 eggs.

In addition to the set arrangements above, the competent authority will check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

Whenever confirmatory testing is conducted, additional samples shall be collected for the possible testing of antimicrobials or bacterial growth inhibitors, as follows: birds shall be taken at random from within each poultry house of birds on the holding, normally up to five birds per house, unless the competent authority deems it necessary to sample a higher number of birds.

Additionally, samples of feed and water can be taken to determine whether the results of the confirmatory test may have been affected by the use of antimicrobials.

If antimicrobials or bacterial growth inhibitors are detected, the *Salmonella* infection shall be considered to be confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a

justification to the CA with the reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc., the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and *Salmonella* results, biosecurity measures, not relation with any foodborne outbreak last years, etc).

2.3.2 Vaccination

Compulsory		
Forbidden		

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

If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Vaccination shall be carried out in accordance with Article 3 of Regulation (EC) No 1177/2006. Vaccination of breeding hens is not mandatory, but if it is carried out, only vaccines with prior marketing authorisation from the Spanish Medical and Health Products Agency or the European Commission in accordance with Regulation (EC) No 726/2004 may be used.

Where one of the five serotypes of *Salmonella* is confirmed on broiler breeder holdings, the above-mentioned measures at least shall be adopted and, in addition, the next batch of birds introduced must be pullets vaccinated with authorised vaccines or autovaccines in accordance with the legislation in force, before starting the laying stage. Once vaccination has been carried out, at least the following information will be entered in the register of treatment with medicinal products: date of vaccination, name of the vaccine(s) administered, type of vaccine(s) administered, quantity (number of doses and quantity of each dose), name and address of the supplier of the medicinal product and identification of the batch of animals treated. Vaccine use must also be recorded using a computer application.

Most FBOs vaccinate breeder's flocks in Spain. The vaccination strategy is variable, depending on the holding or even the flock. Last years around 3,5 doses per bird were used in breeding birds.

2.3.3 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the shed that hosts the infected flock has been depopulated, an efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by a disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has

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elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of *Salmonella* spp. in the environment.

After depopulation of an infected flock, the competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals.

To verify cleaning and disinfection, two or more moistened fabric swabs of at least 900 cm2 per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1ml of the mixture and inoculate the modified Rappaport-Vassiliadis semisolid medium plates (MSRV).

These samples must be analysed in authorised laboratories in the framework of the national *Salmonella* monitoring and control programmes.

The detection methods used must be the same as for the other samples under the SNCP and the results must be recorded using the MAPA computer application for self-controls. This samples must be recorded alongside the samples for the outgoing flock.

The sampling sheet for own checks must be used when sending such samples to the laboratory.

If there is a positive result (we detect *Salmonella* spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (Salmonella enteritidis, Salmonella typhimurium)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target** *Salmonella* serovars (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain

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

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and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. The monitoring and control have focused on *S*. Enteritidis and *S*. Typhimurium.

Data on breeding flocks of *Gallus gallus* were monitored and collected throughout 2004 on the basis of instructions given at Community level in order to meet the target for the reduction of prevalence laid down in Regulation (EC) No 2160/2003 of the European Parliament and of the Council on the control of Salmonella and other specified food-borne zoonotic agents. The data obtained from the study showed prevalence of the five serotypes (SE, ST, SH, SV, SI) in the production phase to be 16.6 %, rising to 20.3 %for *Salmonella* spp.

The evolution of prevalence of the monitored Salmonella serotypes in flocks of breeding hens of the species *Gallus Gallus* is attached (see part IV: Maps). The most prevalent target serotypes in 2023 were *S.* Infantis and *S.* Enteritidis, followed by *S.* Typhimurium, *S.* monophasic Typhimurium and *S.* Hadar (a file containing the evolution of prevalence is enclosed).

2.3.5 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation

In cases where birds are subject 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 (including the correct implementation of biosecurity measures).

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.

2.3.6 System to monitor the implementation of the programme

Please describe

Taking account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, 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; lastly, it is responsible for reporting on the development of the disease.

The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all of the results.

Lastly, we have a monitoring plan for own checks and inspection of own-check laboratories: In order to verify that own checks are being performed correctly, the competent authority will implement the following "Monitoring Plan for FBO checks and inspection of laboratories testing FBO samples" (document available on the website):

The Official Veterinary Services carry out quality controls on own checks on a percentage of holdings, selected each year in accordance with the following ranked risk criteria:

- Holdings where results for the serotypes being monitored were negative in own checks and positive in official controls.
- Holdings where results for the serotypes being monitored were negative in own checks but for which there was a Public Health notification of a positive result.
- Holdings where results for the serotypes being monitored were negative in own checks but positive results were obtained for the LOD in effectiveness checks.
- At random on holdings where results for the serotypes being monitored were negative in own checks and no official controls were carried out.

This will involve 5% of the holdings in each Autonomous Community. If there are fewer than 20 holdings in a Community, they will be carried out on at least one farm. The control will involve conducting a survey to verify whether the requirements of the programmes are being met. The Autonomous Community may decide to carry out a site inspection of an own-check sampling exercise. In this case, the own-check sampling must take place in the presence of the official veterinarian who, as an observer, will attempt to identify practices that do not correspond to the procedures for sampling set out in detail in the National Programmes and applicable to own checks. Close attention will be paid to critical aspects of those procedures that could presumably affect the results (such as the use of peptone as an enrichment medium for boot swabs, origin, expiry; representativeness of the sample: number of steps taken and surface area covered; where appropriate, dispersion of the collection of aliquots of faeces to generate sufficient representativeness in pools, etc). The manner and location of storage of the sample when delivered to the laboratory must also be checked, as must compliance with the maximum deadlines set for receipt of the samples. It is very important that before any own checks are carried out on holdings, and whenever routine official controls are carried out, the holding information recorded in the own-check application is consulted. During this inspection the competent authority must also ask any questions considered necessary and request the necessary documentation on the performance of own checks. The official veterinarian must note down the results of the control in an inspection

report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, will be used by the competent authority to draw up an appraisal report. In the event that any shortcomings are detected, these must be reported to the producer as soon as possible to be corrected immediately for future own checks, without prejudice to any administrative consequences this may have. The competent authority must issue a copy of the report to the party responsible for taking the own-check samples. If the competent authority considers it appropriate, duplicate samples will be taken. One of the samples will be taken by the official veterinarian using his or her own materials. This sample will be retained by the veterinarian and will be sent to an official laboratory together with the sampling sheet. The other sample will be taken by the party responsible for taking the own-check samples, using material provided by that party. It will remain in that party's possession and must be analysed in the same way as any other own-check sample. In those cases where there are significant discrepancies between the results of the official controls and the own checks in the same flock, the competent authority may, if it considers it appropriate, request the strains isolated from the flock in question from the own-check laboratory where they were tested and test them in an official laboratory of the Autonomous Community concerned. Inspections in laboratories will take place in accordance with the document enclosed above. Each Autonomous Community must have inspected all the laboratories in its territory within two years.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.

2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and specificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness.
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		Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system).
		Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

Name	Due date (in month)	Means of verification
Prior knowledge of the SNCP requirements.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August- September (year N)	Intermediate follow-up technical report (data of first semester).
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).

3. IMPACT

3.1 Impact and ambition

()

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for the target Salmonella serovars: S. enteritidis (SE), S. typhimurium (ST)(including the antigenic formula 1,4,[5],12: i:-), S. hadar (SH), S. infantis (SI) and S. virchow (SV).

The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agrifood chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporating a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-), S. Virchow (SV), S. Infantis (SI) and S. Hadar (SH). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of *Salmonella* serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities

(NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the Salmonella Control Programme.

ANNEX

- I. Baseline population data
- II. Targets for 2025-2027
- III. Legal basis for the implementation of the programme
- IV. Maps (as relevant)

I. Baseline population data

Table 1 for year 2025: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	1,000		1,000	5
Adult flocks	1,680	1,650	1,680	1,650
Number of adult flocks v done at the hatchery	vhere FBO sampling is	0	0	0
Number of adult flocks vidone at the holding	vhere FBO sampling is	1,650	1,680	1,650

Comments:

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2026: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	1,000		1,000	5
Adult flocks	1,680	1,650	1,680	1,650
Number of adult flocks v done at the hatchery	where FBO sampling is	0	0	0
Number of adult flocks v done at the holding	vhere FBO sampling is	1,650	1,680	1,650

Comments:

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2027: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	1,000		1,000	5
Adult flocks	1,680	1,650	1,680	1,650
Number of adult flocks v done at the hatchery	where FBO sampling is	0	0	0
Number of adult flocks vidone at the holding	vhere FBO sampling is	1,650	1,680	1,650

Comments:

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

II. Targets for 2025-2027

Table 2 for year 2025: Targets on laboratory tests on official samples from breeding flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	4,800
Serotyping	120
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	10

Table 2 for year 2026: Targets on laboratory tests on official samples from breeding flocks of Gallus gallus

Type of test (description)	Number of planed tests
Bacteriological detection test	4,800
Serotyping	130
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	10

Table 2 for year 2027: Targets on laboratory tests on official samples from breeding flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	4,800
Serotyping	140
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	10

Table 3 for year 2025: Targets on official samples from breeding flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,000	1,680
N of flocks in the programme	1,000	1,680
N of flocks planned to be checked (b)	5	1,650
No of flock visits to take official samples (c)	5	2,400
N of official samples taken	30	4,835
	⊠ SE+ ST + SH +SI + SV	⊠ SE+ ST + SH +SI + SV
Target serovars (d)	☐ SE+ ST	☐ SE+ ST
	□ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	2	10
Possible N of flocks to be depopulated	2	10
Total N of birds to be slaughtered/culled	18,000	89,000
Total N of eggs to be destroyed	n/a	700,000
Total N of eggs to be heat treated	n/a	500,000

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 3 for year 2026: Targets on official samples from breeding flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,000	1,680
N of flocks in the programme	1,000	1,680
N of flocks planned to be checked (b)	5	1,650
No of flock visits to take official samples (c)	5	2,400
N of official samples taken	30	4,835
	⊠ SE+ ST + SH +SI + SV	⊠ SE+ ST + SH +SI + SV
Target serovars (d)	☐ SE+ST	□ SE+ST
	☐ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	2	8
Possible N of flocks to be depopulated	2	8
Total N of birds to be slaughtered/culled	18,000	69,000
Total N of eggs to be destroyed	n/a	560,000
Total N of eggs to be heat treated	n/a	400,000

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 3 for year 2027: Targets on official samples from breeding flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,000	1,680
N of flocks in the programme	1,000	1,680
N of flocks planned to be checked (b)	5	1,650
No of flock visits to take official samples (c)	5	2,400
N of official samples taken	30	4,835
	⊠ SE+ ST + SH +SI + SV	⊠ SE+ ST + SH +SI + SV
Target serovars (d)	□ SE+ ST	□ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	1	6
Possible N of flocks to be depopulated	1	6
Total N of birds to be slaughtered/culled	9,000	52,000
Total N of eggs to be destroyed	n/a	420,000
Total N of eggs to be heat treated	n/a	300,000

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 4 for year 2025: Targets on vaccination for breeding flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	1,680
Number of flocks expected to be vaccinated	1,530
Number of birds expected to be vaccinated	13,490,400
Number of doses expected to be administered	48,565,440

Table 4 for year 2026: Targets on vaccination for breeding flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	1,680
Number of flocks expected to be vaccinated	1,530
Number of birds expected to be vaccinated	13,490,400
Number of doses expected to be administered	48,565,440

Table 4 for year 2027: Targets on vaccination for breeding flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	1,680
Number of flocks expected to be vaccinated	1,530
Number of birds expected to be vaccinated	13,490,400
Number of doses expected to be administered	48,565,440

III. Legal basis for the implementation of the programme) (TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

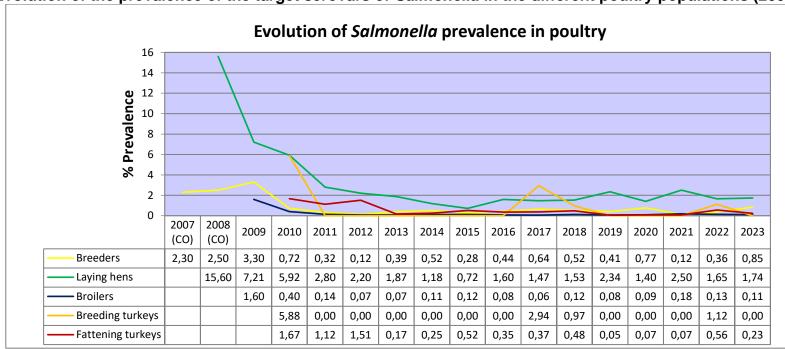
EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010R0200-20190310&qid=1652941483997
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of
 the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of
 salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

IV. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of Salmonella in the different poultry populations (2007-2023)



b. Most prevalent serotypes of Salmonella in the different poultry populations (2023)

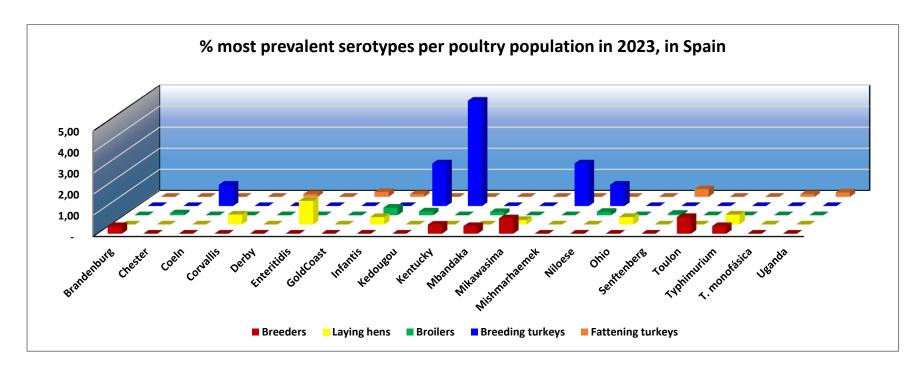
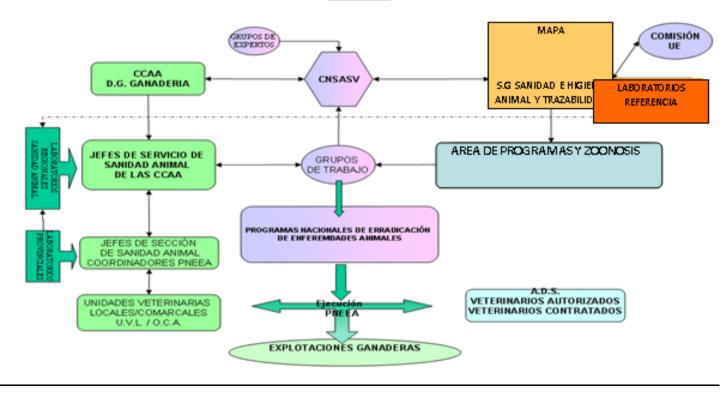
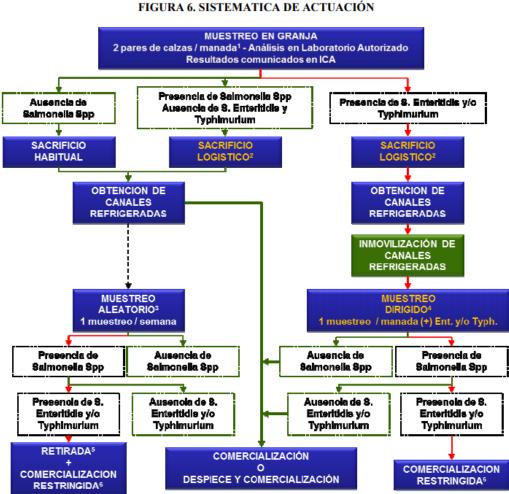


Diagramme of veterinary services

AUTORIDADES COMPETENTES: DISTRIBUCIÓN DE RESPONSABILIDADES Y RELACIONES EN EL ÁMBITO DE LOS PROGRAMAS NACIONALES DE ERRADICACIÓN DE ENFERMEDADES DE LOS ANIMALES



<u>Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):</u>



Para comercialización en fresco siempre incluir en etiquetado o en documento de acompañamiento la leyenda:

"Este producto debe ser totalmente cocinado antes de su consumo"





Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for years 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Zoonotic Salmonella Programme Control programme – Reduction of prevalence of Salmonella serotypes in Laying flocks of Gallus gallus 2025-2027

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	ZOONOTIC SALMONELLA
Animal population/Species	Laying flocks Gallus gallus
Implementation Year	2025-2027

CONTACT PERSON on Zoonotic Salmonella programme:

Name	Cristina Caballero Fernández		
e-mail	ccaballero@mapa.es		
Job type within the CA	Head of Service of Zoonoses		

(maximum 200 words)

Salmonella in Laying flocks Gallus gallus Programme – 2025-2027

1.RELEVANCE

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

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

- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents

- Regulation (EU) No 517/2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in laying hens of *Gallus gallus*- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

Yes
No
If no, please explain:

1.2 Needs and specific objectives

The aim of the programme is to implement all relevant measures in order to reduce the prevalence of <i>Salmonella enteritidis</i> (SE) and <i>Salmonella typhimurium</i> (ST) (including the serotypes with the antigenic formula I,4,[5],12:i:-) in adult laying hens of <i>Gallus gallus</i>
('Union target') as follows:
$\ \square$ 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%
\square An annual minimum percentage of reduction of positive flocks of adult laying hens equal to at least 20% where the prevalence in the preceding year was more than or equal to 10% and less than 20%
A reduction of the maximum percentage equal to 2% or less of positive flocks of adult laying hens
☐ The Member States has less than 50 flocks of adult laying hens: the target is to have not more than one adult flock remaining positive.
The Union target shall be achieved every year based on the monitoring of the previous year.

Definition of positive

A laying flock shall be considered to have produced a positive result for the purposes of determining whether the Community target has been met:

- a) when the presence of the relevant Salmonella serotypes, other than vaccine strains, has been detected in one or more samples taken from the flock, even if the relevant Salmonella serotype is only detected in a 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 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 decides to perform a confirmatory analysis, the final valid result shall be the result of the aforementioned confirmatory analysis.

1.3 Complementarity with other actions — European added value

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

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

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

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as *Salmonella*, through consequent EU legal provisions for the control and progressive reduction of the prevalence of Salmonella, supported on baseline studies with EFSA scientific assessment to establish the initial epidemiological situation of *Salmonella* in poultry and the different targets for prevalence reduction.

Therefore, the project is a continuation of the previous programmes for the control of *Salmonella* annually presented to the EU since the establishment of the prevalence reduction target, which was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be implemented in all Member States (MSs) with harmonised veterinary measures, in order to raise the level of public and animal health in the EU, while allowing the rational development of the livestock sector and providing a safer EU trade of poultry and poultry products in the EU single market.

(0)

Furthermore, as the programme is based on an EU harmonised system, the results are comparable across MSs, and allows for spatial and temporal trend analysis at EU level.

It also has an international dimension, as it boosts the confidence not only of the EU Member States and its consumers but also of Third Countries, which can rely on a solid system that ensures the detection of *Salmonella* spp., study the trends and sources of the infection in animal and human populations and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence of the EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and the economy, giving benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

The programme covers all flocks of adult laying hens of *Gallus gallus* but does not apply to flocks for private domestic use or leading to the direct supply, by the producer, of small quantities of table eggs to the final consumer or to local retail establishments directly supplying the eggs to the final consumer. For the latter case (direct supply), national rules are adopted ensuring *Salmonella* control in these flocks.

The programme covers also all rearing flocks of future laying hens.

Yes ⊠ No □

If no, please explain on which flocks:

It will be implemented in all holdings of *Gallus gallus* laying hens (both adult laying and rearing hens). On laying hen holdings where the producer directly supplies small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer, at least one FBO control should be done per year in all the flocks present in the farm at that moment. The competent authorities of the Autonomous Communities shall take any action required to ensure control and monitoring of salmonellosis with public health significance.

This programme will not be implemented at holdings that produce primary products for own consumption (for private domestic use). Holdings to which the programme will apply must be authorised and registered by the competent authorities.

For the purposes of the programme an epidemiological unit shall be considered to be a laying hen flock, defined as all poultry of the same health status kept on the same premises or within the same enclosure; in the case of housed poultry, this includes all birds sharing the same airspace, in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Flocks of breeding hens shall be identified individually.

To identify the flocks on a holding the REGA code will be used, adding a capital letter corresponding to the shed (this letter must be written on the entrance door to the shed) and the date of entry of the birds into that shed, in the format mmyyyy. REGA + SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mmyyyy).

(maximum 500 words)		
Fill in Table 1) in the Annex to this Form.		
This programme will be implemented on the whole territory of the Member State		
Yes ⊠ No □		
If no, please explain:		
(maximum 500 words)		

1.5 Notification of detection of target Salmonella serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ⊠ No □

If yes, please describe the procedure briefly.

If no, please explain:

All legal or natural persons, and particularly veterinarians, must notify the competent authorities of any confirmed or suspected cases of *Salmonella*, whether or not they are related to measures in the framework 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 be also 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 them 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 the serotyping or commission another laboratory, authorised for the purposes of the PNCS, as described at 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 received 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 FBO 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 the programme.

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

(maximum 500 words)

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of Salmonella cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on *S*. Enteritidis and *S*. Typhimurium.

During 2004, the monitoring and data collection of *Gallus gallus* in laying flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of *Salmonella* and other specified food-borne zoonotic agents.

Since the beginning of the implementation of *Salmonella* Control Programme in laying hens until nowadays, the prevalence of *Salmonella* has dropped from 15,6% (2008) to <2%, which corroborates the effectiveness of the programme. The prevalence of *S.* Enteritidis and *S.* Typhimurium in 2023 stands on 1.74%.

The most prevalent salmonellas with importance in public health in 2023 are *S*. Enteritidis in first place, followed by *S*. Typhimurium and *S*. Typhimurium monophasic strain.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of laying flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining biosecurity measures in free-range production systems, that are increasing progressively as a result of consumers' demand. These production systems could make difficult to guarantee a *Salmonella*-free environment, and control measures should focus on those achievable actions, such as feed control, hygiene practices between flocks, correct training and awareness of all workers, limited external visits, frequent rodent control, keeping clean and without residues the outdoors' facilities, keeping controlled the herbage, thoroughly cleaning and disinfection techniques after a positive result, with adequate verification analysis, by-products and manure management, etc.

Fill in **Table 4** (as appropriate) in the Annex to this Form.

1.6. Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.

See reply in the point 1.5 (repeated question).

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

As mentioned in section 1.1. the MS attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval. This includes:

- that the appropriate measures are taken with regards to biosecurity, collection, transportation and storage of samples, and EU microbiological criteria in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*.
- if birds from flocks infected with SE or ST are slaughtered, the necessary measures are 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.
- -laboratory accreditation, analytical methods used for the detection of the target *Salmonella* serovars, antimicrobial controls and transportation of and storage of samples tasks are all performed according to the respective current EU legislation [accreditation requirement according to Art 37(4) of EU Regulation 2017/625].

Yes ⊠ No □

If no, please explain:

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (RD 637/2021, establishing rules for the management of poultry farms and National Animal Health Law 8/2003). Biosecurity measures shall be checked at least once a year, following the protocol for the verification of biosecurity measures in laying hens flocks stablished in this programme.

When a slaughterhouse recieve a positive flock, it will be slaughter at the end of the day, in order to reduce cross contamination, and cleaning and disinfection will follow. Furthermore, slaghterhouses shall include in their sampling plans poultry carcasses from flocks with unknown or positive *Salmonella* status for SE and ST.

Samples shall be sent to the laboratories referred to in Regulation 2160/2003, within 24 hours after collection. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat 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.

Laboratory accreditation is governed by Regulation 2017/625 and microbiological criteria by Regulation 2073/2005.

The checks made by the competent authorities (laboratory tests or documentary checks on the records of the holding) must guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate, a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the *Salmonella* serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not be taken in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

(maximum 200 words)

2.1.1 Minimum sampling requirements for food business operators (FBO)

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

- a. Rearing flocks: day-old chicks, four-week-old birds, two weeks before moving to laying phase or laying unit
- b. Adults breeding flocks: every 15 weeks during the laying period

Yes ⊠ No □

if no, please explain - Indicate also who takes the FBO samples, and, if additional FBO sampling, going beyond the minimum sampling requirements, is performed, please describe what is done

Samples shall be taken in accordance with the minimum requirements laid down in Part B of Annex II of Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

- Zoonosis / Zoonotic agent: Salmonella spp. with public health significance (ST and SE)
- Flocks of birds producing eggs for human consumption:
 - 1.1. Rearing flocks.
 - 1.2. Adult breeding birds.
- Stages of production to be covered by sampling:
 - I. Day-old chicks
 - II. Pullets two weeks before transfer to the laying unit
 - III. Every 15 weeks during the laying phase (from 24 +2 weeks)

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding *Salmonella*, as reflected in the programme.

The owner of the holding shall be responsible for carrying out own checks, including sampling, in the form and under the conditions provided for by this programme. Sampling may also be carried out by qualified staff of the laboratory performing the analyses. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

All the results of the sample analysis must be known before the animals leave for the slaughterhouse and suitably notified in accordance with the legislation in force.

The data and information obtained from holdings where own checks are performed (Owncheck 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 FBO own-checks application within one month since receiving the laboratory result, on the understanding that - barring exceptions - results will be available on average within 10-15 days of the date of sampling. All the data from the sampling annex must be properly filled in because it will not be possible to record the samples on the application if any of the data is 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 SNCP.

2.1.2 Specific requirements laid down in Annex II.D of Regulation (EC) No 2160/2003 will be complied with where relevant.

In particular:

- due to the presence of SE or ST (including monophasic ST 1,4,[5],12:i:-) in the flock, eggs cannot be used for human consumption unless heat treated;
- eggs from these flocks shall be marked and considered as class B eggs

Yes	∇	No [_
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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 limiting 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, issuing a first detection report when *Salmonella* has been isolated and identified, and send it to the Competent Authority (CA) of the corresponding Autonomous Community (CA), as soon as possible, and always within 24 hours from obtaining the result.

At this moment, the SSVVOO (Official Veterinary Services) of animal health will communicate it:

- to the farmer, so that, once the analytical result is known, he/she does not commercialize eggs for fresh consumption, and carries out all the necessary actions to comply with the regulations in force in this respect.
- to the SSVVOO of public health, so that they can supervise the correct withdrawal of the sale of those eggs.

Subsequently, and always as soon as possible, the isolated strain of *Salmonella* will be serotyped.

Based on the group diagnosis, the laboratory that carries out the serotyping, will issue a first serotyping report, which will state whether target *Salmonella* serovars (*S.* Enteritidis and *S.* Typhimurium, including its monophasic variant) are discarded, or if on the contrary, a target serovar (Enteritidis or Typhimurium, including its monophasic variant) cannot be discarded.

If the first option occurs (detected serovars are not EU target serovars), upon receipt of this report by the SSVVOO of livestock, the restrictions imposed will be lifted.

- 1. If the target serovars are discarded, two situations arise, depending on whether the laboratory is able to identify additional serovars to the target serotypes under control or not:
- Those laboratories that are only able to identify the target serovars under control, will not need to do anything else after the issuance of this first serotyping report (no further reports would be necessary).
- In the event that the laboratories are able to identify additional serovars in addition to the target serovars under control, serotyping will continue until a second serotyping report is issued noting the serovar identification.
- 2. If the target serovars under control are not discarded, it is necessary to continue with the serotyping procedure until the second serotyping report is issued, and there are also two situations, depending on whether the laboratory is able to identify additional serovars to those target serovars under control or not:
- Those laboratories that are only able to identify the target serovars under control, will issue a second serotyping report indicating that the serovars under control have been discarded, or on the contrary, indicating the target serotype under control that they have identified.
- In the case of laboratories that are able to identify additional serovars to those target serovars under control, they will continue with the serotyping until issuing a second serotyping report, stating the identification of the serovar (which could be a target serovar under control or another).

If necessary, the differentiation of the vaccine strain (with the appropriate differentiation methods according to the vaccine used) or the confirmation of monophasic S. Typhimurium (by a PCR method) will also be carried out.

As mentioned above, in order to correctly carry out the differentiation of vaccine strains, it is necessary for the laboratory to have information on the vaccination status of the herd and the vaccine used in each case.

If after the issuance of this second report, the target serovars under control are discarded, after the receipt of this report by the SSVVOO of livestock, the restrictions imposed will be lifted.

All reports will be issued within 24 hours after obtaining the result, and will be sent to the SSVVOO of livestock of the corresponding autonomous community, within 24 hours after its issuance.

The Central Veterinary Laboratory has sent a technical note to all laboratories participating in the NCCP, describing the procedure to be followed by the laboratories that carry out the detection and serotyping of these strains.

2. MEASURES TO BE ADOPTED IN CASE OF POSITIVE RESULT FOR *S.* ENTERITIDIS OR *S.* TYPHIMURIUM (INCLUDING ITS MONOPHASIC STRAINS):

The minimum measures to be adopted when the presence of S. Enteritidis or S. Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, is detected in a flock of birds are as follows:

1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection in accordance with the epidemiological enquiry attached to the programme. Where appropriate, official samples of feed and/or water used on the holding or to supply the flock may be taken.

If the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified and shall carry out the appropriate investigation in order to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

2. No live birds may be moved into or out of this site unless prior authorisation has been obtained for them to leave for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document made out by the competent authority stating at least the number of animals and the necessary information for identifying the holding and the transporter.

When birds from infected flocks are slaughtered or destroyed, steps must be taken to reduce the risk of spreading zoonoses as far as possible. Slaughtering shall be carried out in accordance with Community legislation on food hygiene.

- 3. Products obtained from these birds may be placed on the market for human consumption only in compliance with the Community legislation in force on food hygiene and with part E of Annex II of 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 category B eggs as defined in Commission Regulation (EU) No 2023/2465, which completes Council and Parliament Regulation (EU) No 1308/2013 on marketing standards for eggs;
- b) they shall be marked with the indication referred to in Article 9 of Commission Regulation (EC) No 1308/2013 which clearly distinguishes them from Category 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 stablished 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 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

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samples may be taken of the feed and/or water used on the holding or given to the positive flock.

In the event of recurrent positive results, if the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified in order to carry out the appropriate investigation to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

2. Thorough checking of biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on laying poultry holdings.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene and Traceability 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 its communication to the Commission and reporting on the development of the disease.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

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Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and applying the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fisheries and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health, for zoonoses. Its tasks include the following:

- a) Coordinating animal health actions across the different administrations.
- b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.
- c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.
- d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The

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Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of the other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc.), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the CA. The information is thus subject to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc., and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an additional quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents available on the website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/4plancontroloficialdeatcdef_tcm30-431061.pdf https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.6.

2.3.1 Official controls at holding, flock and hatchery levels

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a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as *Salmonella* control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of *Salmonella*. There are guides to Good Hygiene Practices that have been drawn up with the aim of encouraging the use of appropriate hygiene practices on holdings for monitoring hazards in primary production and related activities and are specifically aimed at the prevention and control of *Salmonella* of public health importance. To this end, model Guidelines to Good Hygiene Practice on Laying Hen Farms have been produced in conjunction with representatives of the laying hen sector (INPROVO - Organización Interprofesional del Huevo y sus Productos, Inter-professional Egg and Egg Products Organisation) and the Ministry of Agriculture, Fisheries and Food. They are available in printed form for distribution to livestock farmers and the competent authorities, and on the MAPA website: http://www.mapa.es/or the INPROVO website www.inprovo.com.

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves bioseguridad.aspx

Operators of laying hen holdings must have a code of good hygiene practice in place to achieve the aim of this national *Salmonella* surveillance and control Programme, and shall ensure that the health information is kept up-to-date. In addition, the following records must be kept at holdings:

- a) A record of the type and source of feed supplied to the animals.
- b) A record of the outbreak of diseases that could affect the safety of animal by-products.
- c) An up-to-date visitors' register, listing the people and vehicles that have entered the holding.
- d) A record of medicinal treatments, containing the information specified under Article 8 of Royal Decree 1749/1998 setting out the applicable control measures for certain substances and their residues in live animals and their products, including the vaccinations referred to in this programme.
- e) All the results of the *Salmonella* analyses and controls carried out on a flock, including those carried out in the hatchery or rearing shed of origin of the flock in question, must be kept by the owner of the holding for at least three years and the records of the flock currently in production must, without fail, be kept at the holding.
- f) The holding register shall be used to record incoming and outgoing flocks of birds. The flock sheet must be kept for at least two years after the flock is slaughtered.
- g) There must also be a documentary record of:
- the protocols and records of cleaning and disinfection work (dates, products used, the person or company responsible for this work).

- analyses to check that cleaning and disinfection operations carried out during the depopulation period have been effective in guaranteeing control of Salmonella with public health significance.
- the programmes and records of insect and rat extermination operations (dates, products used, procedure to check the effectiveness of the programme, etc.).
- h) Producers of rearing pullets must report on the health status of the breeding flock of origin and on any vaccinations and own-checks during the rearing of the pullets; this information must accompany the pullets when they are transferred to the producing holdings.

The owner of the holding must be in possession of all the compulsory health documentation and record all the necessary data so that the competent authority can regularly check compliance with the health programme referred to in this paragraph as well as the code of good hygiene practices, in particular the records mentioned above (a),b),c),d) and e)).

Without prejudice to Royal Decree 637/2021, the holder must adopt protective livestock rearing measures to control the introduction of or contamination by Salmonella spp on holdings, and in particular:

- a) The design and maintenance of the installations are suitable for preventing the entry of Salmonella spp.;
- b) Appropriate measures are taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease; It is mandatory for holdings to carry out rat extermination programmes using their own resources or by authorised companies.
- c) Day-old chicks come from breeding holdings and hatcheries which 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 were satisfactory. 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.

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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, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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 (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.;
- I) 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.

- A
- n) Appropriate measures are taken to ensure correct management of animal by-products not intended for human consumption.
- **b)** Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:
- in one flock per year per holding comprising at least 1,000 birds;
- at the age of 24 +/- 2 weeks in laying flocks housed in buildings where the relevant Salmonella was detected in the preceding flock;
- in any case of suspicion of *Salmonella* infection when investigating foodborne outbreaks in accordance with Article 8 of Directive 2003/99/EC or any cases where the competent authority considers it appropriate, using the sampling protocol laid down in point 4(b) of Part D to Annex II to Regulation (EC) No 2160/2003;
- in all other laying flocks on the holding in case Salmonella Enteritidis or *Salmonella* 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, 2) who is taking the official samples

Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by other sufficiently trained authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

Official monitoring of at least one flock of adult laying hens per holding per year shall be carried out at all holdings with over 1000 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 (FBO 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 on the holding in the event that any of the serotypes covered by the programme have been detected in one of the flocks on 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.

(0)

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 poultry are not affected by the use of antimicrobials in their 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 samples at other stages of the food chain as considered appropriate by the competent authorities.

c) EU conditions for confirmatory testing are complied with and confirmatory testing is not applied routinely

Yes	\boxtimes	No	

In exceptional cases, and with a view to ruling out false positives or false negatives for samples taken as part of official controls or FBO own checks, the competent authority may decide to carry out confirmatory analyses, according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of *Salmonella* serotypes subject to control in poultry farms", available on the MAPA's website:

- i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected from a surface of at least 900 cm², or 5 faeces samples or 5 pairs of boot swabs and two additional faeces or boot swab samples may be collected; however, a sub-sample of 25 grams must be collected of each faecal material and dust sample for analysis; all samples must be analysed separately, or
- ii) bacteriological investigation of the caeca and oviducts of 300 birds, or
- iii) bacteriological investigation of the shell and the content of 4 000 eggs from each flock, in pools of maximum 40 eggs.

In addition to the set arrangements above, the competent authority will check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

Whenever confirmatory testing is conducted, additional samples can be collected for the possible testing of antimicrobials or bacterial growth inhibitors as follows: birds shall be taken at random from within each poultry house of birds on the holding, normally up to five birds per house, unless the competent authority deems it necessary to sample a higher number of birds.

Additionally, samples of feed and water can be taken to determine whether the results of the confirmatory test may have been affected by the use of antimicrobials.

If antimicrobials or bacterial growth inhibitors are detected, the *Salmonella* infection shall be considered to be confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a justification to the CA with their reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc, the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and *Salmonella* results, biosecurity measures, not relation with any foodborne outbreak last years, etc.).

d) Number of official confirmatory samples

1	2	3	4
For routine samples taken at the holding	N of flocks positive to SE/ST	Out of the flock in column 2, N of cases where official confirmatory samples ³ were taken	Out of the N of cases in column 3, N of cases where confirmatory samples were negative
FBO samples ¹	28	5	2
Official samples ²	35	0	0

⁽¹⁾ Reg 517/2011, point 2.2.1 of the Annex

What happened to the flocks counted under 4 (re checked for the presence of Salmonella? Checked for the presence of antimicrobials?

In 2023, 5 flocks were sampled for confirmatory tests after positive results to SE/ST (monophasic strain included).

In 2 cases the confirmatory tests were negative, and the following actions were varied.

In one case the birds were decided to be slaughtered and no more correlative routine sampling of the FBO and Official samples were taken. In the other case, the restrictions were lifted and the sampling followed until the end of the productive life, diminishing the temporal distance between FBO own-checks and adding environmental samples to the scheme.

⁽²⁾ Reg 517/2011, point 2.2.2 of the Annex

⁽³⁾ Reg 2160/2003, point II.D.4 of the Annex

The premises were cleaned, disinfected and disinsected and before entering new birds it was made the sampling for verification of cleaning and disinfection, with negative results.

Flocks with negative results in the confirmatory tests are sampled to detect the use of antimicrobial products and in all cases results were negative.

2.3.2 Vaccination

□ Voluntary☑ Compulsory□ Forbidden
The use of <i>Salmonella</i> vaccines is in compliance with provisions of Article 3 of Regulation (EC) No 1177/2006.
Yes ⊠ No □
If no, please explain. If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Laying hens shall be vaccinated pursuant to Regulation (EC) No 1177/2006.

All laying hens shall be subject to mandatory vaccination programmes against *Salmonella* Enteritidis, to reduce shedding and the contamination of eggs, at least during the rearing phase. The only exceptions will be holdings that the competent authority deems to have adequate biosecurity measures and to have fully implemented a plan for monitoring and control of *Salmonella* and that have demonstrated its effectiveness by having tested negative for *S.* Enteritidis and *S.* Typhimurium, including monophasic strains of *Salmonella* typhimurium with the antigenic formula 1,4,[5],12:i:-, for at least the past twelve months (in FBO 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.

Vaccination is one of the main measures available to control *Salmonella* Enteritidis. In order to keep the prevalence low and continue to decrease it while protecting public health, vaccination shall be mandatory.

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 can be used for vaccinating flocks. Attenuated vaccines, for which there is no suitable way of bacteriologically distinguishing between vaccine strains and field strains, cannot 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.

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Once vaccination has been carried out, at least the following information will be entered in the register of treatment with medicinal products: date of vaccination, name of the vaccine(s) administered, type of vaccine(s) administered, quantity (number of doses), name and address of the supplier of the medicinal product and identification of the batch of animals treated.

The owner of every rearing farm must certify the vaccination of every lot of chicks for the laying holding of destination, stating the type of vaccine used and the vaccination dates.

2.3.3 Efficacy of disinfection

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

Once the infected flock has been depopulated, an efficient and thorough cleaning (including complete removal of the bedding and excrement) shall be undertaken, followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. As soon as sufficient time has elapsed after disinfection, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection process and the absence of *Salmonella* spp. in the environment.

The competent authorities shall check the suitability of the cleaning, disinfection and depopulation measures adopted in the hen houses and, where appropriate, will authorise installations to be occupied by new animals. The competent authority can take environmental samples to verify the effectiveness of cleaning and disinfection when they deem appropriate.

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, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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 FBO 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 (Salmonella spp.), cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected.

Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (Salmonella enteritidis, Salmonella typhimurium)

Give a short summary of the outcome of the **monitoring of the target** *Salmonella* **serovars** (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain)

Monitoring and control of *Salmonella* in Spain has been carried out since 1993 in accordance with Council Directive 92/117/EEC concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning, repealed by Directive 2003/99/EC.

During the period from October 2004 to September 2005, a reference study was carried out on the prevalence of *Salmonella* in flocks of *Gallus gallus* laying hens at Community level; the data were monitored and collected in flocks of *Gallus gallus* laying hens in accordance with the guidelines laid down at Community level by Commission Decision 2004/665/EC of 22 September 2004.

The data obtained by holding according to the study showed the prevalence of serotypes Enteritidis and Typhimurium to be 51.5 % and 73.2 % for Salmonella spp.

The development of the prevalence of *Salmonella* in flocks of *Gallus gallus* laying hens was as follows, *S*. Enteritidis being the most prevalent target serotype (see attached document layers prevalence).

The most prevalent target serotypes in 2023 were *S*. Enteritidis, followed by S. Typhimurium and *S*. Typhimurium monophasic strain.

The prevalence of *S*. Enteritidis and *S*. Typhimurium in 2023 stands on 1.74%.

2.3.5 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

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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, including the correct implementation of biosecurity measures.

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.

2.3.6 System to monitor the implementation of the programme

Please describe

Taking into account 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, 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; 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 FBO own checks and official controls. Information from FBO 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 in their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Lastly, we have a monitoring plan for own checks and inspection of own-check laboratories: In order to verify that FBO own checks are being performed correctly, the competent authority will implement the following Monitoring Plan for FBO own checks and inspection of own-check laboratories (available in the website):

The Official Veterinary Services will carry out quality control of the FBO own checks on a percentage of holdings selected every year according to the following hierarchy of risk criteria:

• holdings with own checks yielding negative results for the serotypes subject to monitoring and positive official control results.

- holdings with own checks yielding negative results for the serotypes subject to monitoring regarding which any positive results are reported for public health purposes.
- holdings with own checks yielding negative results for the serotypes subject to monitoring and analysis of the check on positive LODs.
- random checks among holdings with own checks yielding negative results for the serotypes subject to monitoring and subject to not official checks.

These shall be carried out on 10% of the holdings in every Autonomous Community. In any Autonomous Community with fewer than 10 holding checks shall be conducted on at least one farm.

The control shall consist of an on-site inspection of the taking of samples for own checks and conducting an investigation to check compliance with the requirements of the programme.

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 FBO 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 FBO own checks are carried out on holdings and whenever routine official checks are carried out, the information of the holdings recorded on the FBO own checks application shall be 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 performing 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 at 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 think it is necessary. 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 ask the own-check

laboratory that analysed the strains isolated from that flock to supply them for analysis in an official laboratory in the Autonomous Community concerned.

Laboratory inspections shall be carried out in accordance with the document inserted above. Every Autonomous Community must have inspected all the laboratories on its territory within two years.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc.). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method,	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories.

	etc.). Impact on sensitivity and especificity.	Implement protocols of quality procedures in the lab.
	(Low risk)	Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated egg or egg-products. Impact on public health, on food safety, on farmer's production (Medium risk)	Rigorous accomplishment of the control programme. Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and restrictive measures and improve animal health in order to avoid new cases.

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.			
Name	Due date (in month)	Means of verification	
Prior Knowledge of the SNCP requirements.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).	
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.	
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.	
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August- September (year N)	Intermediate follow-up technical report (data of first semester).	
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.	
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).	

3. IMPACT

3.1 Impact and ambition

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Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of laying flocks of Gallus gallus remaining positive for the target Salmonella serovars: S. enteritidis (SE), S. typhimurium (ST)(including the antigenic formula 1,4,[5],12: i:-), S. hadar (SH), S. infantis (SI) and S. virchow (SV).

The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agrifood chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding hens (breeding flocks of *Gallus gallus*), but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on salmonella control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 2% or less the maximum percentage of adult laying flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility of the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities

(NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the Salmonella Control Programme.

ANNEX

- V. Baseline population data
- VI. Targets for 2025-2027
- VII. Legal basis for the implementation of the programme
- VIII. Maps (as relevant)

V. Baseline population data

Table 1 for year 2025: Flocks subject to the programme

	Total number of flocks of layers in the MS	Number of flocks covered by the programme	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling will take place
Rearing flocks	1,450		1,450	10
Adult flocks	3,500	3,500	3,500	950
Number of holdings with more than 1,000 laying hens				950
Number of flocks in these holdings			3,230	
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2026: Flocks subject to the programme

	Total number of flocks of layers in the MS	Number of flocks covered by the programme	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling will take place
Rearing flocks	1,450		1,450	10
Adult flocks	3,500	3,500	3,500	950
Number of holdings with more than 1,000 laying hens				950
Number of flocks in these holdings			3,230	
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2027: Flocks subject to the programme

	Total number of flocks of layers in the MS	Number of flocks covered by the programme	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling will take place
Rearing flocks	1,450		1,450	10
Adult flocks	3,500	3,500	3,500	950
Number of holdings with more than 1,000 laying hens			950	
Number of flocks in these holdings			3,230	
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

VI. Targets for 2025-2027

Table 2 for year 2025: Targets on laboratory tests on official samples from laying hens flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	2,000

Serotyping	350
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	60

Table 2 for year 2026: Targets on laboratory tests on official samples from laying hens flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	2,000
Serotyping	350
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	70

Table 2 for year 2027: Targets on laboratory tests on official samples from laying hens flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	2,000

Serotyping	350
Antimicrobial detection test	25
Test for verification of the efficacy of disinfection	70

Table 3 for year 2025: Targets on official samples from laying hens flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,450	3,500
N of flocks in the programme	1,450	3,500
N of flocks planned to be checked (b)	10	950
No of flock visits to take official samples (c)	10	950
N of official samples taken	30	2,085
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ST
	☐ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	2	50
Possible N of flocks to be depopulated	2	45
Total N of birds to be slaughtered/culled	50,000	1,000,000
Total N of eggs to be destroyed	n/a	60,000
Total N of eggs to be heat treated	n/a	14,000,000

⁽a) Including eligible and non-eligible flocks

Table 3 for year 2026: Targets on official samples from laying hens flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,450	3,500
N of flocks in the programme	1,450	3,500
N of flocks planned to be checked (b)	10	950

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

No of flock visits to take official samples (c)	10	950
N of official samples taken	30	2,095
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ ST	⊠ SE+ ST
	□ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	2	48
Possible N of flocks to be depopulated	2	43
Total N of birds to be slaughtered/culled	50,000	955,556
Total N of eggs to be destroyed	n/a	57,600
Total N of eggs to be heat treated	n/a	13,440,000

⁽a) Including eligible and non-eligible flocks

- (b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 3 for year 2027: Targets on official samples from laying hens flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	1,450	3,500
N of flocks in the programme	1,450	3,500
N of flocks planned to be checked (b)	10	950
No of flock visits to take official samples (c)	10	950
N of official samples taken	30	2,095
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ ST
	□ others, please specify:	□ others, please specify:

Possible N of flocks infected by target serovars	1	46
Possible N of flocks to be depopulated	1	41
Total N of birds to be slaughtered/culled	25,000	911,111
Total N of eggs to be destroyed	n/a	55,200
Total N of eggs to be heat treated	n/a	12,880,000

- (a) Including eligible and non-eligible flocks
- (b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 4 for year 2025: Targets on vaccination for laying hens flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	3,500
Number of flocks expected to be vaccinated	3,500
Number of birds expected to be vaccinated	80,150,000
Number of doses expected to be administered	248,465,000

Table 4 for year 2026: Targets on vaccination for laying hens flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	3,500
Number of flocks expected to be vaccinated	3,500
Number of birds expected to be vaccinated	80,150,000
Number of doses expected to be administered	248,465,000

Table 4 for year 2027: Targets on vaccination for laying hens flocks of *Gallus gallus*

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	3,500
Number of flocks expected to be vaccinated	3,500
Number of birds expected to be vaccinated	80,150,000
Number of doses expected to be administered	248,465,000

VII. Legal basis for the implementation of the programme) (TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

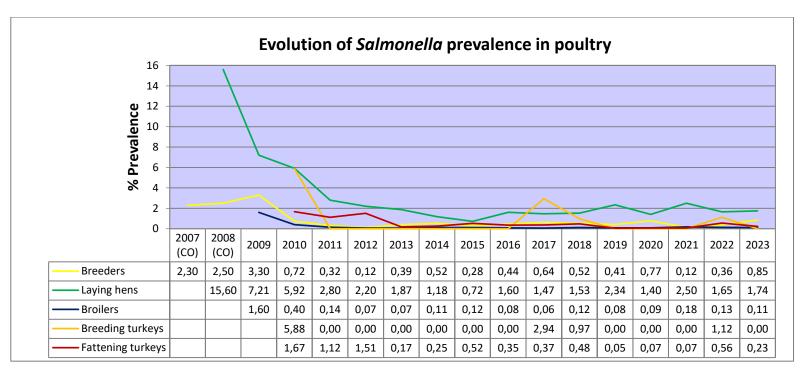
EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of
 the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and
 amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0517-20190310&qid=1652941558459
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of
 the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of
 salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

VIII. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2023)



b. Most prevalent serotypes of Salmonella in the different poultry populations (2023)

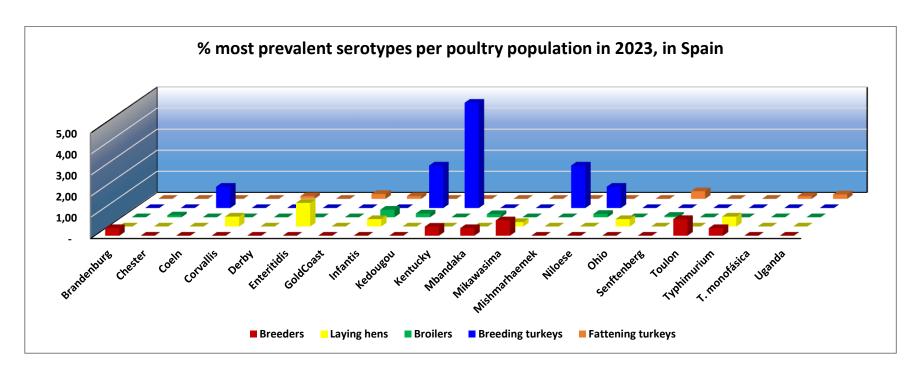


Diagramme of veterinary services

AUTORIDADES COMPETENTES: DISTRIBUCIÓN DE RESPONSABILIDADES Y RELACIONES EN EL ÁMBITO DE LOS PROGRAMAS NACIONALES DE ERRADICACIÓN DE ENFERMEDADES DE LOS ANIMALES

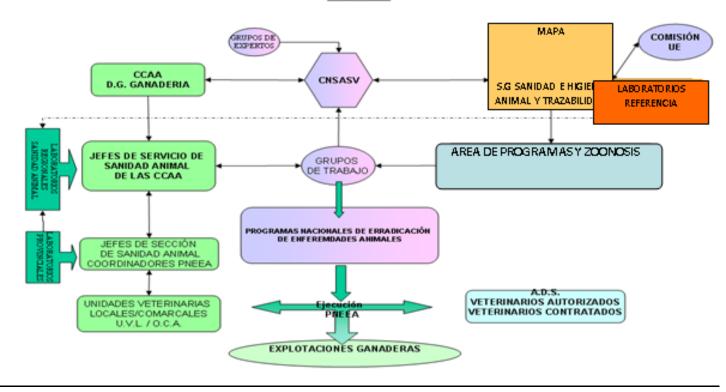
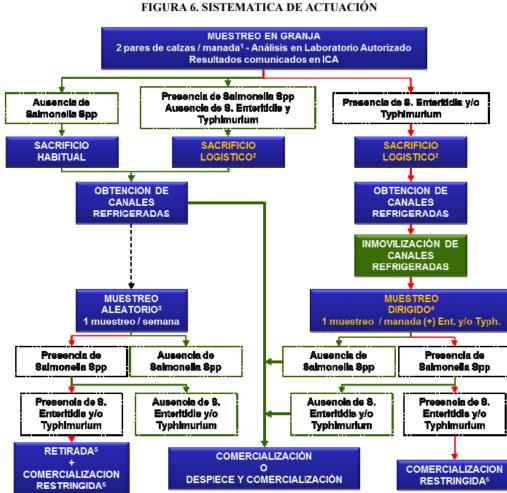


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):



Para comercialización en fresco siempre incluir en etiquetado o en documento de acompañamiento la leyenda: "Esta producto debe ser totalmente cocinado antes de su consumo"





Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for years 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Zoonotic Salmonella Programme Control programme – Reduction of prevalence of Salmonella serotypes in Broiler flocks of Gallus gallus 2025-2027

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	ZOONOTIC SALMONELLA
Animal population/Species	Broiler flocks <i>Gallus gallus</i>
Implementation Year	2025-2027

CONTACT PERSON on Zoonotic Salmonella programme:

Name	Cristina Caballero Fernández
e-mail	ccaballero@mapa.es
Job type within the CA	Head of Service of Zoonoses

Salmonella in Broiler flocks Gallus gallus Programme for years- 2025-2027

1.RELEVANCE

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

By submitting this programme, the Member State (MS) attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval, in particular: - Regulation (EC) No 2160/2003 on the control of <i>Salmonella</i> and other specified food-borne zoonotic agents - Regulation (EU) No 200/2012 concerning a Union target for the reduction of <i>Salmonella enteritidis</i> and <i>Salmonella typhimurium</i> in flocks of broilers broilers- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of <i>Salmonella</i> in poultry
Yes ⊠ No □
If no, please explain:
(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce the maximum annual percentage of flocks of *broilers* remaining positive to *Salmonella enteritidis* (SE) and *Salmonella typhimurium* (ST) (including the serotypes with the antigenic formula 1,4,[5],12:i:-)('Union target') to 1% or less.

Yes ⊠ No □

If no, please explain:

The aim of this programme is to reduce the maximum percentage of broiler flocks which test positive for *Salmonella* Enteritidis and *Salmonella* Typhimurium, including the monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1% or less.

A flock of broilers shall be considered <u>positive</u> for the purpose of verifying the achievement of the Community target where: a) the presence of *Salmonella* Enteritidis and/or *Salmonella* Typhimurium (other than vaccine strains) was detected in the flock; or b) antimicrobials or bacterial growth inhibitors have been detected.

Positive flocks of broilers will be counted only once per round, irrespective of the number of sampling and only be reported in the year of the first positive sampling.

If Salmonella spp. is detected, the samples must be serotyped. If either of the mentioned serotypes are detected in the samples, appropriate measures will be taken in accordance with Regulation 2160/2003 and explained in the program.

(maximum 500 words)

1.3 Complementarity with other actions — European added value

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

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

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

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as *Salmonella*, through consequent EU legal provisions for the control and progressive reduction of the prevalence of *Salmonella*, supported on baseline studies with EFSA scientific assessment to establish the initial epidemiological situation of *Salmonella* in poultry and the different objectives for prevalence reduction.

Therefore, the project is a continuation of the previous programmes for the control of *Salmonella* annually presented to the EU since the establishment of the prevalence reduction target, which was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be applied in all Member States (MSs) with harmonised veterinary measures, in order to raise the level of public and animal health in the EU, while allowing rational development of the livestock sector and provides a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme is based on an EU harmonised system, the results are comparable across MSs and allows for spatial and temporal trend analysis at EU level.

It also has an international dimension, as it boosts the confidence not only of EU Member States and its consumers but also of Third Countries, which can rely on a solid system that ensures the detection of *Salmonella* spp., studies trends and sources of infections in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars of public health significance are detected. Thus, it helps to increase the confidence in EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and the economy, bringing benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

This programme will be implemented on all broiler flocks of *Gallus gallus*

Yes ⊠ No □			
If no, please explain on which flocks:			
It will be applied to all holdings of broilers of the species <i>Gallus gallus</i> intended for commercial slaughter. On broiler holdings involved in 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 that 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' means 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, adding 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 + SHED (CAPITAL LETTER) + DATE OF ENTRY OF BIRDS (mm/yyyy).			
(maximum 500 words)			
Fill in Table 1) in the Annex to this Form.			
This programme will be implemented on the whole territory of the Member State			
Yes ⊠ No □			

If no, please explain:	
	(maximum 500 words)

1.5 Notification of detection of target Salmonella serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority (CA) by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ⊠ No □

If yes, please describe the procedure briefly.

If no, please explain:

All legal or natural persons, and particularly veterinarians, must notify the competent authorities of any confirmed or suspected cases of *salmonella*, regardless of 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. The laboratory may carry out the serotyping itself or send the samples to another laboratory authorised under the SNCP, as described in this programme. If the serotyping shows positive results for one of 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 FBO 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 FBO 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 the programme.

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

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on *S*. Enteritidis and *S*. Typhimurium.

During 2004, the monitoring and data collection of *Gallus gallus* broiler flocks was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of *Salmonella* and other specified food-borne zoonotic agents.

Since the beginning of the implementation of the *Salmonella* Control Programme in broilers until nowadays, the prevalence of *Salmonella* has dropped from 1,6% (2009) to 0,11% (2023), which corroborates the effectiveness of the programme.

The most prevalent salmonellas with importance in public health in 2023 are *S*. Enteritidis, in first place, followed by *S*. Typhimurium monophasic strain and *S*. Typhimurium.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of broiler flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining biosecurity measures in free-range production systems, that are increasing progressively as a result of consumers' demand. These production systems could make difficult to guarantee a *Salmonella*-free environment, and control measures should focus on those achievable actions, such as feed control, hygiene practices between flocks, correct training and awareness of all workers, limited external visits, frequent rodent control, keeping clean and without residues the outdoors' facilities, keeping controlled the herbage, thoroughly cleaning and disinfection techniques after a positive result, with adequate verification analysis, by-products and manure management, etc.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

As mentioned in section 1.1. the MS attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval. This includes:
- that the appropriate measures are taken with regards to biosecurity, collection, transportation and storage of samples, and EU microbiological criteria in fresh poultry meat in birds from flocks infected with <i>Salmonella enteritidis</i> or <i>Salmonella typhimurium</i> .
-laboratory accreditation, analytical methods used for the detection of the target <i>Salmonella</i> serovars, antimicrobial controls and transportation of and storage of samples tasks are all performed according to the respective current EU legislation [accreditation requirement according to Art 37(4) of EU Regulation 2017/625].
Yes ⊠ No □
If no, please explain:
Biosecurity measures are part of the SNCP and there are national rules reinforcing them (RD 637/2021, establishing rules for the management of poultry farms and National Animal Health Law 8/2003). Biosecurity measures shall be checked at least once a year, following the protocol for the verification of biosecurity measures in broiler flocks stablished in this programme.
When a slaughterhouse receives a positive flock, it will be slaughter at the end of the day, in order to reduce cross contamination, and cleaning and disinfection will follow. Furthermore, slaughterhouses shall include in their sampling plans poultry carcasses from flocks with unknown or positive <i>Salmonella</i> status for SE and ST.
Samples shall be sent to the laboratories referred to in Regulation 2160/2003, within 24 hours after collection. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat 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.
Laboratory accreditation is governed by Regulation 2017/625 and microbiological criteria by Regulation 2073/2005.
(maximum 200 words)
1.1 Minimum sampling requirements for food business operators
Samples at the initiative of the FBO must be taken and analysed to test for the target
Salmonella serovars respecting the following minimum sampling requirements:
All flocks of broilers within three weeks before slaughter
Yes ⊠ No □

If no, please explain. Indicate also who takes the FBO samples.

All broiler flocks on all the holdings covered by this programme will be sampled as part of a programme of FBO 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 they have to be suitably notified in accordance with the legislation in force. Samples shall be taken in accordance with the following minimum requirements:

- Zoonoses / Zoonotic agent Salmonella with public health significance (ST and SE).
- Broiler flocks intended for human consumption.
- Production phases which must cover sampling: Chicks in the 3 weeks prior to slaughter.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding *Salmonella*, as reflected in the national program.

Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding or it 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 done in accordance with the conditions set in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

In those herds in which a thinning or partial depopulation is to be carried out, a FBO own-check must be done within 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 FBO self-control must be repeated.

Recording of results in the Ministry's own-check computer application is mandatory.

The data and information collected on holdings where FBO 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 will 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 checks) will not be valid in the context of the SNCP. However, where there is a positive test result for *Salmonella*, given its significance for public health, it must be notified as specified in the SNCP.

The CA accepts to derogate from this sampling rule and instead of this the FBOs shall sample at least one flock of broilers per round on holdings with more than one flock where:

- (i) an all in / all out system is used in all flocks of the holding;
- (ii) the same management applies to all flocks;
- (iii) feed and water supply is common to all flocks;
- (iv) during at least the last six rounds, tests for *Salmonella* spp. according to the sampling scheme set out in the first subparagraph in all flocks on the holding and samples of all flocks of at least one round were carried out by the competent authority;

(v) all results from the testing according to the first subparagraph and point (b) for SE or ST were negative.			
Yes ⊠ No □			
If yes, please indicate how many holdings and flocks are concerned			
Since the introduction of the SNCPs for broiler chickens in Spain, this exception has been applied to only one holding. It may be applied for the years covered by this programme, but until the programme is implemented each year, we do not know whether the sector will request this and therefore whether the CA will authorise it and it will be applied.			
The CA accepts to derogate from the general sampling rule and authorises FBO sampling in the last six weeks prior to the date of slaughter in case the broilers are either kept more than 81 days or fall under organic broiler production according to Commission Regulation (EC) No 889/2008. Yes ☑ No □			
If yes, please indicate how many holdings and flocks are concerned.			
Even if it is applied, we cannot specify the number of holdings and flocks until the programme has been completed.			
During 2023, less than 200 holdings were authorised for this derogation.			

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene and Traceability 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 its communication to the Commission and reporting on the development of the disease.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and applying the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001, setting up the veterinary health warning system, created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fisheries and Food (MAPA), and its members represent all the Autonomous Communities and the Ministry of Health for zoonoses. Its tasks include the following:

- a) Coordinating animal health actions across the different administrations.
- b) Studying measures for preventing, controlling, combating and eradicating the diseases covered by the national programmes.
- c) Monitoring the development of the epidemiological situation with regard to animal diseases at national, European and international level.
- d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned

controls and verifications, and monitoring of achievement of targets (activity indicators) please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of the Salmonella National Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained, we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc.), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the CA. The information is thus subject to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc., and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an additional quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents available on the website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higieneganadera/4plancontroloficialdeatcdef tcm30-431061.pdf https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higieneganadera/5planinspeccioneslabatc tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.6.

2.3.1 Official controls at feed level

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

Control measures to prevent the introduction of *Salmonella* spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities.

As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of 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 authorized the Available treatment or use of additives. at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

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The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of *Salmonella* and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of *Salmonella* in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including *Salmonella*. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding, flock and hatchery levels

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as *Salmonella* control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of *Salmonella*. There are guides to Good Hygiene Practice Guides that have been developed with a view to encouraging the use of appropriate hygiene practices on farms to control dangers in primary production and related activities, with special emphasis on the prevention and control of *Salmonella* of significance to public health. To this end, a model Guide to Good Hygiene Practices for the control and prevention of zoonotic *Salmonella* on broiler holdings has been drawn up with representatives from the broiler sector (PROPOLLO an inter-professional organisation for poultry farming in Spain) and the Ministry of Agriculture, Fisheries and Food, copies of which have been published for distribution among livestock farmers and the competent authorities. It has also been posted on the MAPA website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves bioseguridad.aspx

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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.

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- b) Appropriate measures must be taken to control rodents, insects, wild birds and other domestic or wild animals which might introduce the disease. A rodent control programme must be carried out either by the holding itself or by authorised establishments.
- c) Day-old chicks come from breeding holdings and hatcheries that have passed the checks set up to prevent vertical transmission of *S*. Enteritidis and *S*. Typhimurium, including the monophasic strains of *Salmonella* typhimurium with the antigenic formula 1,4,[5],12:i:-, and are certified by the supplier as originating in breeding holdings free of the five serotypes (*S*. Enteritidis, *S*. Typhimurium, including the monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, *S*. Virchow, *S*. Infantis and *S*. Hadar), and documentation including the results and dates of the laboratory analyses (own checks and official sampling) performed since the last official sampling at the source holding must be made available to the purchaser.
- d) Appropriate washing, cleaning, disinfection and rat extermination measures are taken in the production sheds and ancillary structures and on the materials and tools used in the production activities.
- e) Analyses are performed to check that sufficient cleaning and disinfection has been carried out. To verify cleaning and disinfection one or more moistened fabric swabs of at least 900 cm² per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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

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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.
- I) 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 638/2019 sets out the basic conditions to be met by the cleaning and disinfection centres for vehicles used for road transport in the livestock sector.

- **b)** Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:
 - in one flock of broilers per year on 10% of holding comprising at least 5,000 birds

Yes ⊠ No □

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples will be taken by the qualified or authorised official veterinarian, or in some cases under veterinary supervision by sufficiently trained and authorised personnel. The sample collection sheet shall identify the person performing the sample and his/her job position.

Each year on 10% of holdings with more than 5,000 birds at least one flock on each holding will be checked. In the ACs with 10 holdings or fewer, the official control will be carried out on at least one holding. The risk criteria for selecting this 10% of holdings include the following:

- a) Holding characteristics:
 - type of production
 - size of holding (population sections)
 - provincial poultry density (measured here by number of holdings)

b) Background of the holdings:

- changes in the results obtained in previous years on the holdings from which samples were taken.
- prioritise holdings on which no information is available.

c) Non-compliances:

 prioritise establishing a major risk of those farms where unrectified non-compliances have been detected in the biosafety surveys and in surveys where positive results were obtained.

Sampling shall take place within the last three weeks before the birds are sent for slaughter. Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check). Whenever it is considered necessary, official samples of animal feed and drinking water and environmental samples may be taken to confirm the effectiveness of cleaning and disinfection measures. Other types of samples may also be taken 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.

epidemiological parameters such as biosafety conditions, distribution or flock size.
c) EU conditions for confirmatory testing are complied with and confirmatory testing is not applied routinely
Yes ⊠ No □
d) Official confirmatory sampling (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery):
After positive official samples at the holding
 □ Always □ Sometimes (criteria apply) ⋈ Never
After positive FBO samples at the holding
 □ Always □ Sometimes (criteria apply) ☑ Never
When official confirmatory sampling is performed, additional samples are taken for checking the presence of antimicrobials: ☐ Always ☐ Sometimes ☐ Never
Please insert any comments. Describe the criteria used to determine if confirmatory sampling is performed. Indicate also which samples (if any) are taken to check the presence of antimicrobials.

Confirmatory analyses are not carried out for broilers.

d) Article 2 of Regulation (EC) No 1177/2006 (antimicrobials shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision. For samples please describe the samples taken, the analytical method used, the result of the tests.

The competent authorities must carry out checks (laboratory tests or documentary checks on the records of the holding) in order to guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate, a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the *Salmonella* serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not be taken in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the birds have been removed, the holding will be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks will be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples will be taken to check the effectiveness of the cleaning and disinfection and to make sure that *Salmonella* is no longer present in the environment.

The competent authorities will check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and,

where appropriate, will authorise restocking with new animals. The competent authority can take environmental samples to verify the effectiveness of cleaning and disinfection when they deem appropriate.

To verify cleaning and disinfection, two or more moistened fabric swabs of at least 900 cm² per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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 SNCP.

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 to Salmonella spp. cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (*S. enteritidis, S. typhimurium*)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target** *Salmonella* serovars (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain

Monitoring and control of *Salmonella* in Spain has been carried out since 1993 in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning.

During the period from October 2005 to September 2006, a reference study was carried out on the prevalence of *Salmonella* in flocks of broilers of the *Gallus gallus* species at Community level; the analysis and sampling of the selected chicken flocks was carried out in accordance with the guidelines laid down at Community level by Commission Decision 2005/636/EC.

The data obtained in the study showed the prevalence of serotypes Enteritidis and Typhimurium in broiler flocks to be 28.2% and 41.2% for *Salmonella* spp.

The development of prevalence of *Salmonella* subject to controls in flocks of *Gallus gallus* broilers was shown above, with *S.* Enteritidis, followed by *S.* monophasic Typhimurium and *S.* Typhimurium, the more prevalent serotypes under control.

2.3.5 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks

Measures and applicable legislation as regard as the registration of holdings:

Legislative measures and provisions concerning the registration of livestock farms.

The obligation to register livestock farms in Spain derives primarily from Article 39 of Law 8/2003 of 24 April 2003 on animal health. More specifically, in poultry farming, the obligation to register poultry farms is regulated as follows:

Holdings of broiler chickens will be entered in the General Register of Livestock Holdings (REGA, Royal Decree 479/2004) with a code/register number, irrespective of their size, and will be classified as: meat production farms.

All holdings, except those excluded in Article 1 of Royal Decree 637/2021, must comply with the provisions stablished in this regulation on the organisation of poultry rearing, concerning the minimum conditions to be met by poultry holdings with regard to buildings and installations, hygiene and health conditions, location, poultry identification, holding register, holding record book, the duties of the holder of the establishment and the minimum welfare conditions to be observed for poultry.

For the purposes of the programme, 'epidemiological unit' will mean the flock of birds, defined as all birds reared for meat production with the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit. In the case of housed poultry, this includes all birds sharing the same airspace in accordance with Article 2(3)(b) of Regulation (EC) No 2160/2003. To identify flocks within a holding, the REGA code will be used, adding a capital letter corresponding to the shed and the date of entry of the birds in the format mm/yyyy, as specified in this programme.

2.3.6 System to monitor the implementation of the programme

Please describe

Taking into account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, 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; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Lastly, we have a monitoring plan for FBO own checks and the inspection of own check laboratories: In order to verify that the own checks are being carried out correctly, the competent authority may carry out the following monitoring plan for own checks and the inspection of own check laboratories (available in MAPA website). The official veterinary services will run a quality control on the own checks on a percentage of holdings, selected annually in accordance with the following hierarchised risk criteria:

- Holdings where own checks show negative results for the serotypes subject to control and official controls show positive results.
- Holdings where own check show negative results for the serotypes subject to control and on which there is a public health communication concerning positive results.
- Holdings where own checks show negative results for the serotypes subject to control and positive results in the analysis of the LOD (limit of detection) effectiveness check.
- On a random basis, between holdings with own checks with negative results for the serotypes subject to control and with no official checks. When this inspection is carried out, the control will involve performing a survey to check compliance with the specifications in the programmes and an in-situ inspection of sampling for FBO own checks. In this case, own check sampling will be in the presence of the official veterinarian who will try, as an observer, to identify practices which do not correspond to the procedures detailed for sampling 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: number of 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 they consider appropriate and will request the necessary documentation in relation to the performance of own checks. The official veterinarian will set out 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.

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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 FBO own check sampling, using material provided by that person. It will remain in his/her possession, and must be analysed in the same way as any other own check. In cases of significant discrepancies between the official control results and the own checks on the same flock; the competent authority may request, where it considers appropriate, the isolated strains from the flock in question, from the own check laboratory which analysed them, to perform an analysis of them in an official laboratory of its Autonomous Community.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples.

	sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Periodic checks of the results and adjustment scheduling when necessary.
Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples,		Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories.
	inappropriate detection method, etc). Impact on sensitivity and especificity.	Implement protocols of quality procedures in the lab.
	(Low risk)	Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed.	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.
	(Low risk)	
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals).
		Maximise biosecurity awareness.
		Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system).
		Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated poultry meat. Impact on public health on food safety on farmer's	Rigorous accomplishment of the control programme and of the next stages of the agrifood chain (hygiene process, slaughtering process).
	health, on food safety, on farmer's production. (Medium risk)	Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different
		competencies (Public Health and Animal

Health) to initiate a rapid response to the alert,		
investigations and corrective actions		
established in the SNCP (in case the cause of		
contamination was at farm level).		

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

measures) are not milestones.			
Name	Due date (in month)	Means of verification	
Prior knowledge of the SNCP requirements.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).	
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.	
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.	
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August- September (year N)	Intermediate follow-up technical report (data of first semester).	
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.	

Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	(year N+1)	Final follow-up technical report (final data).
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3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

The programme establishes the implementation of veterinary measures focused to increase public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agrifood chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering or cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of broiler flocks of *Gallus gallus*, but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on *Salmonella* control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of broiler flocks of *Gallus gallus* remaining positive for the target Salmonella serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of

- ()
- *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of *Salmonella* serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility of the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella_general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the Salmonella Control Programme.

ANNEX

- IX. Baseline population data
- X. Targets for 2025-2027
- XI. Legal basis for the implementation of the programme
- XII. Maps (as relevant)

IX. Baseline population data

Table 1 for year 2025: Flocks subject to the programme

	Number of holdings
Total number of holdings with broilers in the MS	4,200
Total number of houses in these holdings	39,000
Number of holdings with more than 5 000 broilers	4,000

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2026: Flocks subject to the programme

	Number of holdings
Total number of holdings with broilers in the MS	4,200
Total number of houses in these holdings	38,500
Number of holdings with more than 5 000 broilers	4,000

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2027: Flocks subject to the programme

	Number of holdings
Total number of holdings with broilers in the MS	4,200
Total number of houses in these holdings	38,500
Number of holdings with more than 5 000 broilers	4,000

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; **Source of the data**: "MAPA"

X. Targets for 2025-2027

Table 2 for year 2025: Targets on laboratory tests on official samples from broiler flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	480
Serotyping	180
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	40

Table 2 for year 2026: Targets on laboratory tests on official samples from broiler flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	480
Serotyping	180
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	40

Table 2 for year 2027: Targets on laboratory tests on official samples from broiler flocks of *Gallus gallus*

Type of test (description)	Number of planed tests
Bacteriological detection test	480
Serotyping	180
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	40

Table 3 for year 2025: Targets on official samples from broiler flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	18	38,982
N of flocks in the programme	18	38,982
N of flocks planned to be checked (b)	5	460
No of flock visits to take official samples (c)	5	480
N of official samples taken	15	508
	⊠ SE+ ST + SH +SI + SV	⊠ SE+ ST + SH +SI + SV
Target serovars (d)	□ SE+ ST	□ SE+ ST
	□ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	0	38

⁽a) Including eligible and non-eligible flocks

Table 3 for year 2026: Targets on official samples from broiler flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	18	38,482
N of flocks in the programme	18	38,482
N of flocks planned to be checked (b)	5	460
No of flock visits to take official samples (c)	5	480
N of official samples taken	15	508
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Target serovars (d)	⊠ SE+ ST	⊠ SE+ST
	□ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	0	36

⁽a) Including eligible and non-eligible flocks

- (b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH + SI + SV

Table 3 for year 2027: Targets on official samples from broiler flocks of Gallus gallus

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	18	38,482
N of flocks in the programme	18	38,482
N of flocks planned to be checked (b)	5	460
No of flock visits to take official samples (c)	5	480
N of official samples taken	15	508
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ST
	□ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	0	34

⁽a) Including eligible and non-eligible flocks

- (b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH + SI + SV

XI. Legal basis for the implementation of the programme) (TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

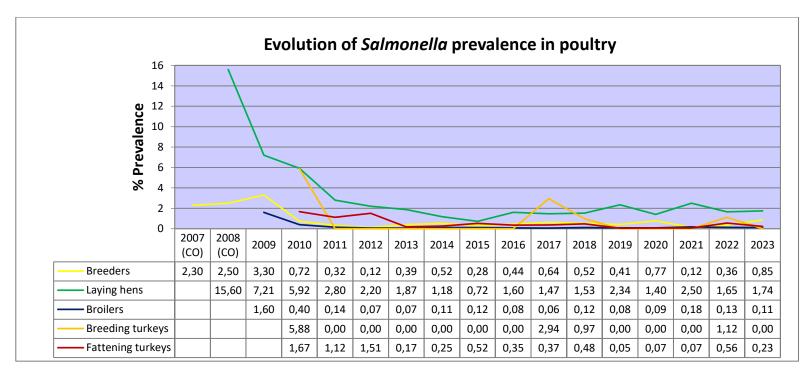
EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 200/2012 of 8 March 2012 concerning a Union target for the reduction of Salmonella enteritidis and Salmonella typhimurium in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0200-20190310&qid=1652941636751
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of
 the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of
 salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

XII. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2023)



b. Most prevalent serotypes of Salmonella in the different poultry populations (2023)

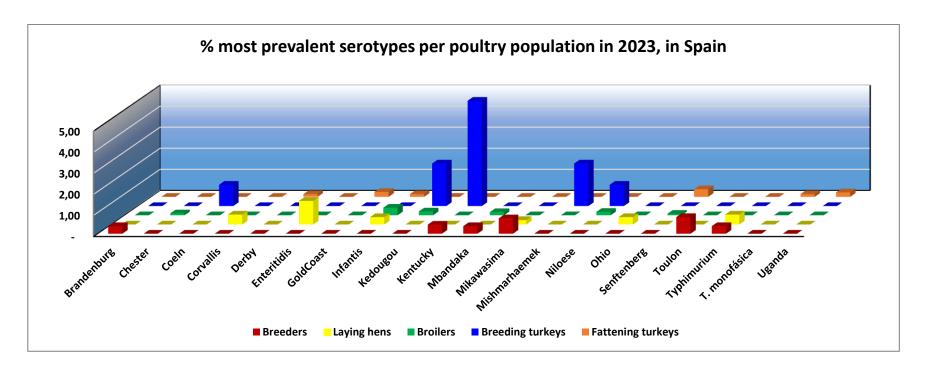


Diagramme of veterinary services

AUTORIDADES COMPETENTES: DISTRIBUCIÓN DE RESPONSABILIDADES Y RELACIONES EN EL ÁMBITO DE LOS PROGRAMAS NACIONALES DE ERRADICACIÓN DE ENFERMEDADES DE LOS ANIMALES

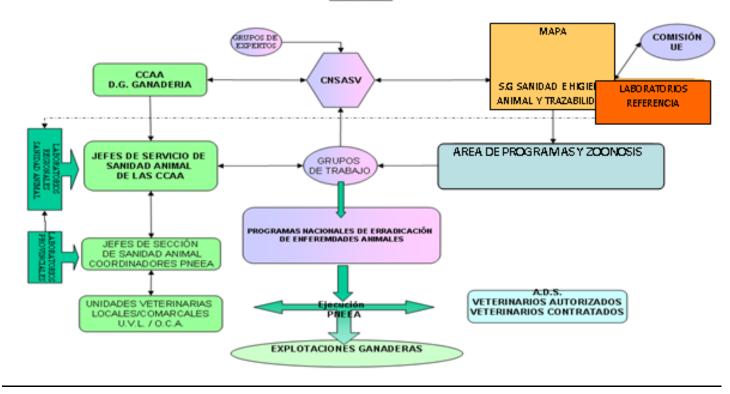


Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):

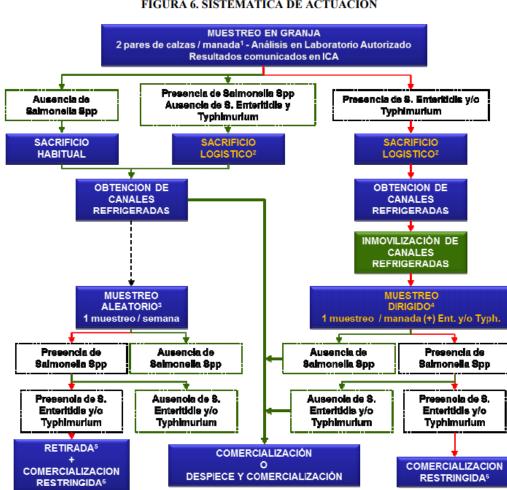


FIGURA 6. SISTEMATICA DE ACTUACIÓN

Para comercialización en fresco siempre incluir en etiquetado o en documento de acompañamiento la leyenda: "Esta producto debe santotalmente cocinado antes de su consumo"





Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Zoonotic Salmonella Programme Control programme – Reduction of prevalence of Salmonella serotypes in Breeding flocks of Turkeys 2025-2027

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	ZOONOTIC SALMONELLA
Animal population/Species	Breeding flocks Turkeys
Implementation Year	2025-2027

CONTACT PERSON on Zoonotic Salmonella programme:

Name	Cristina Caballero Fernández
e-mail	ccaballero@mapa.es
Job type within the CA	Head of Service of Zoonoses

Salmonella in Breeding flocks Turkeys Programme – 2025-2027

1.RELEVANCE

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

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

- Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

of the national programmes for the control of Salmonella in poultry		
Yes 🛛	No □	
If no, ple	ease explain:	
	(m	aximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of flocks of breeding turkeys remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Yes ⊠ No □

If no, please explain:

The answer is yes, but S. Hadar, S. Infantis and S. Virchow are not target serovars.

The National Programme takes account of the specifications set out in Commission Regulation 1190/2012 implementing Regulation 2160/2003 with regard to the Community objective of reducing the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in turkeys. Accordingly, the target will be the reduction of the maximum percentage of positive adult breeding turkey flocks to *Salmonella* Enteritidis and *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

In case the number of breeding turkeys is fewer than 100 flocks, the Community target would be no more than one adult breeding turkey flock continuing to test positive.

For the purposes of verifying the attainment of the Community objective, a flock of turkeys shall be considered positive when:

- a) the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:- (therefore different from the vaccine strains) has been detected in the flock, or
- b) when antimicrobials or bacterial growth inhibitors have been detected in the flock.

Positive flocks of turkeys shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

If either of the two mentioned serotypes is detected or *Salmonella* spp. is detected, the appropriate measures are explained in the programme

(maximum 500 words)

For MS with less than 100 flocks of breeding turkeys, the Union target shall be that annually no more than one flock of adult fattening turkeys may remain positive.		
Yes ⊠ No □		
If no, please explain:		
Spain has less than 100 adult breeding flocks (99 in 2023).		
(maximum 500 words)		

1.3 Complementarity with other actions — European added value

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

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other

countries, potential to develop mutual trust/cross-border cooperation among EU countries, EU and non-EU countries, etc.

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

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as *Salmonella*, through consequent EU legal provisions for the control and progressive reduction of the prevalence of *Salmonella*, supported on baseline studies with EFSA scientific assessment to establish the initial epidemiological situation of *Salmonella* in poultry and the different objectives for the reduction of the prevalence.

Therefore, the project is a continuation of previous programmes for the control of *Salmonella* annually presented to the EU since the establishment of the prevalence reduction target, which was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be implemented in all Member States (MSs) with harmonised veterinary measures, in order to raise the level of public and animal health in the EU, while allowing the rational development of the livestock sector and providing a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme is based on an EU harmonised system, the results are comparable across MSs, and allows for spatial and temporal trend analysis at EU level.

It also has an international dimension, as it boosts the confidence not only of EU Member States and its consumers but also of Third Countries, which can rely on a solid system which ensures the detection of *Salmonella* spp., studies trends and sources of infections in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence in EU products and promote national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and the economy, bringing benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

This programme will be implemented on all breeding flocks of turkeys

Yes ⊠ No □	
If no, please explain on which flocks:	
It shall apply on all holdings where turkeys are reared for breeding in accordance with point the Annex to Commission Regulation (EU) No 1190/2012.	int 1

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 the REGA code will be used, adding a capital letter corresponding to the shed (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) + DATE

(maximum 500 words)

Fill in Table 1) in the Annex to this Form.

This programme will be implemented on the whole territory of the Member State

Yes
No
If no, please explain:

(maximum 500 words)

1.5 Notification of detection of target Salmonella serovars

OF ENTRY OF BIRDS (mmyyyy).

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.

laboratory performing the analyses.		
Yes □ No □		
If yes, please describe the procedure briefly.		
If no, please explain:		
All individuals or companies, and particularly veterinary officers, must notify the compete		

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

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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 this programme. If the serotyping shows positive results 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 report the results, without prejudice to the provisions of the previous paragraph.

To ensure suitable traceability of the samples taken during FBO 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 the programme.

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

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of Salmonella cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on *S*. Enteritidis and *S*. Typhimurium.

During 2006, the monitoring and data collection of flocks of turkeys was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of Salmonella and other specified food-borne zoonotic agents.

Since the beginning of the implementation of the Salmonella Control Programme in breeding turkeys until nowadays, the prevalence of Salmonella has dropped from 5,88% (2010) to 0% (2023), which corroborates the effectiveness of the programme.

The most prevalent Salmonella spp. in breeding turkeys in 2023 is S. Kentucky, followed by S. Kedougou and S. Mishmarhaemek.

The application of biosecurity measures is one of the key obstacles hampering the control of Salmonella cases.

The production sector of turkey breeding flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to establishing and maintaining an extremely high level of biosecurity measures before and after a positive result (as the introduction of birds and incubated eggs Salmonella-free, introduction of feed, keeping strict hygiene practices between flocks, correct training and awareness of all workers, limiting external visits, frequent rodent control, thoroughly cleaning and disinfection techniques and adequate verification analysis, adequate facilities maintenance, by-products and manure management, etc.).

Furthermore, the mandatory slaughtering and destruction of the birds and eggs in case of a positive target serotype, with the consequent compensation of the costs, could suppose a technical and financial problem both for the farmer and for the CA, depending on the number and the age of the birds.

2. QUALITY

2.1 **Concept and methodology (Programme activities/measures)**

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

As mentioned in section 1.1. the MS attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval. This includes:

- that the appropriate measures are taken with regards to biosecurity, collection, transportation and storage of samples, and EU microbiological criteria in fresh poultry meat in birds from flocks infected with Salmonella enteritidis or Salmonella typhimurium.
- -laboratory accreditation, analytical methods used for the detection of the target Salmonella serovars, antimicrobial controls and transportation of and storage of samples tasks are all performed according to the respective current EU legislation [accreditation requirement according to Art 37(4) of EU Regulation 2017/625].

Yes ⊠ No □

If no, please explain:

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (RD 637/2021, establishing rules for the management of poultry farms and National Animal Health Law 8/2003). Biosecurity measures shall be checked at least once a year, following the protocol for the verification of biosecurity measures in broiler flocks stablished in this programme.

When a slaughterhouse receives a positive flock, it will be slaughter at the end of the day, in order to reduce cross contamination, and cleaning and disinfection will follow. Furthermore, slaughterhouses shall include in their sampling plans poultry carcasses from flocks with unknown or positive *Salmonella* status for SE and ST.

Samples shall be sent to the laboratories referred to in Regulation 2160/2003, within 24 hours after collection. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat 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.

Laboratory accreditation is governed by Regulation 2017/625 and microbiological criteria by Regulation 2073/2005.

(maximum 200 words)

2.1.1 Minimum sampling requirements for food business operators

The EU minimum requirements for FBO sampling are as follows:		
□ Rearing flocks: at day-old, at four weeks of age, two weeks before moving to laying phase or laying unit □ Adult flocks: Every third week during the laying period at the holding or at the hatchery (only at the holding for flocks producing hatching eggs intended for trade within the union). The last sampling session takes place withing three weeks before slaughter. Yes ☑ No □		
Indicate also who takes the FBO samples		
Samples shall be taken in accordance with the following minimum requirements:		
- Flocks of breeding turkeys: stages of production to be covered by sampling		
1.1 Rearing flocks. I. One-day old turkeys.		
II. 4-week old turkeys.		
III. 2 weeks before moving to the laying unit or phase.		
1.2. Adult flocks. I. Every 3 weeks during the laying period.		

II. Turkeys during the 3 weeks prior to departure to the slaughterhouse.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding *Salmonella*, as reflected in this program.

The results of the analysis on the samples must be known before the animals leave for the slaughterhouse. Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding or may be carried out by qualified staff of the laboratory performing the analyses. The veterinarian responsible for the holding shall ensure that the sampling protocol is in accordance with the conditions laid down in this programme. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

Recording results in the Ministry's own-check application

The data and information collected in the holdings where the own checks are performed (ANNEX FOR OWN-CHECK SAMPLES), as well as the laboratory results shall be recorded in the computer application of the National programme for monitoring *Salmonella* https://servicio.mapa.gob.es/

The results of the own-check samples must be recorded in the own-check application, together with the required accompanying data, within one month of the laboratory analysis result being obtained; the results must be obtained within 15 days of the sampling, on average, except in exceptional circumstances. The sampling annex must be filled in appropriately because it will not be possible to record the samples in the application if any data is missing.

All the samples and data referring to the samples flocks that are not recorded in the applications of the ministry (official control and own check) shall not be validity for the SNCP. However, any positive results for *Salmonella*, which is considered to have public health significance, should be notified as determined by the SNCP.

If the EU target is achieved for more than 2 consecutive calendar years in the whole member state, the CA has accepted to implement the derogation of point 2.1.(a)(iv) of Annex to Regulation (EU) No 1190/2012 and therefore the EU minimum requirements for FBO sampling frequency at the holding on adult flocks is every four weeks. However, the CA may decide to keep or revert to a three-week testing interval in the case of detection of the presence of the relevant *Salmonella* serotypes in a breeding flock on the holding and/or in any other case deemed appropriate by the CA.

Yes No No I

If no please explain. Indicate also 1) if additional FBO sampling going beyond EU minimum requirements is performed (to be described) 2) who is taking the official samples

Despite that the EU target has been reached last years, the Spanish programme does not allow the derogation to extend the sampling frequency on holding to every four weeks. The sampling of adult flocks shall be done every 3 weeks in all circumstances.

The protocol is explained on the previous point.

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

Please indicate also if birds are slaughtered or killed and destroyed, and if eggs are
destroyed or heat treated. Please specify the options applied.

Yes ⊠ No □

If no, please explain.

If either of the two serotypes (*S.* Enteritidis or *S.* Typhimurium, including strains with the antigenic formula 1,4,[5],12:i:-) is detected in any of the samples taken from fattening or breeding turkey flocks, the appropriate measures shall be taken and shall involve at least the following:

1. In all turkey flocks in which a positive result was obtained, an in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection, in accordance with the epidemiological survey attached to the programme. If it is considered necessary, an official sample may be taken of the feed and/or water being used on the holding or given to that flock.

If the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified and shall carry out the appropriate investigation in order to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

- 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 FBO own checks are being carried out correctly on these flocks.
- 3. No movements of live turkeys to or from the area shall be permitted unless prior authorisation has been obtained for them to leave the holding for the purposes of slaughter or destruction. Any transfer of animals must be accompanied by a health document to be drawn up and completed by the competent authority indicating at least the number of animals and the information necessary to identify the holding and the transporter.
- 4. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and part E of Annex II to Regulation (EC) No 2160/2003. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.
- 5. Furthermore, with regard to breeding turkeys, non-incubated eggs from the flock must be destroyed. However, such eggs may be used for human consumption if they are treated in a manner that guarantees the elimination of *Salmonella* in accordance with Community

legislation on food hygiene and in compliance with the provisions of part D of Annex II to Regulation (EC) No 2160/2003.

Where eggs for hatching from flocks in which a *Salmonella* serotype is present are still present in a hatchery, they must be destroyed or treated in accordance with Regulation (EC) No 1069/2009 of the European Parliament and the Council.

6. Once the birds have been removed, the holding shall be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks shall be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples shall be taken to check the effectiveness of the cleaning and disinfection and to make sure that *Salmonella* is no longer present in the environment. The competent authorities shall check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and, if appropriate, shall authorise restocking with new animals.

For the cleaning and disinfection procedure to be considered valid, measures explained in this programme shall be performed.

7. The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected.

However, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

- 8. The competent authorities shall be informed of the dates of departure of the birds in the flock, disinfection, taking of environmental samples and restocking, and all these processes shall be duly recorded for possible consultation by the competent authorities. Depopulation of the shed in which the positive flock was kept (and, when appropriate, slaughter or destruction of the animals) and restocking must all take place under official supervision.
- 9. If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals or anybody who can be considered as a risk in order to determine whether there are any *Salmonella* spp. carriers among them.
- If, however, a serotype not concerned by the control programme is identified, the following measures shall be taken:
- 1. An in-depth epidemiological investigation shall be carried out to attempt to identify the cause of the positive result and detect the source of infection. Where appropriate, official samples may be taken of the feed and/or water used on the holding or given to the positive flock.

In the event of recurrent positive results, if the epidemiological investigation concludes that the origin of the infection is likely to be a hatchery, a breeding flock or a rearing breeding flock of the pullets, the Competent Authority of the establishment of origin shall be notified in order

to carry out the appropriate investigation to confirm the origin of the infection and ensure its control (e.g. taking samples for epidemiological investigation and reviewing the biosecurity of the holding). If the likely origin of the infection is a hatchery, the CA may review the compliance of the conditions of authorisation and biosecurity requirements.

2. Thorough checks on the biosecurity measures for all flocks on the holding in accordance with the procedure for checking biosecurity measures on turkey holdings.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene and Traceability 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. This Subdirectorate is the main responsible for the programme and for its coordination, through regular communications and meetings with regional authorities and with NRL and stakeholders.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and applying the established preventive and control measures).

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Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fisheries 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 regarding animal diseases at national, European and international level.
- d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain, and may also include the professional association of veterinary officers. The role of this consultative committee would be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained, we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the

authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc.), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the CA. The information is thus subject to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc., and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an additional quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/5planinspeccioneslabatc_tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available on the website and in point 2.3.8.

2.3.1 Official controls at feed level

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

Control measures to prevent the introduction of *Salmonella* spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities.

As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market, which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of Salmonella spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no Salmonella contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) No. 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for *Salmonella* (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for *Salmonella*, an identification of the serotype must be requested. Only in the case of *S*. Enteritidis, *S*. Typhimurium, *S*. Infantis, *S*. Virchow and *S*. Hadar, notification will be made through the Alert Network.

In case of a positive result for Salmonella spp., the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat Available treatment or the use of authorized additives. at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of *Salmonella* and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of *Salmonella* in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology,

including *Salmonella*. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding and flock

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as *Salmonella* control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of *Salmonella*. There are "Guides to Good Hygiene Practice for the prevention of zoonotic *Salmonella* in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Fisheries and Food. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves-bioseguridad.aspx

Turkey holding operators shall have a code of good hygiene practice adapted from that applying to breeding turkeys holdings to achieve the aim of this national *Salmonella* surveillance and control programme, and shall ensure that the health information is kept upto-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).

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- 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 turkeys must report on the health status of the breeding flock of origin and on any vaccinations and own checks during the rearing of the turkeys; this information must accompany the turkeys 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 poults come from holdings free from the said serotypes, and documentation including the results and dates of the laboratory analyses (own checks and official sampling) performed since the last official sampling at the source holding must be made available to the purchaser;
- d) Appropriate washing, cleaning, disinfection and rat extermination measures are taken in the production sheds and ancillary structures and on the materials and tools used in the production activities;
- e) Tests are carried out to ensure that the cleaning and disinfection operations were performed appropriately.

To verify cleaning and disinfection two or more moistened fabric swabs of at least 900 cm² per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them

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well and then take 0.1 ml 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;
- I) Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.
- b) Routine official sampling scheme when FBO sampling takes place at the hatchery: EU minimum requirements are implemented i.e. official sampling are performed:
 - once a year, all flocks with at least 250 adult breeding turkeys between 30 and 45
 weeks of age and in all holdings with elite, great grand-parents and grand-parent
 breeding turkeys; the competent authority may decide that this sampling may also
 take place at the hatchery; and

Associated with document Ref. Ares(2025)13267		
 all flocks on holdings in case of detection of Salmonella enteritidis or Salmonella typhimurium from samples taken at the hatchery (FBO or official samples), to investigate the origin of infection; Yes ☒ No □ 		
If no please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples		
Official samples must be taken by the qualified or authorised veterinarian or in some cases by sufficiently trained authorised personnel under veterinary supervision. The sample collection sheet shall identify the person performing the sample and his/her job position. The official sampling shall cover at least:		
1. Breeding turkeys		
• Once a year, all flocks on holdings with at least 250 adult breeding turkeys between 30 and 45 weeks of age and all holdings with elite, great-grandparent and grandparent breeding turkeys.		
• All flocks on holdings where <i>Salmonella</i> Enteritidis or <i>Salmonella</i> Typhimurium, including monophasic <i>Salmonella</i> 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 <i>Salmonella</i> 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) EU conditions for confirmatory testing are complied with and confirmatory testing is not applied routinely		
Yes ⊠ No □		

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):

hatchery, or suspicion of false positivity on FBO samples taken on the holding) are negative,

d) If confirmatory samples taken at the holding (after positive results at the

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
infe	ected and eradication measures are implemented, if negative, all restrictive measures are
lifte	ed
	None of these measures

Describe also if any other measures are implemented

In exceptional cases, and with a view to ruling out false positives or false negatives, the competent authority may decide to carry out confirmatory analyses on breeding turkeys, according to the "Harmonized Protocol for the authorization of sampling and confirmatory analysis after detecting the presence of *Salmonella* serotypes subjected to control in poultry farms" (available on the website):

- i) by taking 5 faeces samples or 5 pairs of boot swabs and 2 dust samples of 250 millilitres containing at least 100 grams of dust collected from various locations distributed throughout the shed; dust may also be collected using fabric swabs of at least 900 cm² or replacing the dust samples by 2 extra samples of faeces or boot swabs; however, a 25 g sub-sample must be taken for analysis from each sample of faecal material or dust; all samples must be analysed separately, or
- ii) bacteriological investigation of the caeca and oviducts of 300 birds, or
- iii) bacteriological investigation of the shell and content of 4,000 eggs from each flock in pools of maximum 40 eggs.

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 order to check that there has been no use of antimicrobials that might affect the results of the sampling analyses.

If antimicrobials or bacterial growth inhibitors are detected, *Salmonella* infection shall be considered confirmed.

The harmonised protocol of the confirmatory tests establishes that confirmatory tests will be authorised only in exceptional cases. When FBO apply for them, they shall submit a justification to the CA with the reasons. If the CA considers that the justification is appropriate or the CA considers that there could be doubts about the results (false positive or false negative results), i.e. doubts on correct sampling, problems with transport of the samples, etc., the CA may authorise the confirmatory testing, provided the holding comply certain requirements established in the protocol (type of production, compliance with SNCP and Salmonella results, biosecurity measures, not relation with any foodborne outbreak last years, etc.).

d) Antimicrobial control

Article 2 of Regulation (EC) No 1177/2006 (antimicrobials shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).

For samples please describe the samples taken, the analytical method used, the result of the tests.

The competent authorities must carry out checks (laboratory tests or documentary checks on the records of the holding) in order to guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate, a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling. Sample specifications shall be made according to the laboratory indications.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the Salmonella serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Vaccination

\boxtimes	Voluntary	
	Compulsory	
	Forbidden	

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

If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc).

Vaccinations are performed in accordance with Article 3 of Commission Regulation (EC) No 1177/2006. Vaccination is not compulsory, 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

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batch of animals treated, and vaccine use shall be registered by means of a computerised application.

2.3.4 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the shed housing where the infected flock was detected 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. The competent authority can take environmental samples to verify the effectiveness of cleaning and disinfection when they deem appropriate

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 authorit)y, shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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 SNCP.

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 to Salmonella spp., cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.5 Monitoring of the target Salmonella serovars (Salmonella enteritidis, Salmonella typhimurium)

Give a short summary (from last 5 years) of the outcome of the **monitoring of the target** *Salmonella* serovars (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain

Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonosis and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning.

A reference study was made of prevalence at Community level of *Salmonella* in turkey flocks of the species Meleagris gallopavo between October 2006 and September 2007. Analyses were made and samples taken from selected flocks of turkeys in accordance with Community guidelines as laid down in Commission Decision 2005/662/EC.

According to information obtained from the study, prevalence of *S*. Enteritidis and *S*. Typhimurium serotypes in breeding turkey flocks was 0% and 2.8% in turkeys for fattening, rising to 5.3% in breeding turkeys and 56.3% in turkeys for fattening for *Salmonella* spp.

The evolution of the prevalence of the types of *Salmonella* covered by checks on breeding turkey flocks is shown in the attached graphic (see part IV. Maps).

2.3.6 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks

The obligation to register livestock holdings in Spain derives, firstly, from Article 39 of Law N° 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.

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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, the REGA code will be used, adding a capital letter corresponding to the shed (this letter must be written on the door to the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

REGA + SHED (CAPITAL LETTER) + ENTRY DATE OF THE BIRDS (mm/yyyy)

2.3.7 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation

In certain cases, the competent authority can order the compulsory slaughter of breeding turkeys that tested positive for the *Salmonella* serotypes covered by the checks.

In these cases, the animals must be slaughtered in accordance with the provisions of Articles 20 and 21 of Law N° 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, including correct implementation of biosecurity measures.

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.

2.3.8 System to monitor the implementation of the programme

Please describe

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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, 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; lastly, it is responsible for reporting on the development of the disease. The Autonomous Communities are responsible for the direct implementation and monitoring of the activities to be carried out under the programme. In addition, to facilitate monitoring and follow-up of the data obtained, we have two computer applications for recording information from own checks and official controls. Information from own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Finally, a plan to control own checks and inspect own-check laboratories is in place.

With a view to ascertaining that the own checks are being performed correctly, the competent authority may carry out the following plan to control own checks and inspect own-check laboratories (available on the website):

The official veterinary services shall perform a quality control of the own checks in a certain percentage of holdings, selected annually on the basis of the following prioritised risk criteria:

- 1. Holdings in which own checks have shown negative results for the serotypes covered by the checks and official controls have shown positive results.
- 2. 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.
- 3. Holdings with negative results for own checks relating to the serotypes covered by the checks and positive LOD effectiveness control analysis.
- 4. 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 FBO 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 FBO. 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 owncheck 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 owncheck results on the same flock, the competent authority may request, if it deems it necessary, the isolated strains of the said flock from the own-check laboratory that analysed them in order to perform an analysis of them in an official laboratory in its Autonomous Community.

The inspections in the laboratories shall take place in accordance with the document attached above. Within two years, each Autonomous Community must have inspected all the laboratories in its territory.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the	Appropriate training of the FBO/ veterinarians responsible of sampling.

	laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.	
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.	
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and specificity. (Low risk)	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab. Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).	
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.	
5	Non-compliance of the EU target for the reduction of the prevalence (Low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system).	

	Re-design	future	SNCP	(not	allowing
	exceptions to reduce frequency of FBO checks,				
	increasing minimum frequency on sampling).				

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

medsures) are not innestones.							
Name	Due date (in month)	Means of verification					
Prior knowledge of the SNCP requirements.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).					
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.					
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.					
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August- September (year N)	Intermediate follow-up technical report (data of first semester).					
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.					
Central follow-up analysis and verification of the	March-April (year N+1)	Final follow-up technical report (final data).					

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agrifood chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector of breeding turkeys, but there are other expected target groups: the food industry and the food consumers, who will benefit of greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on *Salmonella* control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: S. Enteritidis (SE), S. Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.

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Long-term effect of the programme: source of information on the evolution and behaviour of salmonella serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the AACC (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the Salmonella Control Programme.

ANNEX

- XIII. Baseline population data
- **XIV.** Targets for 2025-2027
- XV. Legal basis for the implementation of the programme
- XVI. Maps (as relevant)

Baseline population data XIII.

Table 1 for year 2025: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	80		80	2
Adult flocks	105	105	105	105
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2026: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	80		80	2
Adult flocks	105	105	105	105
Comments:				

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

Table 1 for year 2027: Flocks subject to the programme

	Total number of flocks of breeders in the MS	Number of flocks with at least 250 adult breeders	Number of flocks where FBO sampling shall take place	Number of flocks where official sampling shall take place
Rearing flocks	85		85	2
Adult flocks	110	110	110	110

Comments:

All cells shall be filled in with the best estimation available. The above data refer to 05/2023; Source of the data: "MAPA"

XIV. Targets for 2025-2027

Table 2 for year 2025: Targets on laboratory tests on official samples from breeding flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	221
Serotyping	15
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	5

Table 2 for year 2026: Targets on laboratory tests on official samples from breeding flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	221
Serotyping	20
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	5

Table 2 for year 2027: Targets on laboratory tests on official samples from breeding flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	231
Serotyping	23
Antimicrobial detection test	5
Test for verification of the efficacy of disinfection	5

Table 3 for year 2025: Targets on official samples from breeding flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	80	105
N of flocks in the programme	80	105
N of flocks planned to be checked (b)	2	105
No of flock visits to take official samples (c)	2	105
N of official samples taken	14	231
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ST
	□ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	1	1
Possible N of flocks to be depopulated	1	1
Total N of birds to be slaughtered/culled	1,500	2,500
Total N of eggs to be destroyed	n/a	5,000
Total N of eggs to be heat treated	n/a	10,000

⁽a) Including eligible and non-eligible flocks

Table 3 for year 2026: Targets on official samples from breeding flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	80	105
N of flocks in the programme	80	105
N of flocks planned to be checked (b)	2	105

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

No of flock visits to take official samples (c)	2	105
N of official samples taken	14	231
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ ST
	□ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	1	1
Possible N of flocks to be depopulated	1	1
Total N of birds to be slaughtered/culled	1,500	2,500
Total N of eggs to be destroyed	n/a	5,000
Total N of eggs to be heat treated	n/a	10,000

- (a) Including eligible and non-eligible flocks
- (b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH + SI + SV

Table 3 for year 2027: Targets on official samples from breeding flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	80	110
N of flocks in the programme	80	110
N of flocks planned to be checked (b)	2	110
No of flock visits to take official samples (c)	2	110
N of official samples taken	14	241
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ ST	⊠ SE+ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	1	1
Possible N of flocks to be depopulated	1	1
Total N of birds to be slaughtered/culled	1,500	2,500
Total N of eggs to be destroyed	n/a	5,000
Total N of eggs to be heat treated	n/a	10,000

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH + SI + SV

Table 4 for year 2025: Targets on vaccination for breeding flocks of Turkeys

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	105
Number of flocks expected to be vaccinated	63
Number of birds expected to be vaccinated	189,000
Number of doses expected to be administered	699,300

Table 4 for year 2026: Targets on vaccination for breeding flocks of Turkeys

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	105
Number of flocks expected to be vaccinated	63
Number of birds expected to be vaccinated	189,000
Number of doses expected to be administered	699,300

Table 4 for year 2027: Targets on vaccination for breeding flocks of Turkeys

Type of test (description)	Target on vaccination
Number of flocks in the Salmonella programme	110
Number of flocks expected to be vaccinated	66
Number of birds expected to be vaccinated	198,000
Number of doses expected to be administered	732,600

XV. Legal basis for the implementation of the programme) (TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

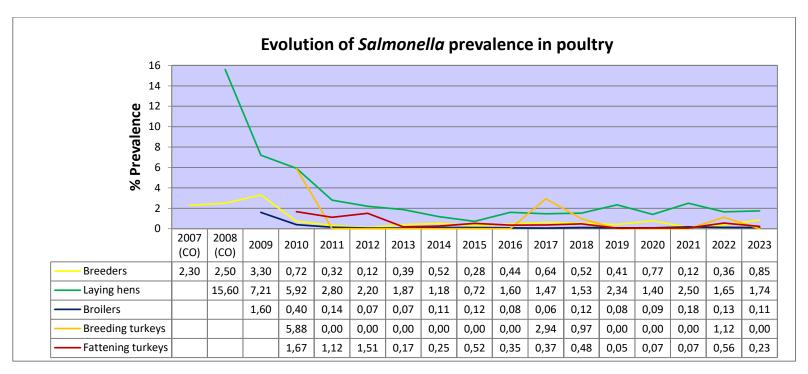
EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of Salmonella Enteritidis and Salmonella Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R1190-20190310&qid=1652941712941
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of
 the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of
 salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

XVI. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2023)



b. Most prevalent serotypes of Salmonella in the different poultry populations (2023)

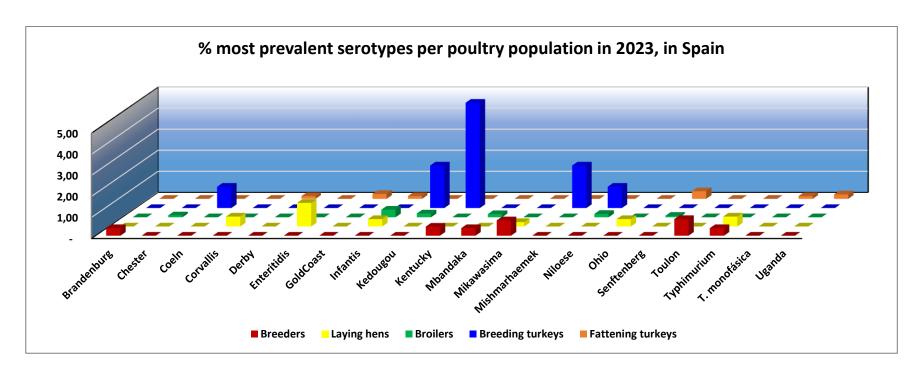
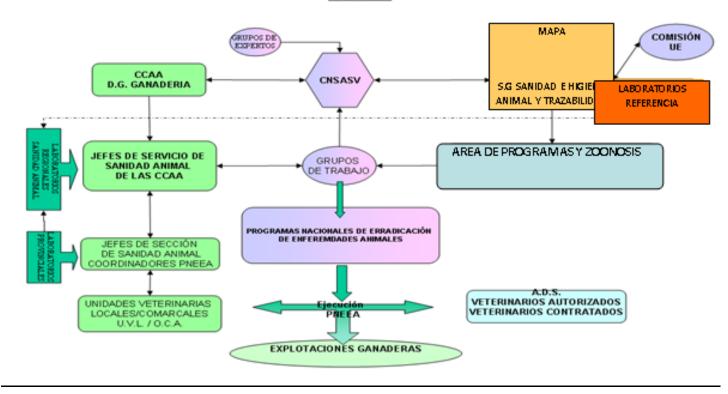
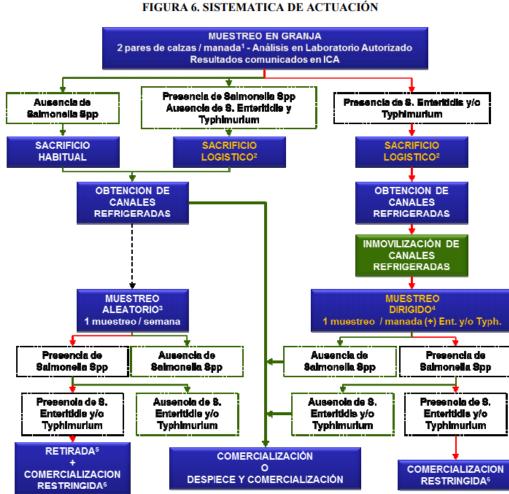


Diagramme of veterinary services

AUTORIDADES COMPETENTES: DISTRIBUCIÓN DE RESPONSABILIDADES Y RELACIONES EN EL ÁMBITO DE LOS PROGRAMAS NACIONALES DE ERRADICACIÓN DE ENFERMEDADES DE LOS ANIMALES



<u>Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):</u>



Para comercialización en fresco siempre incluir en etiquetado o en documento de acompañamiento la leyenda:

"Este producto debe ser totalmente cocinado entes de su consumo"





Single Market Programme (SMP Food)

EU co-funded Zoonotic *Salmonella* programme for year 2025-2027



SUBMISSION FORM: DESCRIPTION OF THE ACTION

(Annex 1 – Description of the action (part B))

Zoonotic Salmonella Programme Control programme – Reduction of prevalence of Salmonella serotypes in Fattening flocks of Turkeys 2025-2027

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

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

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

For more information or questions on the eGRANTS Portal Submission System, please access the <u>EU Funding & Tenders Portal</u> or contact the <u>IT Helpdesk</u>

APPLICANT (Name of EU / non-EU country)	SPAIN
Disease	ZOONOTIC SALMONELLA
Animal population/Species	Fattening flocks Turkeys
Implementation Year	2025-2027

CONTACT PERSON on Zoonotic Salmonella programme:

Name	Cristina Caballero Fernández
e-mail	ccaballero@mapa.es
Job type within the CA	Head of Service of Zoonoses

Salmonella in Fattening flocks Turkeys Programme – 2025-2027

1.RELEVANCE

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

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

- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry

of the national programmes for the control of <i>Salmonella</i> in poultry
Yes ⊠ No □
If no, please explain:
(maximum 200 words)

1.2 Needs and specific objectives

The **aim of the programme** is to implement all relevant measures in order to reduce to 1% or less the maximum percentage of flocks of fattening turkeys remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST) (including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

Yes ⊠ No □

If no, please explain:

The answer is yes, but S. Hadar, S. Infantis and S. Virchow are not target serovars.

The National Programme takes account of the specifications set out in Commission Regulation (EC) No 1190/2012 implementing Regulation (EC) No 2160/2003 regarding the Community target of reducing the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium in turkeys. The target will be the reduction of the maximum percentage of fattening turkey positive to *Salmonella* Enteritidis and *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:-, to 1 % or less.

For the purposes of verifying the attainment of the Community target, a flock of turkeys shall be considered positive when:

- a) the presence of *Salmonella* Enteritidis or *Salmonella* Typhimurium, including monophasic strains of *Salmonella* Typhimurium with the antigenic formula 1,4,[5],12:i:- (therefore different from the vaccine strains) has been detected in the flock, or
- b) when antimicrobials or bacterial growth inhibitors have been detected in the flock.

Positive flocks of turkeys shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

If either of the two mentioned serotypes is detected or *Salmonella* spp. is detected, the appropriate measures are explained in the programme.

(maximum 500 words)

For MS with less than 100 flocks of adult fattening turkeys, the Union target shall be the	nat
annually no more than one flock of adult fattening turkeys may remain positive.	

Yes □ No ☒

If no, please explain:

Spain has more than 100 flocks.

(maximum 500 words)

1.3 Complementarity with other actions — European added value

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

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

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

The project holds on previous actions initiated at EU level from 1993, for the surveillance and control of zoonotic agents such as *Salmonella*, through consequent EU legal provisions for the control and progressive reduction of the prevalence of *Salmonella*, supported on baseline studies with EFSA scientific assessment for establishing the initial epidemiological situation of *Salmonella* in poultry and the different objectives for prevalence reduction.

Therefore, the project is a continuation of the previous programmes for the control of *Salmonella* annually presented to the EU since the establishment of the prevalence reduction target, which was progressively amended until reaching a fixed target.

The programme has a trans-national and European dimension, as it has to be implemented in all Member States (MSs) with harmonised veterinary measures, in order to raise the level of public and animal health in the EU, while allowing the rational development of livestock sector and providing a safer EU trade of poultry and poultry products in the EU single market.

Furthermore, as the programme is based on an EU harmonised system, the results are comparable between MSs, and it allows spatial and temporal trend analysis at EU level.

It also has an international dimension, as it boosts the confidence not only of EU Member States and its consumers but also of Third Countries, who can rely on a solid system which ensures the detection of *Salmonella* spp., studies the trends and sources of infections in animal and human populations, and implements appropriate control actions in case *Salmonella* spp. and *Salmonella* serovars with public health significance are detected. Thus, it helps to increase the confidence on EU products and promotes national and European exports, so all countries would benefit from the project (directly and indirectly) as it fosters animal health, public health and the economy, bringing benefits worldwide.

(maximum 500 words)

1.4 Target population and Area of the implementation

This programme will be implemented on all Fattening flocks of turkeys
Yes ⊠ No □
If no, please explain on which flocks:
It shall apply on all holdings where turkeys are reared for slaughter in accordance with point 1 of the Annex of 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.

(maximum 500 words)

This programme shall not apply to holdings that produce primary products intended for selfconsumption (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 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, REGA code shall be used, adding a capital letter corresponding to the shed (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) + DATE OF ENTRY OF BIRDS (mmyyyy). (maximum 500 words) Fill in **Table 1**) in the Annex to this Form. This programme will be implemented on the whole territory of the Member State Yes 🛛 No □

1.5 Notification of detection of target Salmonella serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

Yes ⊠ No □

If yes, please describe the procedure briefly.

If no, please explain:

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.

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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 SNCP, to do so. If the serotyping shows positive results 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 a FBO own check, the competent authority must be notified as soon as possible, and never later than 24 hours after the laboratory and the owner of the holding receive the results of the analysis.

As soon as the operator becomes aware of the existence of a positive result, he shall be responsible for taking the appropriate measures, as set out in this programme for cases where the *Salmonella* serotypes concerned by the programme are detected. The competent authority may carry out a confirmatory analysis in exceptional cases and if it is considered appropriate.

It is mandatory to record all the results of FBO own checks using the computer application developed to this end for the authorised laboratories to report the results, without prejudice to the provisions 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 the programme.

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

(maximum 500 words)

1.6 Epidemiological situation background

Describe the epidemiological disease situation background i.e. describe key obstacles and constraints hampering the control of *Salmonella* cases.

Salmonella surveillance and control in Spain has been carried out since 1993, in accordance with Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against certain zoonoses and zoonotic agents in animals and products of animal origin, in order to prevent outbreaks of food-borne infections and intoxications. This surveillance and control has been focused on *S*. Enteritidis and *S*. Typhimurium.

During 2006, the monitoring and data collection of flocks of turkeys was carried out following the guidelines issued at Community level to set the prevalence reduction target contemplated in Regulation (EC) No. 2160/2003 of the Parliament and the Council on the control of *Salmonella* and other specified food-borne zoonotic agents.

Since the beginning of the implementation of the *Salmonella* Control Programme in fattening turkeys until nowadays, the prevalence of *Salmonella* has dropped from 1,67% (2010) to 0,23% (2023), which corroborates the effectiveness of the programme.

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The most prevalent salmonellas with importance in public health are *S*. Infantis in first place, followed by *S*. monophasic Typhimurium.

The application of biosecurity measures is one of the key obstacles hampering the control of *Salmonella* cases.

The production sector of fattening flocks faces several challenges for the implementation of the programme that could hamper the control, mainly related to maintain adequate facilities for turkey production complying at the same time the necessary level of general biosecurity measures.

2. QUALITY

2.1 Concept and methodology (Programme activities/measures)

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

As mentioned in section 1.1. the MS attests that the relevant provisions of the EU legislation will be implemented during its entire period of approval. This includes:

- that the appropriate measures are taken with regards to biosecurity, collection, transportation and storage of samples, and EU microbiological criteria in fresh poultry meat in birds from flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*.
- -laboratory accreditation, analytical methods used for the detection of the target *Salmonella* serovars, antimicrobial controls and transportation of and storage of samples tasks are all performed according to the respective current EU legislation [accreditation requirement according to Art 37(4) of EU Regulation 2017/625].

Yes ⊠ No □

If no, please explain:

Biosecurity measures are part of the SNCP and there are national rules reinforcing them (RD 637/2021, establishing rules for the management of poultry farms and National Animal Health Law 8/2003). Biosecurity measures shall be checked at least once a year, following the protocol for the verification of biosecurity measures in broiler flocks stablished in this programme.

When a slaughterhouse receives a positive flock, it will be slaughter at the end of the day, in order to reduce cross contamination, and cleaning and disinfection will follow. Furthermore, slaughterhouses shall include in their sampling plans poultry carcasses from flocks with unknown or positive *Salmonella* status for SE and ST.

Samples shall be sent to the laboratories referred to in Regulation 2160/2003, within 24 hours after collection. If not sent within 24 hours, they must be stored refrigerated. They may be transported at ambient temperature as long as excessive heat 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.

Laboratory accreditation is governed by Regulation 2017/625 and microbiological criteria by Regulation 2073/2005.

(maximum 200 words)

2.1.1 Minimum sampling requirements for food business operators

Samples at the initiative of the FBO's will be taken and analysed to test for the target <i>Salmonella</i> serovars respecting the following minimum sampling requirements: All flocks of fattening turkeys within three weeks before slaughter. Yes ☑ No □
163 🔼 140 🗀
The competent authority may authorise sampling in the last six weeks prior to the date of slaughter in case the turkeys are either kept more than 100 days or fall under organic turkey production according to Commission Regulation (EC) No 889/2008.
Yes ⊠ No □
If no, please explain. Indicate also who takes the FBO samples. If the derogation is applied, how many holdings and flocks are concerned
In general terms, common turkey production cycles in Spain go beyond 100 days, and some FBO are authorised to do the sampling in the last six weeks prior slaughtering (in 2023, around 360 holdings were authorised).
Samples shall be taken in accordance with the following minimum requirements:
Sampling of all the flocks on a holding in the course of own checks shall be performed by the holder and the veterinarian responsible for the holding or may be carried out by qualified staff

of the laboratory performing the analyses. The veterinarian responsible for the holding shall

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verify that the sampling protocol is done in accordance with the conditions set in this programme.

Samples of faeces from all flocks on the holding shall be taken using boot swabs during the three weeks prior to the birds' departure for the slaughterhouse. The results of the analyses on the samples must be known before the animals leave for the slaughterhouse. The sample collection sheet shall identify the person performing the sample, his/her job position and the company to which he/she belongs.

The competent authority may authorise sampling in the last six weeks prior to the date of slaughter in case the turkeys are:

- kept more than 100 days or;
- reared using organic production methods according to Regulation (EC) No 2018/848.

Environmental sampling should also be carried out to verify the cleaning and disinfection after each emptying of the shed. The repopulation of the shed shall only be done after obtaining a negative result regarding *Salmonella*, as reflected in this program.

RECORDING OF RESULTS USING THE MINISTRY'S COMPUTER APPLICATION

The data and information obtained from holdings where FBO 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 will 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 is missing. All the samples and data referring to the flocks sampled (official controls and own checks) that are not recorded in the Ministry's applications will not be valid for the purposes of the PNCS. Nevertheless, any positive result for *Salmonella*, which is considered to have public health significance, must be notified as laid down in the PNCS.

2.2 Programme participants (stakeholders)

Cooperation and division of roles and responsibilities

Indicate participants (stakeholders such as competent authorities, testing laboratories, authorised private veterinarians, other stakeholders as relevant) involved in the planning and implementation of the programme; what are their roles and responsibilities; who reports to whom; what are the reporting arrangements.

Indicate who is overall responsible for the programme and how the overall responsible coordinates with other stakeholders; how effective communication will be ensured.

Structure and organization of the Competent Authorities (from the central CA to the local CAs)

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Please provide a short description and reference to a document presenting this description. Please insert the functioning url if applicable.

Participants involved in the planning and/or implementation of the programme are the following: competent authorities (central and regional level), National Reference Laboratory and regional testing laboratories, private veterinarians and stakeholders.

For the purposes of this programme, the competent authorities shall be those of the Autonomous Communities and the General State Administration responsible for animal health matters.

The Subdirectorate-General for Animal Health and Hygiene of the Ministry of Agriculture, 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. This Subdirectorate is the main responsible for the programme and for its coordination, through regular communications and meetings with regional authorities and with NRI and stakeholders.

The Autonomous Communities (regional authorities) are responsible for the direct implementation and monitoring of the activities to be carried out under the programme.

Private veterinarians and the food-business operators (FBO) are responsible for the implementation of the measures of the programme (appropriate sampling, sending samples to authorised laboratories and applying the established preventive and control measures).

Authorised laboratories (official or private) are responsible for the adequate testing and notification of the results.

Royal Decree 1440/2001 of 21 December 2001 setting up the veterinary health warning system, created the "National Veterinary Health Warning System Committee" (a diagram of the Health Warning System Network (RASVE) is enclosed), which is responsible for studying and proposing measures to prevent, control, combat and eradicate diseases covered by national programmes. Its tasks were reinforced by Law No 8/2003 on animal health. This committee is attached to the Ministry of the Agriculture, Fisheries 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 regarding animal diseases at national, European and international level.
- d) Proposing relevant measures.

This national committee could agree to set up a consultative committee on avian salmonellosis, which would be attached to it, and would include members of the most representative organisations and associations in this sector in Spain and may also include the professional association of veterinary officers. The role of this consultative committee would

be to advise the Committee when requested to do so and also to put any relevant issues to it for consideration.

2.3 Management; controls and verifications, quality assurance and monitoring and evaluation strategy

Describe the activities planned to ensure that the implementation of the programme activities is of high quality and completed in time (according to the plan/timeline). Explain planned controls and verifications, and monitoring of achievement of targets (activity¹ indicators) - please describe for different programme activities.

Describe the evaluation of the progress indicators (quantitative and qualitative); the outreach of the expected results/outcome (include unit of measurement, baseline and target values). The indicators proposed to measure progress (progress indicators) should be relevant, realistic, and measurable.

Both the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food perform activities to ensure the implementation of *Salmonella* Control Programme. The Autonomous Communities carry out controls at least at the minimum frequency stablished in the programme, in order to detect compliance and non-compliance.

In addition to these responsibilities and the responsibilities of other participants, that are necessary for the implementation of the programme, in order to facilitate the monitoring and follow-up of the data obtained we have two software applications for recording information from industry and official controls. The information from FBO checks is recorded by the authorised laboratories that analyse FBO samples (with deadlines for the recording), and the information from official controls is recorded by the official veterinary services of the Autonomous Communities. Both software applications are interconnected to allow the Competent Authorities the control and verification of the correct implementation of the programme (number of farms/ flocks included, sampling frequency, type of samples, results, etc.), to assure the suitability of the FBO own checks and to guarantee its coherence with the controls carried out by the AC. The information is thus subjected to a double review: the Autonomous Communities review the information from both applications from the flocks located in their territory, and at central level the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results available in the two databases.

There are continuous checks of the results all along the duration of the programme, and the main indicators are thoroughly monitored twice a year by the central authorities, that are included in an intermediate and a final follow-up internal report. Furthermore, the analysis of the results involves other internal reports to support the analysis of the evolution of the epidemiological situation, with information of the positive flocks, the confirmatory tests done, the main serotypes detected, the type of production of the positive flocks, etc., and the EU financing reports (intermediate and final).

Main indicators of progress are: prevalence rates, evolution of the prevalence, serotypes detected, degree of coverage of the controls, vaccination status and results of biosecurity checks.

Lastly, as an additional quality system there is a control and inspection plan for monitoring FBO checks and laboratories testing FBO samples in order to verify that FBO checks are being performed correctly. Documents are available on the MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higieneganadera/4plancontroloficialdeatcdef tcm30-431061.pdf https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higieneganadera/5planinspeccioneslabatc tcm30-431062.pdf

The Official Veterinary Services carry out quality controls on FBO checks on a percentage of holdings, selected each year in accordance with several ranked risk criteria. Official quality controls include a visit to the farm/ laboratory, survey and audit of sampling with official sampling at the same time, if considered, and reporting of the results of the inspection. In the event that any shortcomings are detected, they must be reported to the producer as soon as possible to be corrected immediately in next FBO checks, without prejudice to any administrative consequences they may have. Additional details of the quality monitoring plan are available in the website and in point 2.3.7.

2.3.1 Official controls at feed level

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

Control measures to prevent the introduction of Salmonella spp. in farms through feed are based on the verification of compliance with current feed regulations by the competent authority of the Autonomous Communities.

As described in Article 15 of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the feed operator shall not place unsafe feed on the market which has an adverse effect on human or animal health or which renders the feed obtained from food-producing animals unsafe for human consumption. Therefore, the operator shall take necessary, effective, proportionate and specific measures to continuously minimize potential Salmonella contamination and protect human and animal health. The producer of the feed material shall establish, implement and maintain a permanent written procedure or procedures based on HACCP principles in accordance with Article 6 of Regulation (EC) 183/2005 laying down requirements for feed hygiene. Procedures based on HACCP or guidelines are aimed at significantly reducing the presence of Salmonella and minimizing the re-contamination of the final product or reducing the level of contamination, according to the specific risk assessment of each operator through a strict system of controls throughout the process and the application of various measures aimed at reducing the risk of Salmonella spp. presence. The critical points of the manufacturing process will depend on each operator and will have to take into account the evaluation and control of suppliers (microbiological quality of the raw materials supplied or other factors that may compromise it), the application of cleaning programs and the application of good practice guidelines throughout the production chain (storage of raw materials, manufacturing, storage of the finished product, etc.).

The control measures by the competent authority of the Autonomous Regions include different aspects such as the verification of the purchase of feed from registered or authorized operators, in accordance with Regulation (EC) 183/2005 laying down requirements for feed

hygiene, including the application of systems and self-monitoring based on HACCP principles and guides to good hygiene practices. The objective is to ensure that no *Salmonella* contamination occurs during the processing of poultry feed, guaranteeing feed safety at all stages that may have an impact on feed and food safety, including the primary production of feed and food.

It should also be noted that Regulation (EC) Nº 183/2005 on Feed Hygiene, applicable since January 1, 2006, requires the establishment of harmonized microbiological criteria, based on scientific criteria of Risk Analysis, to harmonize intra-Community trade and ensure that imported feed complies with levels at least equivalent to those produced in the national territory. According to this Regulation, feed exporting companies must comply with specific microbiological criteria. The criteria and targets must be adopted by the EU in accordance with the procedure laid down in Article 31 of the Regulation.

Feed business operators responsible for the primary production of feed must take the necessary measures to prevent, eliminate or reduce feed safety risks during the procurement and storage of raw materials and the subsequent stages of manufacture, preparation, cleaning, packaging, storage and transport of such products (as referred to in Annex I of Regulation 183/2005). They must also keep records detailing the measures taken to control contamination hazards. Other feed business operators must take appropriate measures to ensure the safety of the products they manufacture, transport or use. These measures are more precisely detailed in Annex II of the aforementioned regulation, and they shall apply the principles of the HACCP system, taking corrective measures when the monitoring of a critical point is not controlled and implementing internal procedures to verify that the measures taken are effective. They must also maintain records in order to demonstrate the application of these measures.

Therefore, feed hygiene requirements are verified in all the activities of operators in the animal feed sector, from the primary production of feed to its commercialization, as well as the feeding of food-producing animals and the import and export of feed from and to third countries, with the purpose of adopting the appropriate measures to guarantee the safety of feed at each stage.

It should be noted that there is no Community or national regulation establishing microbiological criteria for *Salmonella* (or other microorganisms) in raw materials and feed of vegetable origin, although there are legal criteria established for raw materials and feed of animal origin.

The program of official controls in animal feed, approved within the National Coordination Commission for Animal Feed (CNCAA), indicates that, given that, in the case of vegetable products (whether raw materials or feed), these determinations do not have a maximum limit established in the current national or Community regulations, in the event of a positive result for *Salmonella*, an identification of the serotype must be requested. Only in the case of *S.* Enteritidis, *S.* Typhimurium, *S.* Infantis, *S.* Virchow and *S.* Hadar, notification will be made through the Alert Network.

In case of a positive result for *Salmonella* spp., the approved HACCP system must apply corrective measures that allow the product, in a new analytical control, to demonstrate that it is suitable to be placed on the market. These measures are included in international, community and national sectoral guides. This is the case of the Guide for the development of feed sanitization standards, prepared in 2007 by the Spanish Confederation of Compound

Feed Manufacturers (CESFAC), which compiles in a single document the possible sanitization systems that can be applied in a factory to obtain microbiologically safe feed, such as heat treatment or the use of authorized additives. Available at: https://cesfac.es/media/attachments/2019/08/08/guia-higienizacin.pdf

The information on the authorization of feed additives, contained in the guides, must be verified with the register of authorized additives which can be accessed through the following link: https://food.ec.europa.eu/safety/animal-feed/feed-additives/eu-register_en

There are no criteria to be followed in the EU zoonosis regulations regarding the potential presence of *Salmonella* and other potential zoonotic agents in feed. The sampling that accompanies the official controls on establishments that destine products for animal feed includes analytical determinations to detect the presence of *Salmonella* in raw materials and feed. In the case of products of plant origin, analytical determinations are carried out taking into account the risk criteria established in public documents approved by the CNCAA in which possible hazards to be controlled in raw materials intended for the manufacture of animal feed and, therefore, in the feed of which they are part (DOC CNCAA 1/2015 vers 1. Main hazards to be controlled in self-control systems). This document has been disseminated to operators in the sector through their associations, the control authority, and is accessible on the SILUM application on the website of the Ministry of Agriculture, Fisheries and Food: https://www.mapa.gob.es/es/ganaderia/temas/alimentacion-animal/acceso-publico/pruebaotros.aspx

Every year, more than 3,000 official inspections are carried out in national establishments destined for animal feed products, verifying the self-controls performed by operators in the sector and more than 1,000 official samples are taken for the determination of microbiology, including *Salmonella*. These data are included in the PNCOCA annual report, distributing the samples among raw materials, compound feed and other products.

2.3.2. Official controls at holding and flock level

a) Please describe the official checks concerning the **general hygiene provisions** (Annex I of Regulation (EC) No 852/2004) including checks on biosecurity measures, and consequences in case of unsatisfactory outcome.

Competent authorities perform the official controls established in EU and national legislation. Checks concerning general hygiene provisions of Regulation EC 852/2004 are included to verify the compliance of all the mandatory requirements for the operators. They also extend to biosecurity checks, that are established in national legislation Royal Decree 637/21, and in vertical legislation for the relevant pathogens (such as *Salmonella* control programme).

The sector is well informed about general hygiene provisions and about hygiene provisions for the prevention of *Salmonella*. There are "Guides to Good Hygiene Practice for the prevention of zoonotic *Salmonella* in holdings for the selection, breeding and rearing of flocks of *Gallus gallus*", that have been drawn up jointly by representatives of the breeding poultry sector and the Ministry of Agriculture, Fisheries and Food. They are available in printed form for distribution to livestock farmers in the sector and the competent authorities, and they are also available for consultation on MAPA's website: https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/bioseguridad-buenas-practicas/aves-bioseguridad.aspx

Turkey holding operators shall have a code of good hygiene practice adapted 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).
 - 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 N° 8/2003 on animal health.

Without prejudice to Royal Decree N° 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.;

- ()
- 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, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform and single culture, or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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;

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- 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;

Appropriate measures must be taken to ensure the proper management of by-products of animal origin not intended for human consumption.

- **b)** Routine official **sampling scheme:** EU minimum requirements are implemented i.e. official sampling are performed:
 - in one flock of fattening turkeys per year on 10% of holding comprising at least 500 fattening turkeys;

Yes ⊠ No □

If no, please explain. Indicate also: 1) if additional official sampling going beyond EU minimum requirements is performed, 2) who is taking the official samples

Official samples must be taken by the qualified or authorised veterinarian or in some cases by sufficiently trained authorised personnel under veterinary supervision. The sample collection sheet shall identify the person performing the sample and his/her job position.

The official sampling shall cover at least:

This shall be done once a year, on at least one flock on 10% of the holdings with at least 500 fattening turkeys and may be repeated whenever the competent authority considers this appropriate.

In any Autonomous Community with fewer than 10 holdings an official control shall be conducted on at least one farm.

Among the risk criteria for choosing 10% of the holdings the following shall be taken into account:

- a) characteristics of holdings:
 - Type of production.
 - Size of the farm (poultry population).
 - Poultry density in the province (measured in this case by the number of holdings).
- b) historical record of holdings
 - Changes in the results obtained in the sampled holdings in previous years.
 - Priority to be given to those holdings on which no information is available.
- c) cases of non-compliance
 - Priority to be given by assigning a greater risk to those holdings on which shortcomings in the biosafety surveys have not been remedied and those on which positive results have been obtained.

Sampling shall take place within the last three weeks before the birds are sent for slaughter.

Sampling performed by the competent authority may replace sampling on the initiative of the food business operator (own check). If necessary, results may be requested of laboratory analyses of the worker/s in charge of the animals in order to determine whether there are any Salmonella spp. carriers among them. All data and information gathered on holdings on which official sampling has been performed (SAMPLING SHEET AND BIOSAFETY PROTOCOLS ANNEX) and the laboratory results shall be recorded in a dedicated computer application developed for the National Programme for the Control of Salmonella. https://servicio.mapama.gob.es/ Other official samples Whenever the competent authorities see the need, official samples of animal feed, drinking water and environmental samples may be taken to check the effectiveness of cleaning and disinfection measures. Other types of samples may also be taken. The competent authority may decide to increase the minimum number of samples in order to ensure representative sampling on a case-by-case evaluation of epidemiological parameters, such as biosecurity conditions, the distribution or size of the flock. c) EU conditions for confirmatory testing are complied with and confirmatory testing is not applied routinely Yes ⊠ No □ d) If confirmatory samples taken at the holding (in addition to the confirmatory samples at the holding which are systematically performed if FBO or official samples are positive at the hatchery): After positive official samples at the holding □ Always ☐ Sometimes (criteria apply) Never
 Never After positive FBO samples at the holding ☐ Always ☐ Sometimes (criteria apply)

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.

When official confirmatory sampling is performed, additional samples are taken for checking

Never

☐ Always □ Sometimes Never
 Never

the presence of antimicrobials:

Confirmatory analyses are not carried out for fattening turkeys.

d) Antimicrobial control

Article 2 of Regulation (EC) No 1177/2006 (antimicrobials shall not be used as a specific method to control *Salmonella* in poultry): please describe the official controls implemented (documentary checks, sample taking) to check the correct implementation of this provision (at the holding and at the hatchery).

For samples please describe the samples taken, the analytical method used, the result of the tests.

The competent authorities must carry out checks (laboratory tests or documentary checks on the records of the holding) in order to guarantee that no antimicrobial medicinal products that might affect the result of analyses have been used.

In addition to the sampling provided for, when appropriate, a random sample of birds may be taken within each shed housing birds on a holding, usually of up to five birds per flock unless the competent authority considers it necessary to include a greater number of birds in the sampling.

The examination shall consist of a test, using accredited techniques to detect the effect of bacterial growth inhibitors or antimicrobials.

Samples of feed and water may be taken simultaneously with the aim of detecting and quantifying the quantity of antimicrobials if necessary.

Where the presence of the *Salmonella* serotypes covered by the programme is not detected but antimicrobials or bacterial growth inhibitory effects are detected it shall be considered and accounted for as an infected flock for the purpose of the Union target.

These samples, in the framework of the SNCP, shall not take in triplicate notwithstanding that these actions can be combined with other programs in which these samples in triplicate are necessary.

If, from this action, derive measures related to the national plan of investigation of residues of veterinary drugs, it will take the appropriate actions, according to the aforementioned regulations.

2.3.3 Efficacy of disinfection

Please state who performs the testing (FBO/CA) and provide a short description of the official procedure to test, after the depopulation of an infected flock, the **efficacy of the disinfection** of a poultry house (number of samples, number of tests, samples taken, etc...).

Once the birds have been removed, the holding will be cleaned efficiently and thoroughly (including complete removal of the bedding and excrement), followed by disinfection, insect removal and rat extermination. The above tasks will be performed using properly authorised and registered products. A suitable time after disinfection is complete, environmental samples

will be taken to check the effectiveness of the cleaning and disinfection and to make sure that Salmonella is no longer present in the environment.

The competent authorities will check whether the cleaning and disinfection measures applied following the destocking of the shed have been performed to a satisfactory standard and, when appropriate, they will authorise restocking with new animals. The competent authority can take environmental samples to verify the effectiveness of cleaning and disinfection when they deem appropriate.

To verify cleaning and disinfection, two or more moistened fabric swabs of at least 900 cm² per swab, moistened using appropriate diluents (such as 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water, sterile water or any other diluent approved by the competent authority), shall be used to swab as large a surface area in different points in the house (floor, walls, feeding equipment, watering equipment, belts, pillars, water and feeding pipes, scrapers and any other difficult point to clean and disinfect).

Samples can be pooled to perform a single culture or by enriching the peptone water separately and then taking 1 ml of the incubated peptone water of each sample, mixing them well and then take 0.1 ml 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 SNCP.

The results must be recorded using the MAPA computer application for FBO 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 for Salmonella spp., cleaning and disinfection should be repeated.

The premises shall not be restocked for 12 days after completion of the cleaning, disinfection, rat extermination and, if necessary, insect removal processes. Repopulation may take place only if the environmental analyses carried out in accordance with the programme are satisfactory, and if biosecurity measures considered inadequate or deficient by the competent authority have been properly corrected. Notwithstanding the above, in those cases where the results of those tests prove the effectiveness of the cleaning and disinfection undertaken, the waiting period may be reduced to a minimum of 7 days.

2.3.4 Monitoring of the target Salmonella serovars (Salmonella enteritidis, Salmonella typhimurium)

Give a short summary (from last 5 years) of the outcome of the monitoring of the target Salmonella serovars (SE, ST) implemented in accordance with Article 4 of Directive 2003/99/EC (evolution of the prevalence values based on the monitoring of animal populations or subpopulations or of the food chain

Council Directive 92/117/EEC, repealed by Directive 2003/99/EC, concerning measures for protection against specified zoonosis and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and food poisoning.

A prevalence reference study was made at Community level of *Salmonella* in turkey flocks of the species Meleagris gallopavo between October 2006 and September 2007. Analyses were made and samples taken from selected flocks of turkeys in accordance with Community guidelines as laid down in Commission Decision 2005/662/EC.

According to information obtained from the study, prevalence of *S*. Enteritidis and *S*. Typhimurium serotypes in breeding turkey flocks was 0% and 2.8% in turkeys for fattening, rising to 5.3% in breeding turkeys and 56.3% in turkeys for fattening for *Salmonella* spp.

The evolution of the prevalence of the types of *Salmonella* covered by checks on fattening turkey flocks is shown in the attached graphic (see part IV. Maps).

2.3.5 System for the registration of holdings and identification of flocks

Give a short description of the system for the registration of holdings and identification of flocks

The obligation to register livestock holdings in Spain derives, firstly, from Article 39 of Law N° 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) N° 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 the REGA code shall be used, adding a capital letter corresponding to the shed (this letter must be written on the door to

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the shed), and the date of entry of the birds to the shed must be written in the format mm/yyyy.

REGA + SHED (CAPITAL LETTER) + ENTRY DATE OF THE BIRDS (mm/yyyy)

2.3.6 System for **compensation to owners** for the value of their birds slaughtered or culled and the eggs destroyed or heat treated

Describe the system for compensation to owners. Indicate how improper implementation of biosecurity measures can affect the payment of compensation

The official veterinary services of the Autonomous Communities (ACs) organise compulsory slaughter and are responsible for providing slaughter compensation. The ACs are responsible for financing this. For broiler chickens and fattening turkeys, slaughter in the case of positive flocks is not compulsory and therefore is not compensated.

2.3.7 System to monitor the implementation of the programme

Please describe

Taking account of the structure and organisation of the Spanish State, the General State Administration — represented by the Subdirectorate-General for Animal Health and Hygiene and Traceability of the Ministry of Agriculture, 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; 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 FBO own checks is recorded by the authorised laboratories that analyse own-check samples, and information from official controls is recorded by the official veterinary services of the Autonomous Communities. The information is thus subject to double review: the Autonomous Communities review the information from both applications on their territory, and the Subdirectorate-General for Animal Health and Hygiene and Traceability globally reviews all the results.

Finally, a plan to control own checks and inspect own-check laboratories is in place.

With a view to ascertaining that the own checks are being performed correctly, the competent authority may carry out the following plan to control own checks and inspect own-check laboratories (document available in the MAPA website).

The official veterinary services shall perform a quality control of the own checks in a certain percentage of holdings, selected annually on the basis of the following prioritised risk criteria:

 Holdings in which own checks have shown negative results for the serotypes covered by the checks and official controls have shown positive results.

- (0)
- 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 CDD 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 OC and FBO own checks. They must check critical aspects of these that can presumably have an impact on the results (e.g. use of enriched peptone water in boot swabs, origin, expiry, representativeness of the sample, number of steps and surface area used, where relevant, dispersion of the aliquots of faeces in order to generate sufficient representativeness in the pools, etc.). How and where the samples are kept before being sent to the laboratory must also be investigated, as must compliance with the deadlines for their being received in the laboratory.

During this inspection, the competent authority shall ask any questions it deems relevant and request the necessary documents regarding implementation of the own checks.

The official veterinarian must note down the results of the control in an inspection report. The information in that report, and any other information obtained when tracing the sample until it arrives in the laboratory, shall be used by the competent authority to draw up an appraisal report. If any anomalies are detected, they shall be reported to the producer as quickly as possible so that they may be corrected immediately for use in successive own checks, irrespective of the administrative effects that could arise in this case in particular. The competent authority shall give a copy of the report to the person responsible for the own-check sampling.

If the competent authority considers it appropriate, duplicate samples shall be taken. One of the samples shall be taken by the official veterinarian, using his own materials, and shall remain in his possession. This sample shall be sent to an official laboratory, together with the sampling sheet. The other sample shall be taken by the person in charge of own-check sampling and shall be taken using materials provided by this person. It shall remain in his possession and must be analysed like any other own check.

Whenever there are large discrepancies between the official control results and the own-check results on the same flock, the competent authority may request, if it deems it necessary, the isolated strains of the said flock from the own-check laboratory that analysed them in order to perform an analysis of them in an official laboratory in its Autonomous Community.

The inspections in the laboratories shall take place in accordance with the document attached above. Within two years, each Autonomous Community must have inspected all the laboratories in its territory.

2.4 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of the programme, and mitigation measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

Note: Uncertainties and unexpected events occur in all organizations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.

Risk No	Description	Proposed risk-mitigation measures
1	Non-compliance of the sampling frame of FBO checks (frequency, protocol, matrix, volume, preparation, conservation and transport of the samples to the laboratory, etc). Impact on the coverage of the programme and on the sensitivity of the monitoring system. (High risk)	Appropriate training of the FBO/ veterinarians responsible of sampling. Periodic surveillance of the FBO database in order to detect non-compliances and apply consequent corrective measures.
2	Non-compliance of the minimum requirements for the official controls (flocks checked, official visits to take samples, adequate sampling, etc). Impact on sensitivity and quality system. (Medium-Low risk)	Appropriate training on sampling protocol and requirements of the SNCP. Adequate estimations and scheduling of the flocks to check and number of necessary visits to take samples. Periodic checks of the results and adjustment scheduling when necessary.
3	Shortcomings on the examination of the samples at the laboratory (invalid samples, inappropriate preparation of the samples, inappropriate detection method, etc). Impact on sensitivity and specificity.	Appropriate training of the laboratory staff. Frequent intercomparison (proficiency) tests organised by the NRL and updating of the SNCP authorised laboratories. Implement protocols of quality procedures in the lab.

	(Low risk)	Official inspections to the laboratories in the frame of the Monitoring Plan inspection of laboratories testing FBO samples (quality system).
4	Delay on the notification of the results to the FBO or to the competent authorities. Impact on the propagation of the disease if implementation of the measures is delayed. (Low risk)	Appropriate awareness and knowledge of deadlines and requirements of the SNCP.
5	Non-compliance of the EU target for the reduction of the prevalence (Medium-low risk)	Frequent monitoring of the results and of the proper implementation of the control and eradication measures. Further analysis of the positive farms (epidemiological survey, analysis of most probable causes of infection, investigation of the results of the farm of origin of the animals). Maximise biosecurity awareness. Prioritise the positive farms in the Monitoring Plan for FBO checks (quality system). Re-design future SNCP (not allowing exceptions to reduce frequency of FBO checks, increasing minimum frequency on sampling).
6	Human salmonellosis cases or foodborne outbreaks due to consumption of contaminated turkey meat. Impact on public health, on food safety, on farmer's production. (Medium risk)	Rigorous accomplishment of the control programme and of the next stages of the agrifood chain (hygiene process, slaughtering process). Rapid coordination and collaboration between Competent Authorities (regional and central, and between authorities with different competencies (Public Health and Animal Health) to initiate a rapid response to the alert, investigations and corrective actions established in the SNCP (in case the cause of contamination was at farm level).

2.5 Milestones

Indicate control points along the programme implementation that help to chart progress.

Note: Deliverables (e.g. intermediate or final report on the implementation of programme measures) are not milestones.

medsures) are not innestones.			
Name	Due date (in month)	Means of verification	
Prior knowledge of the SNCP requirements.	May of the previous year (year N-1). January (year N)	Presentation of the SNCP to CA and stakeholders (May of the year N-1). Publication of the SNCP on the MAPA's website (January year N).	
Periodic regional and central data analysis of the results. Review and identification of possible data recording errors (fixing of bugs).	Not fixed (must be done periodically or when considered, all along the year N)	Analysis of the FBO monitoring system and their results. Review of the regional data recordings for fixing bugs, according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to the laboratories/ stakeholders involved and check their correction.	
Central data review of the results of first semester. Review, identification and correction of possible data recording errors (fixing of bugs).	July-August (year N)	Review of all the data according to the Manual for the review of the data recordings in the FBO and official databases, communication of the errors to regional authorities and corrective measures and check their correction.	
Central follow-up analysis and verification of the implementation and results of the SNCP (first semester).	August- September (year N)	Intermediate follow-up technical report (data of first semester).	
Central data review of the results of second semester. Review, identification and correction of possible data recording errors (fixing of bugs).	November (year N) Updated in March (year N+1)	Review of all the data according to the Manual for the review of the data recordings in the FBO and OC databases, communication of the errors to regional authorities and corrective measures and check their correction.	
Central follow-up analysis and verification of the implementation and results of the SNCP (final period).	March-April (year N+1)	Final follow-up technical report (final data).	

3. IMPACT

3.1 Impact and ambition

Describe **expected impact** (benefit) of the programme (e.g. from the economical and animal health points of view)

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Define the short, medium and long-term effects of the project.

Possible examples: reduction to 1% or less the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for the target *Salmonella* serovars: *S. enteritidis* (SE), *S. typhimurium* (ST)(including the antigenic formula 1,4,[5],12: i:-), *S. hadar* (SH), *S. infantis* (SI) and *S. virchow* (SV).

The programme establishes the implementation of veterinary measures focused to increase the public and animal health, allowing the development of the farming sector.

The programme will have a favourable impact from the economic and sanitary point of view, as it includes preventive and control measures at the level of primary production to fight against one of the most frequent zoonotic agents at EU level. Thus, it will improve the animal health situation on poultry farms and the benefit will also extend to next steps of the agrifood chain, reducing losses on food production industry and preventing negative consequences of human cases and outbreaks of salmonellosis of poultry products origin.

The application of preventive and control measures as biosecurity measures, vaccination, slaughtering, cleaning and disinfection will lead to a decrease on *Salmonella* and, therefore, to a better animal health situation.

The main target group who must implement the programme is the farming sector fattening turkeys, but there are other expected target groups: the food industry and the food consumers, who will benefit of a greater food safety and of the protection of public health and the health of the environment.

The expected effects of the programme are:

- Short-term effect of the programme: implementation of EU requirements on *Salmonella* control programmes, according to EU legislation. Improvement of the level of farm biosecurity, incorporate a sensitive monitoring system to rapid detection of the infection and rapid eradication and control actions.
- Medium-term effect of the programme: keeping the EU reduction target to 1% or less the maximum percentage of fattening turkey flocks remaining positive for the target *Salmonella* serovars: *S.* Enteritidis (SE), *S.* Typhimurium (ST) (including the antigenic formula 1,4,[5],12: i:-). Prevention and reduction of other serotypes of *Salmonella*, due to the programme also includes measures on them, and prevention and control of other pathogens due to general biosecurity measures.
- Long-term effect of the programme: source of information on the evolution and behaviour of *Salmonella* serotypes and their spread in animal production, that will allow the comparison with human salmonellosis and will support decision-making on future measures.

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and information dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.).

Describe how the visibility of EU funding will be ensured.

The project actions will be promoted and the results will be informed to the CA (official veterinary services, policy-makers), to the animal and food sector, to the private veterinary services, and to any other private organisation interested on it (i.e. poultry associations and organisations, third countries, universities, international agencies, etc), through meetings, training courses, seminars or conferences.

The programme is a result of an agreement with regional authorities, NRL and with national health authorities. It is annually presented to them and approved in a specific meeting before the presentation of this project to EU.

It is also presented to poultry associations and organisations before the implementation of the programme in a specific meeting, and it is published in the web page of the Ministry of Agriculture, Fisheries and Food.

Furthermore, any training session, seminars, participation in sector magazine articles or conferences, that may be requested are organised to increase communication, dissemination and visibility to the programme.

All public presentations in seminars or conferences or other communication activities will display the European flag (emblem) and funding statement "funded by the European Union".

The programme will be available in the MAPA's website:

https://www.mapa.gob.es/es/ganaderia/temas/sanidad-animal-higiene-ganadera/sanidad-animal/enfermedades/salmonella/salmonella general.aspx

3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the how will the project impact be ensured and sustained long term? Which parts of the project should be continued or maintained, and which resources will be necessary to continue?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the results of the implementation of this project?

The programme is a result of the implementation of EU legislation in the form of Regulations, so most parts of the project will be continued at least until derogation of these provisions. Nevertheless, if the progress is not correct or the reduction target is not achieved, corrective actions and amendments will be re-assessed.

Human and economic resources are needed to defray the cost of sampling, farm visits, testing, compensation for slaughtering and vaccination costs. Therefore, the EU financial contribution

will help to the correct implementation of the programme. After receiving the EU funds, the coordinator of the project (MAPA) will distribute the funds to each of the involved entities (NRL and regional authorities, who will distribute them to the farmer or the livestock health associations), according to the costs incurred by them.

There is a direct synergy of this programme with the antimicrobial resistance monitoring EU funded programme, that is focused to monitor the AMR in food and farmed animals of zoonotic and commensal bacteria, such as Salmonella. This AMR programme benefits from the samples taken at farm level in the framework of the Salmonella Control Programme, in order to avoid duplication and to minimise the burden on competent authorities.

In the future, there could be possible synergies with other EU funded activities like innovation projects, which could help developing new vaccines or new diagnostic methods and, therefore, could help to achieve the objectives of the Salmonella Control Programme.

ANNEX

- XVII. Baseline population data
- XVIII. Targets for 2025-2027
- XIX. Legal basis for the implementation of the programme
- XX. Maps (as relevant)

XVII. Baseline population data

Table 1 for year 2025: Flocks subject to the programme

	Number of holdings
Total number of holdings with fattening turkeys in the MS	690
Total number of houses in these holdings	4,000
Number of holdings with more than 500 fattening turkeys	685

All cells shall be filled in with the best estimation available. The above data refer to 05/2024; Source of the data: "MAPA"

Table 1 for year 2026: Flocks subject to the programme

	Number of holdings
Total number of holdings with fattening turkeys in the MS	690
Total number of houses in these holdings	4,000
Number of holdings with more than 500 fattening turkeys	685

All cells shall be filled in with the best estimation available. The above data refer to 05/2024; Source of the data: "MAPA"

Table 1 for year 2027: Flocks subject to the programme

	Number of holdings
Total number of holdings with fattening turkeys in the MS	690
Total number of houses in these holdings	4,000
Number of holdings with more than 500 fattening turkeys	685

All cells shall be filled in with the best estimation available. The above data refer to 05/2024; Source of the data: "MAPA"

XVIII. Targets for 2025-2027

Table 2 for year 2025: Targets on laboratory tests on official samples from fattening flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	88
Serotyping	75
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	30

Table 2 for year 2026: Targets on laboratory tests on official samples from fattening flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	88
Serotyping	75
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	30

Table 2 for year 2027: Targets on laboratory tests on official samples from fattening flocks of Turkeys

Type of test (description)	Number of planed tests
Bacteriological detection test	88
Serotyping	75
Antimicrobial detection test	3
Test for verification of the efficacy of disinfection	30

Table 3 for year 2025: Targets on official samples from fattening flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	8	3,992
N of flocks in the programme	8	3,992
N of flocks planned to be checked (b)	2	85
No of flock visits to take official samples (c)	2	90
N of official samples taken	2	119
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ ST	⊠ SE+ST
	☐ others, please specify:	□ others, please specify:
Possible N of flocks infected by target serovars	0	9

⁽a) Including eligible and non-eligible flocks(b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 3 for year 2026: Targets on official samples from fattening flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	8	3,992
N of flocks in the programme	8	3,992
N of flocks planned to be checked (b)	2	85
No of flock visits to take official samples (c)	2	90
N of official samples taken	2	119
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ST
	□ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	0	8

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

Table 3 for year 2027: Targets on official samples from fattening flocks of Turkeys

Type of test (description)	Rearing flocks	Adult flocks
Total N of flocks (a)	8	3,992
N of flocks in the programme	8	3,992
N of flocks planned to be checked (b)	2	85
No of flock visits to take official samples (c)	2	90
N of official samples taken	2	119
	☐ SE+ ST + SH +SI + SV	☐ SE+ ST + SH +SI + SV
Target serovars (d)	⊠ SE+ST	⊠ SE+ ST
	☐ others, please specify:	☐ others, please specify:
Possible N of flocks infected by target serovars	0	7

⁽a) Including eligible and non-eligible flocks

⁽b) A checked flock is a flock where at least one official sampling visit will take place. A flock shall be counted only once even if it was visited several times.

⁽c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.

⁽d) Salmonella enteritidis and Salmonella typhimurium = SE + ST; Salmonella enteritidis, typhimurium, hadar, infantis, virchow = SE+ ST + SH +SI + SV

XIX. Legal basis for the implementation of the programme) (TRACEABILITY, DISEASE NOTIFICATION AND MEASURES FOR EFFECTIVE CONTROL OF THE DISEASE)

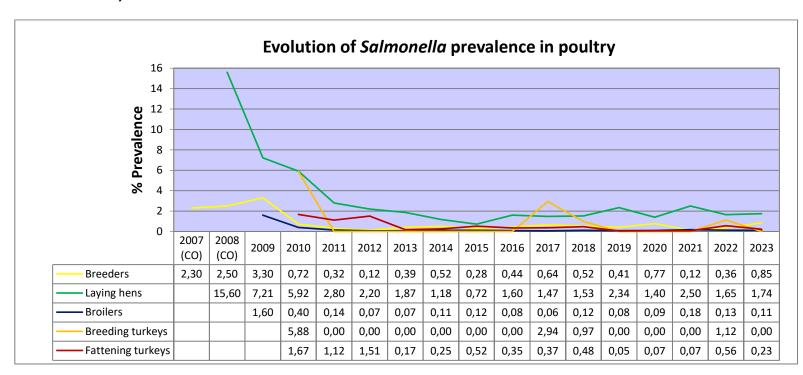
EU countries

- Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R2160-20210421&qid=1652941252241
- Commission Regulation (EU) No 1190/2012 of 12 December 2012 concerning a Union target for the reduction of Salmonella Enteritidis and Salmonella Typhimurium in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R1190-20190310&qid=1652941712941
- Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1177&qid=1652941414224
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003L0099-20130701&qid=1652941345135

XX. Maps (as relevant)

Epidemiological situation:

a. Evolution of the prevalence of the target serovars of *Salmonella* in the different poultry populations (2007-2023)



b. Most prevalent serotypes of Salmonella in the different poultry populations (2023)

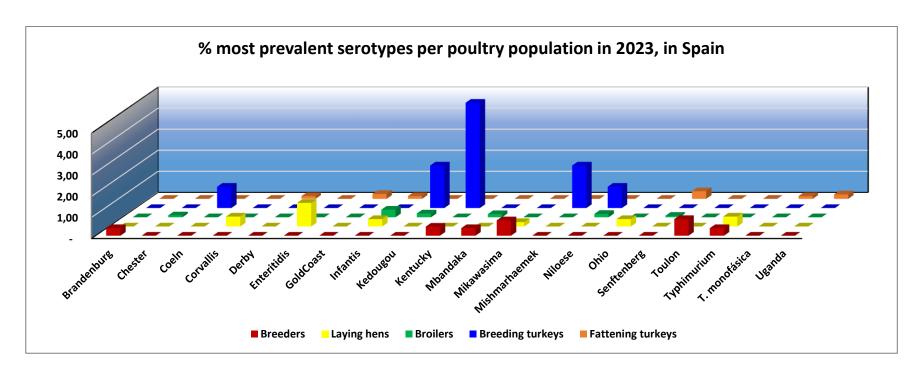
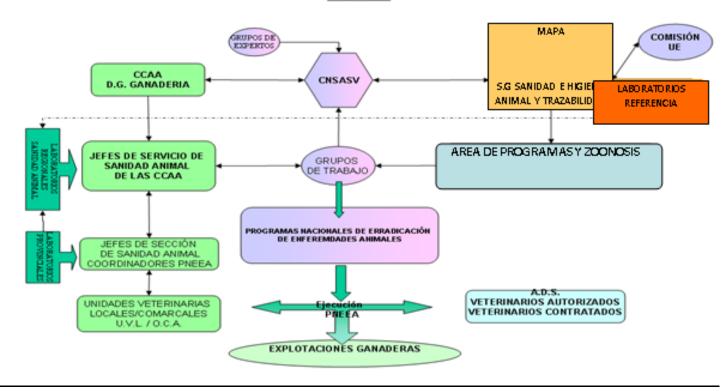
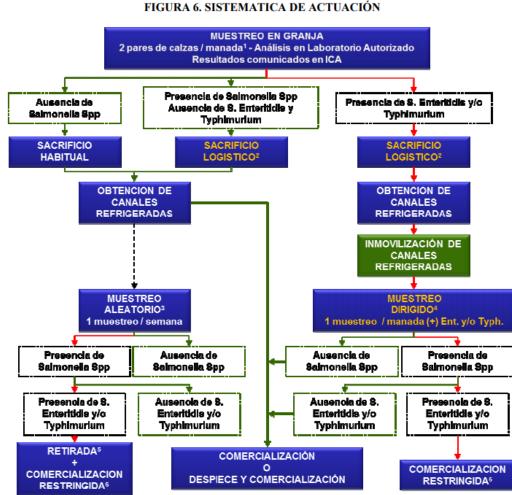


Diagramme of veterinary services

AUTORIDADES COMPETENTES: DISTRIBUCIÓN DE RESPONSABILIDADES Y RELACIONES EN EL ÁMBITO DE LOS PROGRAMAS NACIONALES DE ERRADICACIÓN DE ENFERMEDADES DE LOS ANIMALES



<u>Diagramme of slaughtering procedure on birds sent to the slaughterhouse (example recommended in the guide):</u>



Para comercialización en freaco siempre incluir en etiquetado o en documento de acompeñamiento la leyenda:

"Este producto debe ser totalmente cocinado antes de su consumo"

Proposal ID Call for Proposal Type of Action Topic 101194988 SMP-FOOD-2025-VETPROG-LS-IBA SMP-FOOD-2025-VETPROGR-LS-IBA SMP-AG-LS

Applicant Country

Spain

Disease	Measure Category	Measure Description	Units	Cost Per Unit	ost Per Unit Overheads		CFR	Contribution	
Group: Avian influenza									
Avian influenza	Sampling	Domestic animals sampled	23 520	2.78	-	65 385.60	37.74%	24 676.53	
Avian influenza	Sampling	Wild animals sampled	1 500	5.56	7%	8 923.80	37.74%	3 367.84	
Avian influenza	Testing	ELISA test - other animals	120	4.57	-	548.40	37.74%	206.97	
Avian influenza	Testing	ELISA test - poultry	18 360	4.57	-	83 905.20	37.74%	31 665.82	
Avian influenza	Testing	HI-Test for H5 - other animals	120	5.77	-	692.40	37.74%	261.31	
Avian influenza	Testing	HI-Test for H5 - poultry	4 770	5.77	-	27 522.90	37.74%	10 387.14	
Avian influenza	Testing	HI-Test for H7 - other animals	120	5.77	-	692.40	37.74%	261.31	
Avian influenza	Testing	HI-Test for H7 - poultry	2 385	5.77	-	13 761.45	37.74%	5 193.57	
Avian influenza	Testing	PCR test - other animals	300	22.72	-	6 816.00	37.74%	2 572.36	
Avian influenza	Testing	PCR test - poultry	1 032	22.72	-	23 447.04	37.74%	8 848.91	
Avian influenza	Testing	PCR test - wild birds	18 000	22.72	-	408 960.00	37.74%	154 341.50	
Avian influenza	Testing	Virus isolation test - other animals	15	56.65	-	849.75	37.74%	320.70	
Avian influenza	Testing	Virus isolation test - poultry	15	56.65	-	849.75	37.74%	320.70	
Avian influenza	Testing	Virus isolation test - wild birds	300	56.65	-	16 995.00	37.74%	6 413.91	
		Subtotal for: Avian influenza				659 349.69		248 838.57	
Group: Bovine spongiform encephalop	athy								
Bovine spongiform encephalopathy	Compensation	Bovine animals culled and destroyed	21	400	7%	8 988.00	18.00%	1 617.84	
Bovine spongiform encephalopathy	Testing	Confirmatory tests in bovines	15	77.99	-	1 169.85	18.00%	210.57	
Bovine spongiform encephalopathy	Testing	Primary molecular tests	12	145.87	-	1 750.44	18.00%	315.08	
Bovine spongiform encephalopathy	Testing	RT bov born in MS listed CD 2009/719 HSlhAn	18	12.77	-	229.86	18.00%	41.37	
	Tastina	RT bov born in MS listed CD 2009/719 RiskAn	189 015	12.77	_	0 440 704 55	18.00%	434 469.88	
Bovine spongiform encephalopathy	resting	THE BOY BOTT IN MIC HOLDS OF ECOOPT TO THORSE			_	2 413 721.55			
Bovine spongiform encephalopathy Bovine spongiform encephalopathy	Testing Testing	RT bov not born in MS listed CD 2009/719 HSlhAn	66	12.77	-	842.82	18.00%	151.71	
Bovine spongiform encephalopathy					-		18.00%	151.71 137.92	
	Testing	RT bov not born in MS listed CD 2009/719 HSlhAn	66	12.77	-	842.82	18.00% 18.00%		
Bovine spongiform encephalopathy Bovine spongiform encephalopathy	Testing Testing	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn	66 60	12.77 12.77	-	842.82 766.20	18.00% 18.00%	137.92	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy	Testing Testing	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals	66 60	12.77 12.77	-	842.82 766.20 383.10	18.00% 18.00%	137.92 68.96	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy	Testing Testing	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy	66 60	12.77 12.77		842.82 766.20 383.10	18.00% 18.00%	137.92 68.96	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella	Testing Testing Testing	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals	66 60 30	12.77 12.77 12.77	7% 7%	842.82 766.20 383.10 2 427 851.82	18.00% 18.00% 18.00%	137.92 68.96 437 013.33	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella Salmonella	Testing Testing Testing Compensation	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or	66 60 30 255 000	12.77 12.77 12.77		842.82 766.20 383.10 2 427 851.82 2 182 800.00	18.00% 18.00% 18.00% 23.59%	137.92 68.96 437 013.33 514 922.52 72 694.94	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella Salmonella Salmonella	Testing Testing Testing Compensation Compensation	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or slaughtered	255 000 12 000	12.77 12.77 12.77 8 24	7%	842.82 766.20 383.10 2 427 851.82 2 182 800.00 308 160.00	18.00% 18.00% 18.00% 23.59% 23.59%	137.92 68.96 437 013.33 514 922.52	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella Salmonella Salmonella Salmonella	Testing Testing Testing Compensation Compensation Compensation	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or slaughtered Laying birds of Gallus gallus: Animals culled or slaughtered	255 000 12 000 450 000	12.77 12.77 12.77 8 24 3.5	7%	842.82 766.20 383.10 2 427 851.82 2 182 800.00 308 160.00 1 685 250.00	18.00% 18.00% 18.00% 23.59% 23.59% 23.59%	137.92 68.96 437 013.33 514 922.52 72 694.94 397 550.48 23 675.08	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella Salmonella Salmonella Salmonella Salmonella Salmonella	Testing Testing Testing Compensation Compensation Compensation Sampling	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or slaughtered Laying birds of Gallus gallus: Animals culled or slaughtered Breeding birds of Gallus gallus: Official sampling visit	255 000 12 000 450 000 7 215	12.77 12.77 12.77 8 24 3.5 13.91	7%	842.82 766.20 383.10 2 427 851.82 2 182 800.00 308 160.00 1 685 250.00 100 360.65	18.00% 18.00% 18.00% 23.59% 23.59% 23.59% 23.59%	137.92 68.96 437 013.33 514 922.52 72 694.94 397 550.48 23 675.08 1 069.78	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella Salmonella Salmonella Salmonella Salmonella Salmonella Salmonella Salmonella	Testing Testing Testing Compensation Compensation Compensation Sampling Sampling Sampling	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or slaughtered Laying birds of Gallus gallus: Animals culled or slaughtered Breeding birds of Gallus gallus: Official sampling visit Breeding turkey of Meleagris gallopavo: Official sampling visit Broilers of Gallus gallus: Official sampling visit	255 000 12 000 450 000 7 215 326	12.77 12.77 12.77 8 24 3.5 13.91	7%	842.82 766.20 383.10 2 427 851.82 2 182 800.00 308 160.00 1 685 250.00 100 360.65 4 534.66	18.00% 18.00% 18.00% 23.59% 23.59% 23.59% 23.59%	137.92 68.96 437 013.33 514 922.52 72 694.94 397 550.48 23 675.08 1 069.78 4 774.38	
Bovine spongiform encephalopathy Bovine spongiform encephalopathy Bovine spongiform encephalopathy Group: Salmonella	Testing Testing Testing Compensation Compensation Compensation Sampling Sampling	RT bov not born in MS listed CD 2009/719 HSlhAn RT bov not born in MS listed CD 2009/719 RiskAn Rapid tests on suspect bovine animals Subtotal for: Bovine spongiform encephalopathy Breeding birds of Gallus gallus: Animals culled or slaughtered Breeding turkey of Meleagris gallopavo: Animals culled or slaughtered Laying birds of Gallus gallus: Animals culled or slaughtered Breeding birds of Gallus gallus: Official sampling visit Breeding turkey of Meleagris gallopavo: Official sampling visit	255 000 12 000 450 000 7 215 326 1 455	12.77 12.77 12.77 8 24 3.5 13.91 13.91	7%	842.82 766.20 383.10 2 427 851.82 2 182 800.00 308 160.00 1 685 250.00 100 360.65 4 534.66 20 239.05	18.00% 18.00% 18.00% 23.59% 23.59% 23.59% 23.59% 23.59% 23.59%	137.92 68.96 437 013.33 514 922.52 72 694.94 397 550.48	

Disease	Measure Category	Measure Description	Units	Cost Per Unit	Overheads	Total	CFR	Contribution
Salmonella	Testing	Breeding birds of Gallus gallus: Antimicrobial detection test	75	26.88	-	2 016.00	23.59%	475.57
Salmonella	Testing	Breeding birds of Gallus gallus: Bacteriological detection test 14 400 27.24 - 392 256.00					23.59%	92 533.19
Salmonella	Testing	Breeding birds of Gallus gallus: Serotyping 390 55.68 - 21 715.		21 715.20	23.59%	5 122.62		
Salmonella	Testing	Breeding birds of Gallus gallus: Test for verif. of eff. of disinfection	30	44.86	-	1 345.80	23.59%	317.47
Salmonella	Testing	Breeding turkey of Meleagris gallopavo: Antimicrobial detection test	15	26.88	-	403.20	23.59%	95.11
Salmonella	Testing	Breeding turkey of Meleagris gallopavo: Bacteriological detection test	673	27.24	-	18 332.52	23.59%	4 324.64
Salmonella	Testing	Breeding turkey of Meleagris gallopavo: Serotyping	58	55.68	-	3 229.44	23.59%	761.82
Salmonella	Testing	Breeding turkey of Meleagris gallopavo: test for verif of eff. disinfection	15	44.86	-	672.90	23.59%	158.74
Salmonella	Testing	Broilers of Gallus gallus: Antimicrobial detection test	9	26.88	-	241.92	23.59%	57.07
Salmonella	Testing	Broilers of Gallus gallus: Bacteriological detection test	1 440	27.24	•	39 225.60	23.59%	9 253.32
Salmonella	Testing	Broilers of Gallus gallus: Serotyping	540	55.68	-	30 067.20	23.59%	7 092.85
Salmonella	Testing	Broilers of Gallus gallus: Test for verif. of eff. ff disinfection	Broilers of Gallus gallus: Test for verif. of eff. ff disinfection 120 44.86		•	5 383.20	23.59%	1 269.90
Salmonella	Testing	Fattening turkey of Meleagris gallopavo: Antimicrobial detection 9 26.88 test		-	241.92	23.59%	57.07	
Salmonella	Testing	Fattening turkey of Meleagris gallopavo: Bacteriological detection 264 27.24 test		-	7 191.36	23.59%	1 696.44	
Salmonella	Testing	Fattening turkey of Meleagris gallopavo: Serotyping	225	55.68	-	12 528.00	23.59%	2 955.36
Salmonella	Testing	Fattening turkey of Meleagris gallopavo: Test for verif. of eff. disinfection	90	44.86	-	4 037.40	23.59%	952.42
Salmonella	Testing	Laying birds of Gallus gallus: Antimicrobial detection test	75 26.88 - 2.0		2 016.00	23.59%	475.57	
Salmonella	Testing	Laying birds of Gallus gallus: Bacteriological detection test	gallus: Bacteriological detection test 6 000		-	163 440.00	23.59%	38 555.50
Salmonella	Testing	Laying birds of Gallus gallus: Serotyping	1 050	55.68	-	58 464.00	23.59%	13 791.66
Salmonella	Testing	Laying birds of Gallus gallus: Test for verif. of eff. of disinfection	birds of Gallus gallus: Test for verif. of eff. of disinfection 200		-	8 972.00	23.59%	2 116.49
Salmonella	Vaccination	Breeding birds of Gallus gallus: Purchase of vaccine doses 12 000 000 0.055 7% 7		706 200.00	23.59%	166 592.58		
Salmonella	Vaccination	Breeding turkey of Meleagris gallopavo: Purchase of vaccine doses 90 000 0		0.085	7%	8 185.50	23.59%	1 930.96
Salmonella	Vaccination	Laying birds of Gallus gallus: Purchase of vaccine doses	114 120 000	0.035	7%	4 273 794.00	23.59%	1 008 188.00
		Subtotal for: Salmonella				10 105 203.48		2 383 817.49
		GRAND TOTAL				13 192 404.99		3 069 669.39

ANNEX 2

ESTIMATED BUDGET (LUMP SUM BREAKDOWN) FOR THE ACTION

	Estimated EU contribution									
	WP1 Influenza aviar	WP2 Bovine Spongiform Encephalopathy	WP3 Zoonotic Salmonella	Maximum grant amount ¹						
Forms of funding	Lump sum contribution	Lump sum contribution	Lump sum contribution							
	a	b	c	d = a + b + c						
1 - MAPA	248 838.57	437 013.33	2 383 817.49	3 069 669.39						

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)											
	WP1 [name]	WP2 [name]	WP3 [name]	WP4 [name]	WP5 [name]	WP6 [name]	WP7 [name]	WP8 [name]	WP9 [name]	WP10 [name]	WP [XX]	Requested EU contribution
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	е	f	g	h	i	j	k	I = 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

<u>INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS —</u> 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, nondiscrimination, 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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