

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

Department A Health and Food Unit A2 EU4Health/SMP

Food Programmes for eradication, control and surveillance of animal diseases and zoonoses

submitted for obtaining EU financial contribution

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

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Member state : BULGARIA	
Disease Salmonella	
Animal population Laying flocks of Gallus gallus	
This program is multi annual :	
Request of Union co-financing from beginning:	2023
1. Contact data	
Name	Phone
Email	Your job type within the CA:

Submission Date

Submission Number

05/12/2022 17:17:13

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A. Technical information

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

- Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents,
- Regulation (EU) No 517/2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in laying hens of Gallus gallus,
- Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of *Salmonella* in poultry.

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

1. Aim of the programme

It is to implement all relevant measures in order to reduce the prevalence of *Salmonella* Enteritidis and *Salmonella* Typhimurium (including the serotypes with the antigenic formula I,4,[5],12:i:-) in adult <u>laying</u> hens of *Gallus gallus* ('Union target') as follows:

An annual <u>minim</u> um percentage of reduction of positive flocks of adult laying hens equal to at least 10% where the prevalence in the preceding year was less than 10%.
An annual <u>minimum</u> 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 ma <u>xim</u> um 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.

Additionally to the target of the Program:

- to determine the health status of laying hens of Gallus gallus in Republic of Bulgaria with regard to Salmonella enteritidis and Salmonella Typhimurium(including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i);
- -to achieve the Union target for the reduction of the prevalence of Salmonella Enteritidis and Salmonella Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i)in adult laying hens of Gallus gallus according to the Art. 1 of Regulation 517/2011
- to monitor Salmonella effectively;
- take the action required under Regulation (EC) No. 2160/2003 where target serovars are detected;
- give advice to owners with infected flocks on how to reduce or eliminate Salmonella of public health significance on their premises.

2. The program	ne will be implemented o	n the whole territory of the MS.	
⊠yes	□no		
If No, please explain :			

3. Flocks subject to the programme

The programme covers all flocks of adult laying hens of *Gallus gallus* but does not apply to flocks for private domestic use or leading to the direct supply, by the producer, of small quantities of table eggs to the final consumer or to local retail establishments directly supplying the eggs to the final consumer. For the latter case (direct supply), national rules are adopted ensuring *Salmonella* control in these flocks.

The programme covers also all rearing flocks of future laying hens.

	⊠yes	□no			
If No, p	olease explain :				
		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	116		116	0
	Adult flocks	240	240	240	240
	Number of holdings with	more than 1,000 laying her	าร		109
	Number of flocks in these	e holdings			240
	NB : All cells shall be filled in with the best estimation available.				
Comme	ents (max. 32000 chars):			

4. Notification of the detection of target Salmonella serovars

A procedure is in place which guarantees that the detection of the presence of the relevant *Salmonella* serotypes during sampling at the initiative of the food business operator (FBO) is notified without delay to the competent authority by the laboratory performing the analyses. Timely notification of the detection of the presence of any of the relevant *Salmonella* serotypes remains the responsibility of the food business operator and the laboratory performing the analyses.

⊠yes	□no
if no, please explain :	
5. Biosecurity	measures
FBOs have to	implement measures to prevent the contamination of their flocks.
⊠yes	□по

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

Bio-security is a combination of practices, which are intended to prevent the spread of disease-causing organisms within the poultry farm. Where these are performed in parallel with the sanitation and disinfection procedures, bio-security measures could eradicate or, at least, reduce the level of pathogens to values, at which no hazard of infection would be likely.

The implementation of effective biosecurity measures at primary production to prevent contamination of the flocks under their care is the responsibility of the producer and his/her private veterinary. The Competent Authority carries out inspections on farms for zoonotic disease control, animal welfare reasons, to take samples for residues, to administer and enforce national legislation and to check medicine records

The national legislation (Ordinance 44) stipulates the minimum veterinary requirement that must be implemented in the animal holdings.

Bio-security measures on holdings include:

Health status checks of poultry

On entering to all houses on the farm must be located disinfection barrier

Control of movement of people

Transport hygiene

Feed hygiene

Water hygiene

Rodents, insects and birds control Cleaning and disinfection of buildings Recording of all events and operations

For each building own equipment must be designated All in-all out system The Competent Authority carries out inspections on farms for zoonotic disease control, animal welfare
reasons, to take samples in line of the control programmes (Salmonella, AI), to administer and enforce national legislation and to check medicine records.
6. Minimum sampling requirements for food business operators (FBO):
Samples at the initiative of the FBOs will be taken and analysed to test for the target <i>Salmonella</i> serovars respecting the following minimum sampling requirements:
 a. Rearing flocks: day-old chicks, two weeks before moving to laying phase or laying unit
b. Adults laying flocks: every 15 weeks during the laying period
⊠yes □no
if no, please explain - Indicate also who takes the FBO samples, and, if additional FBO sampling, going beyond the minimum sampling requirements, is performed, please describe what is done.
Samples from poultry flocks are taken by the owner of the holding or a person authorized by the owner (in most of cases a private vet who has a contract signed with the owner) and by the official veterinarians which is a part of the official surveillance program. The official veterinarian responsible for the farm shall provide the training on sampling for the person responsible for the own-check samples. Each year the RFSDs draft a sampling schedule for all poultry farms and hatcheries included in the scope of the programme and located on the territory within its administrative districts. The schedule is drafted for official checks and own-checks.
FBO keeps records of samples taken and made them available for inspection to the Competent Authority. The records shall include data on date when each flock is sampled for Salmonella, the identity of the flock sampled, the age of the flock sampled, the laboratory which undertook the analysis and the result of the tests and make these records available to the Competent Authority for inspection where required.
7. Samples are taken in accordance with provisions of point 2.2 of Annex to Regulation (EU) No 517/2011
⊠yes □no
if no, please explain :

8. Specific requirements laid down in Annex II.D of Regulation (EC) No 2160/2003 will be complied with where relevant. In particular: • due to the presence or the suspicion of the presence of SE or ST (including monophasic ST I,4,[5],12:i:-) in the flock, eggs cannot be used for human consumption unless heat treated; • eggs from these flocks shall be marked and considered as class B eggs.

if no, please explain - Indicate also if prompt depopulation of the infected flocks is compulsory.

In cases of "Suspected herd" infected with Salmonella Enteritidis or Salmonella Typhimurium, the following measures are taken:

- a ban for movement of poultry and eggs from the farm. T
- an epidemiological study;- tracking 10-15 days ago.-
- verification of farm logs and biosecurity measures;
- sampling of feed and water. Fodder samples are taken by the inspectors responsible for the official control of fodder in the ODBH;- t
- additional samples from the other flocks in the hlding

When the laying hens flocks are confirmed for the presence of Salmonella enteritidis or Salmonella typhimurium:

Eggs shall not be used for direct human consumption as table eggs unless they originate from a commercial flock of laying hens subject to a national control programme and not under official restriction.

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 Community legislation on food hygiene.

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, shall be:

-considered as Class B eggs as defined in Article 2(4) of Commission Regulation (EC) No 557/2007 laying down detailed rules for implementing Council Regulation (EC) No 1028/2006 on marketing standards for eggs;

-marked with the indication referred to in Article 10 of Commission Regulation (EC) No 557/2007 which clearly distinguishes them from Class A eggs prior to being placed on the market;

-prohibited access to packaging centres unless the competent authority is satisfied with the measures to prevent possible cross-contamination of eggs from other flocks.

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. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and, once applicable, part E. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1069/2009.

The owner or person responsible for the flock is required to clean and disinfect the building where the infected birds were kept, and provide evidence to the Competent Authority that the cleaning and disinfection has been satisfactory. Re-stocking may not take place until the cleaning and disinfection has been carried out and post cleaning and disinfection swabbing of the poultry house(s) yields negative Salmonella results. The official restrictions are lifted only after full depopulation of the infected flock and satisfactory cleansing (proven by further sampling)and disinfection procedures have been carried out. For premises where a positive target serovar has been detected, an inspection and advisory visit is carried out by a official veterinary. An epidemiological investigation including assessment of biosecurity is carried out using a standard protocol (check list) and recorded on a standard visit form.

A written report on disease control, including biosecurity measures, specifically targeted to the situation on the premises, is provided to the owner.

Restriction measures are not lifted and repopulation of the premises is not permitted if cleaning and disinfection of the premises have not been carried out and subsequent tests have not shown a satisfactory result.

9.If birds from flocks infected with SE or ST are slaughtered, please describe the measures that shall be implemented by the FBO and the CA to ensure that fresh poultry meat meet the relevant **EU microbiological criteria** (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): absence of SE/ST in 5 samples of 25g:

Measures implemented by the FBO (farm level)

Salmonella testing results are included in the Food chain information -

reports of examinations (three weeks before slaughtering) as well as the results of all laboratory testing of the flock for monitored Salmonella serotypes performed during the life cycle of the flock (negative/positive) are included in the document accompanying the poultry to the slaughterhouse. So that information on the test results within the Salmonella control programme is made available to the slaughterhouse.

FBO is required to submit action plan to the regional CA describing:

- -type of the product, assessment of the risk to the public health;
- -identification and information of the batch;
- -revision of the acting procedures, corrective measures to be implemented;
- -name, registration number and information on the food business establishment where the heat treatment is to be done;

Measures implemented by the FBO (slaughterhouse level)

written consent of food business establishment where the heat treatment is to be done;

- -type of heat treatment to be carried out;
- -laboratory control of the processed products;

The food establishments where the meat is to be processed is required to provide records of the processing of the infected batch, plan for cross-contamination prevention, plan for disinfection of

equipment and premises, sampling plan for verification of the heat treatment and disinfection of premises and equipment in order to guarantee that the heat treated meat is not infected and to prevent further contamination of the fresh meat processed in the FBE.

In the event that in the laboratory test of samples are positive 1) the slaughter of hens from this flock is carried out in the manner specified in Art. 43 sec. 6 of Regulation No. 2019/627. Meat obtained from poultry originating from a breeding flock of the species hen (Gallus gallus), in which a positive result of laboratory testing doe SE or ST, or from flocks of unknown epizootic status in terms of Salmonella was obtained, is subjected to industrial heat treatment or other treatment to eliminate Salmonella. Such meat may not be placed on the market fresh, except to be transported to an industrial processing facility, if the facility slaughtering such poultry is unable to undergo an on-site industrial heat treatment or other treatment to eliminate Salmonella. The fresh poultry meat may be place on the market if only meet the relevant EU microbiological criteria (row 1.28 of Chapter 1 of Annex I to Regulation (EC) No 2073/2005): namely absence of SE/ST in 5 samples of 25g:

FBO has to have written consent from the food business establishment where the heat treatment is to be done before sending the infected poultry. The FBO at slaughterhouse has to provide information and records on the control of the processed products. Hi/she is obliged to manage and ensure that the slaughtering of infected flock is carried out separately from the healthy flocks, the premises and equipment of the slaughterhouse to be cleaned and disinfected after the slaughter of the positive flock.

Measures implemented by the CA (farm and slaughterhouse level)

Official veterinarian responsible for the FBE is required to:

- -issue Restriction Act for the infected batch/products;
- -to provide instructions on the measures to be implemented;
- -to carry out expertise in accordance with art. 240 of the LVA and to issue an Expertise act where the type of processing of the meat/products is described.
- -to approve the above described FBO plan;
- -to prepare report on the implementation of the above described plan (all the relevant documents are attached), the report is provided to the RFSD and to the Food Control Directorate, HQ BFSA. The measures are described in details in a BFSA procedure, approved with Ordinance RD 11-1136/20.09.2011.
 - **10. Laboratories** in which samples (official and FBO samples) collected within this programme are analysed are accredited to ISO 17025 standard and the analytical methods for *Salmonella* detection is within the scope of their accreditation.

⊠yes	□no		
If no, please explain :			

11. The analytical methods used for the detection of the target Salmonella serovars is the one defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ISO 6579-2002/Amd1:2007. `Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Salmonella spp Amendment 1: Annex D: Detection of Salmonella spp. in animal faeces and in environmental samples from the primary production stage'.) ; F
Serotyping is performed following the Kaufman-White-Le Minor scheme.	
⊠yes □no	
If no please explain.	
Tour complete tolkon and habite of the EDO altermative meethods if validated in	
For samples taken on behalf of the FBO alternative methods if validated in accordance with the most recent version of EN/ISO16140 may be used.	
⊠yes □no	
If no please explain.	1
12. Samples are transported and stored in accordance with point 3.1 of the Annex to Regulation (EU) No 517/2011. In particular, samples examination shall start in the laboratory within 4 days after sampling.	

If no, please explain:

Samples sent for laboratory tests taken as part of official controls or FBO sampling must be accompanied by a cover letter (two templates for samples taken by the official control and FBO) approved by meand of Order of the Executive Director of the BFSA.

The cover letter shall provide the following information on:1) data and address of the poultry keeper; 2) registration number of the holding 2) number of poultry in the flock, age, category of the flock;4) the number of samples and the type of material collected;45) dates and times of sampling and sending to the laboratory;6) the type of vaccine used in the flock of laying hens and the date of its administration;7) the use of antimicrobials;8) data of the person collecting the samples.

Salmonella NCP samples may only be tested in Competent Authority approved laboratories and these laboratories are required to check the time the sample was taken and ensure that the sample is tested within 4 days of the sampling and within 48 hours of arrival at the laboratory. This is a requirement of accreditation to ISO17025 which specifies that the sample must be taken and treated according to the purpose for which it was intended (i.e. be 'fit for purpose' which is considered to mean fully in compliance with the legislation requirements). Samples that do not comply with these criteria may not be tested as Salmonella NCP samples and the testing laboratory must request another sample from the food business operator. This requirement is subject to inspection during the laboratory inspection visits for ISO17025 accreditation.

In case that: 1) the cover letter (both by the official or FBO) did not contain at least the information above or the the information is not completed; 2) the amount or type of test material does not meet the requirements of the testing system specified in the Programme in question; 3) the conditions for transporting the samples to the laboratory do not meet the requirements set out in par. 3.1.1 of the Annex to Regulation (EU) No 517/2011: the official laboratory informs the respective sender (official veterinarian or farmer) as well as the headquarter of the BFSA of this when accepting the samples for laboratory testing. Than the protocol from the laboratory test contain the information that the test cannot be carried out in accordance with the requirements of the program for control of Salmonella serotypes in respective poultry category.

The official at Headquarter of the BFSA immediately communicate the issue with the relevant regional food safety department for investigation and further measures to be taken (for example: additional sampling, training .etc)

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

Comments (max. 32000 chars):

In accordance with the implementation of Regulation (EU) 2017/625 and in connection with Art. 3, para. 1, item 4 of the Law on the Bulgarian Food Safety Agency, the Bulgarian Food Safety Agency is designated as the competent authority for the official control of feed in the Republic of Bulgaria.

In connection with the fulfillment of the requirements of Art. 9 and Art. 10 of Regulation (EC) No. 183/2005, on feed hygiene and according to the Feed Act, feed sector operators must be approved or registered by the BFSA and entered in a register in accordance with Art. 19 of the regulation.

The registers of the approved and registered operators in the fodder sector are kept and maintained in the ODBH. BFSA maintains and updates the relevant national registers, which are published on its website. Inspections at the facilities in the feed sector are carried out by inspectors/experts responsible for the official control of feed in the respective regional food safety department.

The Bulgarian Food Safety Agency carries out feed sampling as follows:- feed samples at the level of feed raw material and compound feed producers, as well as from wholesalers who offer feed raw materials and compound feed in packaged and bulk form- feed sampling at farm level. The number of samples is determined on the basis of clearly defined risk assessment criteria and in accordance with the provisions of Regulation (EU) No. 2017/625, as well as on the basis of the data from the studies and analyzes carried out in the previous year. This plan includes also a minimum number of salmonella samples taken from consignments of compound poultry feed received from third countries. No positive results were reported for this parameter.

If a positive result is obtained, the measures and actions to be taken will be based on and in accordance with the Operational Plan for Action in Emergency Situations Arising from Feed and the Procedure for Taking Action in the Event of Detection of Salmonella spp. in feed.

In case of positive findings measures are taken in order to ensure the decontamination of feed such as heat treatment or treatment with organic acids or both of them depending on the specific case (sampling reason, type of feed and type of Salmonella serovar, specifically relevant/not relevant). Moreover additional measures have to be put in place by the local veterinary unit: epidemiological investigation, inspection and verification of the good practices, particularly the procedures of cleaning, use of water, storing, pest control program, waste management. If necessary the feed business operator will be requested to increase the checks for Salmonella.

14. Official controls at holding, flock and hatchery level

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

(max. 32000 chars):

All farmers are obligated to have their individual bio security plan and contingency plan, which are subject to approval by the official veterinarian responsible for the control of the holding concerned. The competent authority carries out official controls, where the biosecurity standards are checked. The official controls at the poultry farms are in accordance with the annual control plan drafted by each Regional Food Safety Authority. The plan of official controls applies to all holdings. The official veterinary inspection for Salmonella control (sampling for Salmonella, according to the SCNP) always includes a biosecurity inspection. Additional inspections can be planned based on the risk analysis. The inspections are documented by check list. The official inspections for biosecurity includes supervision of the disinfection efficacy carried out by farmers. This is carried out by official sampling (swabs for testing the disinfection efficacy) each time the official veterinarian considers it necessary.

As mentioned above, the veterinary requirements and biosecurity measures to be implemented by the animal holdings are described in Ordinance 44 concerning the veterinary requirement of animal holdings.

The FBO of poultry holdings are required to draft a bio security plan and contingency plan which are subject of official control.

In case of non-compliances detected during the inspection, official veterinarians gives prescription with corrective measures to be taken by the FBO with a short deadline. Further inspection is carried out by the official to verify the measures taken by the FBO, followed by fines, trade restriction, ban for movement of poultry or eggs or registration withdraw of the holding (depending of the severity of the

deficiency) if the results from this inspection are not satisfactory.

According to the national legislation (the Law on Veterinary Activity, the Law on Management of the Agro-Food Chain and the Law on Feed) the establishments for production, storage and trade in food or feed must be approved and registered by the BFSA and uploaded in the respective registers. The registers of the approved and registered sites are electronic and are publicly available. The official inspections in the establishments for production, storage and trade in food are carried out by the official veterinarians from the BFSA / or the respective RFSD.

The official control of food production, storage and marketing establishments shall be carried out in accordance with the provisions of Regulation (EU) 2017/625 of the European Parliament and of the Council, which lays down specific rules for the organization of official controls on products of animal origin intended for human consumption. The number of samples is calculated by the official veterinarians on the basis of a risk assessment and on the type and quality of the materials involved in the processing of the food, as well as on the basis of the results of previous inspections. Sampling of food of poultry origin should be carried out in accordance with the provisions of Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs. The frequency of sampling may be increased or decreased depending on the results obtained from the examination of the samples. Annually, the Regional Directorates for Food Safety prepare programs for the number of inspections of the establishments controlled by them for production, storage and trade in animal products.

- 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.

$\boxtimes yes$	□no	
		al official sampling going beyond EU minimum requirements is
performed give a desc	ription of what is done 2)who	is taking the official samples

at the holding which are sy	rstematically performed if FBO or official
samples are positive at the hat	chery):
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 samp taken for checking the presence	ling is performed, additional samples are e of antimicrobials:
Always Sometin	mes 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.

he procedures related to confirmatory sampling is explained above. In case of confirmed presence of antimicrobials but negative confirmatory sampling, the flock is considered as suspected for being infected with Salmonella. Measures to be taken in case of SE /ST positive flocks, or other Salmonella spp or suspected flock to be positive for these Salm. spp are described in point A 9 and 10.

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

- ¹Reg 517/2011, point 2.2.1 of the Annex
- ² Reg 517/2011, point 2.2.2 of the Annex
- ³ Reg 2160/2003, point II.D.4 of the Annex

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

The confirmation sampling (repeated testing) is not implemented routinely after positive result in FBO samples. It is implemented in exceptional cases only if the Competent Authority has reasons to question the results of the initial testing and shall be carried out with the sampling protocol defined in Annex II, D, 4 (b) (i), (ii) or (iii) of Regulation (EC) No 2160/2003 (including the sampling for the detection of antimicrobials).

Following placing of official restrictions, infection detected by operator sampling may, in some cases depending on the situation, be confirmed by samples taken by the Competent Authority as detailed in Annex II, D, 4 (b) (i), (ii) or (iii) of Regulation (EC) No 2160/2003. The decision to carry out confirmatory sampling is based on assessment of the situation on the premises, including the potential for the cross contamination during sampling by the operator, potential for the cross contamination at the laboratory during the testing process and biosecurity/farm hygiene and history of Salmonella spp isolation on the premises. No confirmatory testing is carried out following detection of a positive through official sampling unless exceptional circumstances (such as confirmation of laboratory cross contamination) require it.

The eggs from the flocks subject of confirmatory testing are treated as eggs form flocks suspected to be infected by SE or ST.

d. Article 2 of Regulation (EC) No 1177/2006 (antimicrobials shall not be used as a specific method to control Salmonella in poultry): please describe the official controls implemented (documentary checks, sampletaking) to check the correct implementation of this provision. For samples please describe the samples taken, the analytical method used, the result of the tests.

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

Antimicrobial treatment may not be used for the control of Salmonella within the framework of the National Control Programme, except within the limits set by Commission Regulation (EC) No.1177/2006 The official veterinary inspection for Salmonella control (sampling for Salmonella, according to the SCNP) always includes checks of the record kept in the farm including those related to VMP used Official controls on the use of antimicrobials:

• Documentary checks: medicine record documentary checks are carried out during every farm inspection visit (official visits to take official samples, to inspect operator Salmonella NCP sampling records and for other purposes). Therefore inspection of medicine records and operator NCP sampling records is carried out on every breeding chicken premise. If antimicrobials have been used, consideration is given to the validity of the results of samples tested during treatment/withdrawal period which may, depending on the situation, result in more samples being required to be taken by the operator, additional official samples required, a delay in official sampling until antimicrobial treatment is stopped etc. This will depend on the type of antimicrobial used (especially whether it has a known therapeutic

effect against Salmonella), the age of the flock, the risk assessment on the farm etc.

Official sampling for antimicrobial treatment is carried out:

- in any case of confirmatory sampling. If antimicrobials or bacterial growth inhibitors are detected, the Salmonella infection shall be considered as confirmed.
- Suspicion of false results in exceptional cases where the competent authority has reason to question the results of the testing (such as false positive or false negative results), it may decide to repeat the confirmatory sampling
- Test method: if there was a requirement for antimicrobial detection tests as a result of suspicion of use, liver and kidney samples from up to 5 birds per flock are tested with the 4 plate inhibition test and positive results are tested for confirmation of antimicrobial used (mass spectrometry). The flock would be considered positive if results of antimicrobial detection tests are positive.

The sampling under the Animal By-Products legislation is monitored by the Competent Authority with inspections carried out using a risk-based approach.

Restriction measures enforced in cases under 14 A c and 14 A d not lifted if the relevant tests have shown a satisfactory result.

15. :	Salmonella vaccin	ation							
	Voluntary								
	Compulsory								
	Forbidden								
	Use of <i>Salmonell</i> Regulation (EC) N		in compliance	with	provisions	of	Article	3	of
	⊠yes	□no							

If no, please explain. - If performed please describe the vaccination scheme (vaccines used, vaccines providers, target flocks, number of doses administered per bird, etc) (max. 32000 chars):

In BG the use of vaccines for the control of salmonella in poultry is not prohibited.

In the official register of veterinary medicine products there are registered and approved vaccines for Salmonella spp. for birds. The owners of the holdings could use only the approved by BFSA vaccines in the way indicate by the official veterinarian responsible for the poultry holdings. The vaccination scheme shall be approved by the Regional Food Safety Directorate.

When the samples have been taken from vaccinated poultry, the letter accompanying any such samples to the laboratory must specify the type and time of vaccination. The objective is to ensure proper basis for differentiation between vaccination and field strain in accordance with Regulation (EC) 1177/2006. The operator/owner in consultation with his/her veterinarian may consider vaccination of the flock against Salmonella with a product which has a marketing authorisation in your country and complies with the requirements of Commission Regulation (EC) No.1177/2006 for specific control methods in the framework of the national programmes for the control of Salmonella.

Vaccination may only be used as a preventative measure; and it is not an alternative to the requirements in Annex II.C of Commission Regulation (EC) No 2160/2003

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

Describe the system for compensation to owners. Indicate also how improper implementation of biosecurity measures can affect the payment of compensation (max. 32000 chars):

TThe terms and procedures for compensation of owners are described in the national legislation - the Law

of Veterinary Activity (LVA) and Ordinance on the terms and procedures applicable to effecting expenditures related to epizootic risks.

Pursuant to the Ordinance on the terms and conditions for spending the costs for covering the epizootic risks related expenditures compensations are paid to the owners of the animals compulsory culled (slaughtered in slaughterhouses or killed by other way).

According to the national legislation in the in the context of the programme a possibility to pay compensation costs or any financial assistance for food and feed business operator has not been provided.

The valuation of birds is determined by the National statistics institute, by average market price per 1 kilogram live weight for the month and the respective region, as the scale of compensation for birds is publicly available.

Additionally, the national legislation does not provide a compensation for indirect losses by the FBO In case of non compliances / breaches of the biosecurity measures/disregard Ministry/BFSA ordinances/detected during the official control, the compensation is not provided according to the national legislation.

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

(max. 32000 chars):

After a flock infected with relevant serovars is depopulated the house where the birds were kept must be clean and disinfected under the supervision of the CA. Environmental samples have to be taken by the CA (at least five of contact surfaces per premise) inside the house in order to verify the efficacy of the procedure. Samples have to be analyzed in an official laboratory and in case of identification of any Salomonella serovar e new cycle of cleaning and disinfection must be performed and repeated if necessary up to e negative finding.

Re-stocking may not take place until the cleaning and disinfection has been carried out. Negative results is required to lift the restriction measures in the holding.

B. General information

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

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

Bulgarian Food Safety Agency is the competent authority responsible for implementation of the Programme for control of Salmonellosis and other infectious agents causing zoonoses.

Department "Infectious diseases" within Directorate "Animal health and Welfare" at the Headquarters of BFSA has the following responsibilities:

- 1. To draft surveillance programme for Salmonellosis and to submit it for approval to the European Commission.
- 2. To control the implementation of the surveillance programme.
- 3. To collect and analyze the data on the animals tested for salmonellosis
- 4. To summarize the data on positive holdings.
- 5. To keep a register in the database of all holdings with laying hens
- 6. To send annual report to the European Commission.

At regional level the Regional Food Safety Department (RFSD) and the heads of departments "Animal health" have the following responsibilities:

- 1. To control and to implement the Salmonella surveillance programme at regional level.
- 2. To collect and analyze the data on the poultry tested for salmonella in the region.
- 3. To summarize the data on positive animals.
- 4. To summarize the data on the salmonella surveillance costs incurred at regional level.
- 5. To keep a register in the database of all holdings with laying hens.
- 6. To send annual reports containing the data referred to in points 1-5 to Directorate "Animal health and welfare" at BFSA.

Official veterinarians:-

- Assists in the development and updating of the current program, according to the epizootic situation, analysis of the received data, population changes that occurred during the implementation of the program, etc. factors affecting it;
- Monitors and implements the Salmonella Surveillance Program in the respective municipality.-
- Supervises the sampling of laying hens and the sending of the samples for examination in laboratories.
- Collects and analyzes the data from the herds located in the respective municipality, tested for salmonella.
- Summarizes the data on positive herds from livestock facilities located on the territory of the respective municipality.
- Completes and keeps a register in the database for all poultry facilities with laying hens.
- Sends annual reports containing the data specified above.

Data on the implementation of the NSCPs is presented to the CCA at by the laboratories and RFSDs each 6 months in terms of preparing the annual and intermediate reports for the implementation on programmes. In case of positive Salmonella results (related to all Salmonella spp detected as well as

either FBO or official sampling) the labs are requested to inform immediately the CCA. The CCA orders the relevant RFSD to impose the restrictive measures according to the Salmonella spp detected and based on the Salmonella legislation.

2. Legal basis for the implementation of the programme

(max. 32000 chars):

COMMISSION REGULATION (EC) 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

REGULATION (EC) No 1177/2006, 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

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;

COMMISSION REGULATION (EC) No 1237/2007, amending Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Decision 2006/696/EC as regards the placing on the market of eggs from Salmonella infected flocks of laying hens

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

(max. 32000 chars):

Results of the monitoring of the target Salmonella serovars in laying hens for the last 6 years and prevalence of the targeted serovars:

In 2021, 182 flocks were tested, with 2 positive found, resulting in 1.1 % prevalence

In 2020 240 flocks were tested, with 4 positive found, resulting in 1.7 % prevalence

In 2019 211 flocks were tested, with 9 positive found, resulting in 4.3 % prevalence

In 2018 160 flocks were tested, with 3 positive found, resulting in 1.9 % prevalence

In 2017 227 flocks were tested, with 15 positive found, resulting in 6.61 % prevalence

In 2016 233 flocks were tested, with 5 positive found, resulting in 2.15 % prevalence

In 2015 243 flocks were tested, with 4 positive found, resulting in 1.6 % prevalence

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

(max. 32000 chars):

All commercial holdings for laying hens are registered in accordance with Ordinance 25 laying down the minimal requirements regarding welfare during laying hens rearing, SG 42/23. May 2006, amend. SG 29/06. April 2007, transposing COMMISSION DIRECTIVE 2002/4/EC of 30 January 2002 on the registration of establishments keeping laying hens, covered by Council Directive 1999/74/EC.

The register commercial holdings are entered into the national electronic database and maintained by Headquarter at the BFSA. The records on registration of farms are kept at central level (Headquarter at BFSA) and local level (RFSDs).

The size limit for poultry to be registered obligatorily is as follow:

- flocks more than 500 poultry broilers
- flocks more than 250 poultry breeding hens
- flocks more than 350 poultry laying hens
- flocks more than 250 poultry turkeys

No eggs for direct sale are allowed if the holding is not a subject of salmonella official control. Thus the programme covers also the laying holdings with less than 350 birds if there is direct sale of eggs.

The Bulgarian Food Safety Agency is the official competent authority for the registration of animal holdings.

The owners of animal holdings shall submit an application of registration, conformed to a specimen to the director of RFSD.

Within a time period of up to 7 days from the submission of the application, the director of RFSD by an order shall appoint a commission for carrying out of a check for compliance of the holdings with the veterinary medical requirements on animal breeding and welfare.

The commission shall in a period of 3-days present to the director of the RFSD the opinion with a proposal for a registration or a refusal.

When upon the check it is being found out that the holding does not meet the veterinary medical requirements, the commission shall give a written prescription to the applicant, wherein shall fix a deadline for adjustment of the omissions.

When the applicant has removed the omissions before the expiry of the indicated in the prescription deadline, he shall inform in writing the director of RFSD, who within a period of seven-days shall send the commission for a re-check of the holding. The commission shall draft a protocol of the results of the check and shall submit it to the director of RFSD.

The director of RFSD shall enter the animal-breeding holding in the register and shall issue a certificate of registration or shall justify the refusal of the registration if the holding does not meet the veterinary medical requirements. The register contains the following information:

- 1. number and date of the certificate issued;
- 2. the veterinary registration number of the holding;
- 3. name and permanent address of the owner of the holding;
- 4. address/location and type of the holding;
- 5. capacity of the holding;
- 6. type, category and use of the birds in the holding;
- 7. technology of breeding of the birds;
- 8. number and date of the order for delegation of the registration
- 9. changes in the circumstances entered.

Record- keeping at farms.

Each animal holding shall keep records with the following information.

- Total number of birds in the holding
- The new entered birds

- The birds for slaughtering.
- The birds for sale
- The number of death birds

When a farm is inspected by an official veterinarian, the latter has also to perform a thorough check of all the records /logbooks/ that are kept in respective holding.

Each owner is requested to have way of identification of the flocks so that he/ she to provide traceability of the flocks at each time. The way of identification, the type of unique flock number for the purpose of monitoring and traceability of flock is a decision made by the owner. In major cases the flock is identified by number consist: arrival date of the poultry consignment and number of premises

5. System to monitor the implementation of the programme.

(max. 32000 chars):

The chain of the competent authority and system to monitor the implementation of the programme is described in point B 1.

C. Targets

1 Targets related to flocks official monitoring

1.1 Targets on laboratory tests on official samples for year:

2023

Type of the test (description)	Target population	Number of planned tests
Bacteriological detection test	Laying flocks of Gallus gallus	528
Serotyping	Laying flocks of Gallus gallus	20
Antimicrobial detection test	Laying flocks of Gallus gallus	20
Test for verification of the efficacy of disinfection	Laying flocks of Gallus gallus	20

1.2 Targets on official sampling of flocks for year: 2023

Type of the test (description)	Rearing flocks	Adult flocks
Total No of flocks (a)		240
No of flocks in the programme		240
No of flocks planned to be checked (b)		240
No of flock visits to take official samples (c)		266
No of official samples taken		528
Target serovars (d)	SE+ST	SE + ST
Possible No of flocks infected by target serovars		2
Possible No of flocks to be depopulated		2
Total No of birds to be slaughtered/culled		20 000
Total No of eggs to be destroyed	Text	200 000
Total No of eggs to be heat treated	Text	200 000

- (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 serveral times.
- (c) Each visit for the purpose of taking official samples shall be counted. Several visits on the same flock for taking official samples shall be counted separately.
- (d) Salmonella Enteritidis and Salmonella Typhimurium = SE + ST Salmonella Enteritidis, Typhimurium, Hadar, Infantis, Virchow = SE+ ST + SH +SI + SV

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

Type of the test (description)	Target on vaccination
Number of flocks in the Salmonella programme	0
Number of flocks expected to be vaccinated	0
Number of birds expected to be vaccinated	0
Number of doses expected to be administered	0

E. Financial information

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

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursment/payment claim to the EU. Describe the financial flows/circuits followed.

Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

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

The official sampling is performed by the official veterinarians within the structure if BFSA. The sampling equipment is provided by the local CA. The costs for sampling are within the state budget.

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

The samples collected within the National Control Programme are analysed by laboratories accredited for that purpose, designated and approved by BFSA to carry out testing official and FBO samples on Salmonella in poultry within SCP. All are accredited to ISO 17025 and designated in accordance with Article 12 of Regulation (EC) No 2160/2003.

Scope of Activities includes detection of Salmonella in animal faeces, tissue, environmental samples,

feed and water, serotyping.

The analytical methods for the Salmonella detection (defined in Part 3.2 of the Annex of Regulation (EU) No 200/2010 i.e. Amendment 1 of EN/ISO 6579-2002/Amd1:2007.) are within the scope of their accreditation.

The costs for testing are covered by the state budget.

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

The terms and procedures for compensation of owners are described in the national legislation - the Law of Veterinary Activity (LVA)

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

Since the vaccination on the territory of the country is not compulsory, the vaccination is paid by the FBO where applied.

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

Measures related to cleaning and disinfection:

The owner or person responsible for the flock is required to clean and disinfect the building where the

Laying flocks of Gallus gallus	
nfected birds were kept, and provide evidence to the Competent Authority that the cleaning and isinfection has been satisfactory. Re-stocking may not take place until the cleaning and disinfection has seen carried out. Ileaning and disinfection of the premises under official control followed by post cleaning and isinfection of the premises under official control measures in the holding.	
2. Source of funding of eligible measures	
All eligible measures for which cofinancing is requested and reimbursment will be claimed are financed by public fund	s.
⊠yes	
\square no	
3. Additional measures in exceptional and justified cases	
In the "Guidelines for the Union co-funded veterinary programmes", it is indicated that in exceptional and duly justific cases, additional necessary measures can be proposed by the Member States in their application.	эd
f you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also ustification of their cost:	
/a	

Attachments

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- 4) IT CAN TAKE <u>SEVERAL MINUTES TO UPLOAD</u> ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!
- 5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

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