

SANCO/10416/2014

Programmes for the eradication, control and monitoring of certain animal diseases and zoonoses

### The programme for the control of certain zoonotic salmonella in breeding, laying and broiler flocks of Gallus gallus and in flocks of turkeys (Meleagris gallopavo)

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Approved\* for 2014 by Commission Decision 2013/722/EU

\* in accordance with Council Decision 2009/470/EC

version: 2.3

#### PROGRAMME for ERADICATION:

#### ANNEX II - PART A + B

Member States seeking a financial contribution from the Community for national programmes for the control and monitoring of salmonellosis (zoonotic salmonella), shall submit applications containing at least the information set out in this form.

The central data base keeps all submissions. However only the information in the last submission is shown when viewing and used when processing the data.

If encountering difficulties, please contact SANCO-BO@ec.europa.eu

Instructions to complete the form:

1) In order to fill in and submit this form you must have <u>at least</u> the ADOBE version

### Acrobat Reader 8.1.3

(example: 8.1.3, 8.1.4, 8.1.7, 9.1, 9.2,...), otherwise you will not be able to use the form.

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- 2) Please provide as much information as possible. If you have no data for some fields then put the text "NA" (Not applicable) in this field or 0 if it is a numeric field. If you need clarifications on some of the information requested, then please contact <a href="mailto:SANCO-BO@ec.europa.eu">SANCO-BO@ec.europa.eu</a>.
- 3) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page. If the form is not properly and completely filled in, an alert box will appear indicating the number of incorrect fields. Please use the "verify form" button untill all fields are correctly filled in. It is mandatory to fill in the box about Animal populations to make the rest of the questions visible. If you still have any difficulties, please contact SANCO-BO@ec.europa.eu.
- 4) When you have finished filling the form, verify that your internet connection is active and then click on the "submit notification" button below. If the form is properly filled in, the notification will be submitted to the server and a submission number + submission date will appear in the corresponding field.
- 5) IMPORTANT: Regularly save the pdf when you fill it out. After you have received the Submission number, DO NOT FORGET TO SAVE THE PDF ON YOUR COMPUTER FOR YOUR RECORDS!

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#### ANNEX II - PART A

### General requirements for the national salmonella control programmes

Member state: BULGARIA

### (a) State the aim of the programme

(max. 32000 chars):

The target of the Program is to

- determine the health status of poultry of the hen's species in Republic of Bulgaria with regard to Salmonella enteritidis, Salmonella Hadar, Salmonella infantis, S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i), Salmonella virchow and all other types of Salmonella.
- reduction to 1 % or less of the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for Salmonella enteritidis, Salmonella infantis, Salmonella hadar, S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) and Salmonella virchow (the relevant salmonella serotypes).

## (b) Animal population and phases of production which sampling must cover

Demonstrate the evidence that it complies with the minimum sampling requirements laid down in part B of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council OJ L 325, 12.12.2003, p. 1. indicating the relevant animal population and phases of production which sampling must cover

It is mandatory to fill in the box about Animal populations to make the rest of the questions visible.

Animal population B	reeding flocks of Gallus gallus
rearing flocks	⊠ day-old chicks
	two weeks before moving to laying phase or laying unit
adult breeding flocks	every second week during the laying period
	every third week during the laying period

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### (c) Specific requirements

Demonstrate the evidence that it complies with the specific requirements laid down in Parts C, D and E of Annex II to Regulation (EC) No 2160/2003

#### (max. 32000 chars):

In case of suspicion or conformation of Salmonella enteritidis or S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) the NRL shall notify immediately the BFSA. The positive result for target serovars confirmed by NRL is a condition to declare a flock as a positive for target serovars of the control programme.

When a breeding flock of Gallus gallus is suspected of being infected with Salmonella Enteritidis or S. Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) the flock is placed under official control by the Competent Authority following testing carried out according to Annex 2.2.2.2 of Regulation 200/2010/EC. If the flock is in the laying phase no further eggs may be sent for hatching and no birds or hatching eggs may leave the holding.

In the cases of positive results for S. Enteritidis or S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) after own or official sampling the flock is placed under official control by the Competent Authority following sampling and testing of all flocks within the holding. The sampling and testing are carried out according to Regulation 200/2010/EC.

The flock with positive result obtained from own or official sampling and confirmed by NRL is considered as a positive flock for target serovars of the control programme.

In the cases of suspicion of infection the following measures shall be taken by the CA:

- prohibition of the bird and egg movement (movement restriction –if the flock is in the laying phase no further eggs may be sent for hatching and no birds or hatching eggs may leave the holding, except under licence issued by the Regional Food Safety Department.)
- epidemiological investigations
- sampling of other flocks within the holding (Annex 2.2.2.2 of Regulation (EC) 200/2010)
- checks the records keeping at the farms and bio-security measures,
- feed and water sampling,
- traceability of production 10-15 days back. All production on the market shall be placed under restrictive measures as far as possibly.

When infection with S. Enteritidis or S. Typhimurium has been confirmed, the owner is required to have the birds slaughtered in accordance with Community legislation on food hygiene according to the requirements of Annex II.C of Regulation 2160/2003/EC.

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.

Hatching eggs present in the hatchery from the time the flock was suspected to be infected are removed and destroyed in accordance with Regulation (EC) No 1069/2009.

When a breeding flock is infected with S. Hadar, S. Infantis, or S. Virchow, the operator/owner of the flock will be required to draw up a plan in consultation with his/her veterinarian and the Competent Authority for the monitoring and control of the infection. The plan should include an epidemiological

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investigation, a review of biosecurity measures, any additional monitoring procedures, and measures to be taken to reduce or eliminate the infection. As appropriate the flock may be placed under official control

Cleaning and dezinfection of the permises under official control followed by post cleaning and dezinfection sampling. Negative results is required to lift the restriction measures in the holding. 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 line with the requirements of Commission Regulation (EC) No.1091/2005 as regards requirements for the use of specific control methods in the framework of the national programmes for the control of Salmonella. Vaccination may only be used as a preventative measure; it is not an alternative to the requirements in Annex II C of Commission Regulation (EC) No 2160/2003 for the use of specific control methods in the framework of the national programmes for the control of Salmonella.

Antimicrobial treatment may not be used for the control of Salmonella in the national control programme except within the limits set by Commission Regulation (EC) No. No.1177/2006.

### (d) Specification of the following points:

### (d)1. General

## (d) 1.1 A short summary referring to the occurrence of Salmonellosis (Zoonotic Salmonella)

A short summary referring to the occurrence of the salmonellosis [zoonotic salmonella] in the Member State with specific reference to the results obtained in the framework of monitoring in accordance with Article 4 of Directive 2003/99/EC of the European Parliament and of the Council OJ L 325, 12.12.2003, p. 31., particularly highlighting the prevalence values of the salmonella serovars targeted in the salmonella control programmes.

#### (max. 32000 chars):

In Republic of Bulgaria, the Salmonella Control National Programme in breeding flocks has been in operation since 2008 and approved by Commission Decision 2007/873/EO.

The number of breeding flocks positive for Salmonella spp in total is as follow:

-In 2008 – No Salmonella positive serotypes

-In 2009 – 1 flock positive for Salm. Infantis; 1 flock - Salm. Bareilly; 2 floks-

Salm. Senftenberg; 1 flock -Salm. agona

-In 2010 - 3 flocks positive for S. Infantis, 2 flocks - S. hadar, 1 flock- S.Glostrup, 1. flock - S.Seftenberg, 1 flock - S. Corvallis.

-In 2011 – 1 flock positive for S. Typhimurium, 1 flock - S. Agona and S. Livingstone in hatchery.

-In 2012 - 1 flock positive for S.infantis, 2 flocks positive for S.corvalis and 1 flock positive for S.Lomnita.

The data shows that S.Infantis remains the most commonly isolated Salmonella serotype, followed by S. Hadar, S. Agona and S. Senftenberg in the Republic of Bulgaria as a whole.

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The % Salmonella positive flock's prevalence for the Salmonella target serotypes included in the program decreased in 2011 and 2012 to 0.84%. The target of the SCNP in breeding flocks was achieved in 2011 and 2012, namely reduction to 1 % or less of the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for S.Enteritidis, S.Infantis, S.Hadar, S.Typhimurium and Salmonella virchow.

## (d) 1.2 The structure and organization of the relevant competent authorities.

Please refer to the information flow between bodies involved in the implementation of the programme.

#### (max. 32000 chars):

Bulgarian Food Safety Agency (BFSA) is the competent authorities for control of Salmonella and their zoonotic agents.

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 analyse 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 breeding hens
- 6. To send annual report to the European Commission containing the data referred to in points 3-6.

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 analyse 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 breeding hens.
- 6. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health and welfare" at BFSA.

The municipal veterinarian has the following responsibilities:

- 1. To control and to implement the programme for surveillance of salmonella in the relevant municipality.
- 2. To control the sampling of laying hens and the sending of samples to the laboratories.
- 3. To collect and analyse the data on the poultry tested for salmonella in the veterinary units located onthe territory of the relevant municipality.
- 4. To summarize the data on positive animals from the veterinary units located on the territory of the relevant municipality.
- 5. To summarize the data on the salmonella surveillance costs incurred by the relevant municipality.
- 6. To keep a register in the database of all holdings with breeding hens

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7. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health" at the relevant RFSD.

## (d) 1.3 Approved laboratories where samples collected within the programme are analysed.

#### (max. 32000 chars):

The samples collected within the National Control Programme are analysed by laboratories accredited for that purpose, designated and approved by BFSA.

As by 31.01.2012 accredited laboratories for Salmonellosis diagnostics are:

A. within the BFSA system:

- 1. National Reference Laboratory for Salmonellosis diagnostics, Sofia;
- 2. the "Laboratory for bacterial diseases in poultry" at the National Diagnostic and Research Veterinary Institute, Sofia;
- 3. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Shumen;
- 4. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Blagoevgrad;
- 5. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Varna;
- 6. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Vratsa;
- 7. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Haskovo;
- B. Private laboratories:
- 1. the "Laboratory for testing food, feed and biological materials" "Regional Veterinary Station Ruse" SP Ltd.

Any positive isolates obtained within the tests performed therein must be sent for confirmation and typing in the:

National Reference Laboratory for Salmonellosis diagnostics at the National Diagnostic and Research Veterinary Institute (within BFSA), 1606 Sofia, # 15 "Pencho Slaveikov" blvd.; ph. No. (00359 2) 952 3903.

Any results shall be considered as valid only if compliance with the requirements for testing demonstrated with the Commission Regulation (EC) No 213/2009.

The official control samples have to be tested by the accredited laboratories listed in point A (state laboratories). The own-check samples could be tested by the accredited laboratories listed in point A and B (private or state laboratories).

All laboratories involved in the programme must participate in proficiency tests. The NRL has to participates regularly in proficiency tests (serotyping and Salmonella isolation) organised by the EU Reference Laboratory (EURL) for Salmonella. The NRL is responsible for training and organisation of proficiency tests for Salmonella isolation for other laboratories involved in the National Control Programme.

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## (d) 1.4 Methods used in the examination of the samples in the framework of the programme.

#### (max. 32000 chars):

The method recommended by the Community Reference Laboratory for salmonella in Bilthoven , Netherlands shall be used: the method is a modification of ISO 6579 (2002) where a semi-solid medium (MSRV) is used as the single selective enrichment medium. The semi-solid medium should be incubated at 41.5 + -1°C for  $2 \times (24 + -3)$  hours.

As regards the boot swab samples and other feacal material samples, referred to in paragraph 3.1, it is possible to pool incubated BPW enrichment broth for future culture. To do that, incubate both samples in BPW as normal. Take 1 ml of incubated broth from each sample and mix thoroughly, then take 0,1 ml of the mixture and inoculate the MSRV plates in the usual way.

## (d) 1.5 Official controls (including sampling schemes) at feed, flock and/or herd level.

#### (max. 32000 chars):

Official sampling on the feed stuffs from poultry

Bulgarian Food Safety Agency performs sampling of feed stuffs as follow:

- 1. feed sampling done at producers of feed raw materials and wholesale traders in feed raw materials in bulk;
- 2. feed sampling done at farms.

The number of samples has been calculated on the basis of risk assessment in accordance with the provisions of Regulation 882/2004. This Plan involves also a minimum number of Salmonella samples taken from poultry feed consignments imported from third countries.

There have not been any positive results identified concerning this indicator.

If a positive result is to be identified, the measures and actions to be undertaken are pursuant to the provision of Article 396, Paragraph 2, Item 5 of the LVA.

Official control at the other stages of the food chain:

According to the National legislation (Law of veterinary activity and Food law) the establishments for production, storage and trade of animal products have to be approved registered by BFSA and entered into the national electronic database. The public registers of approved establishments are kept in the RFSDs and the BFSA.

The official inspections in establishments for production, storage, and trade of animal products are carried out by the official veterinarians at the BFSA/RFSD.

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The official inspections in the establishments for production, storage and trade with food are carried out in accordance with the Regulation 882/2004 of the European Parliament and the Council Regulation 854/2004 of the European Parliament and the Council, laying down the specific rules for the organisation of official controls on products of animal origin intended for human consumption. The number of samples has been calculated by the official veterinarians on the basis of risk assessment and the type and quality of the materials included in the food processing and the results of the previous inspections. The samples from foods of poultry origin shall be taken and preceded as provided in Regulation 2073/2005. The frequency of sample taking could be increased and decreased on the basis of the results of the sample testing.

Annually the Regional Food Safety Directorates (RFSDs) draft a schedule for the number of inspections in the controlled establishments for production, storage, and trade of animal products.

Concerning the official controls at flock level -the sampling frame shall cover all adult breeding flocks of domestic fowl (Gallus gallus) comprising at least 250 birds (breeding flocks). It shall be without prejudice to the provisions in Regulation (EC) No 2160/2003 and Directive 2003/99/EC as regards the monitoring requirements in other animal populations or other serotypes.

There is a specific Order (ref. No. RD 11-389 of 30.03.2012) officially approving and enter into effect a scheme for sampling of various categories of poultry in accordance with Regulation (EC) No. 2160/2003 and Regulation (EC) No. 200/2010. The scheme specifies the number of samples for the purposes of self-control and official control at hatchery and farm levels. Samples from poultry flocks shall be 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 ownchecks.

### (d)2. Food and business covered by the programme

(d)2.1 The structure of the production of the given species and products thereof.

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(max. 32000 chars):

As by the end of 2012 there are 31 holdings with 323 breeding flocks (1 170 785 breeding hens) and 28 hatcheries located in the territory of the country.

### (d)2.2 Structure of the production of feed

(max. 32000 chars) :

n/a

(d)2.3 Relevant guidelines for good animal husbandry practices or other guidelines (mandatory or voluntary) on biosecurity measures defining at least

### (d)2.3.1 Hygiene management at farms

(max. 32000 chars):

All farmers are obligated to have their individual Guidelines for good farmer practices, which are subject to approval by the official veterinarian responsible for the control of the holding concerned. In the past several informative brochures titled: "How to protect our poultry?; "Six requirements for protection of your poultry" and were distributed to all the 28 Regional Food Safety Directorates of the country and have been provided to the owners of all poultry holdings. This brochure lays down all the measures needed to protect poultry against infection.

The major point for good farmer practices that should be follow by the farmers are concern to:

- the hygiene management at farms,
- themeasures to prevent incoming infections carried by animals, feed, drinking water, people working at farms, and
- the hygiene in transporting animals to and from farms.

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## (d)2.3.2 Measures to prevent incoming infections carried by animals, feed, drinking water, people working at farms

(max. 32000 d	chars):
please see 2.	3.1
(d)2.3.3	Hygiene in transporting animals to and from farms
(max. 32000 d	chars):
please see 2.	3.1
(d)2.4	Routine veterinary supervision of farms

(max. 32000 chars) :

2.4. Routine veterinary supervision of farms.

Every year the 28th RFSDs on the base of risk assessment present plans for controls of poultry farms within the respective region. Those plans are annually approved by the BFSA.

To consider an inspection on farms as an official control in the frame of the salmonella control programme, the official veterinarian on behalf of the Competent Authority shall take official samples for detecting of Salmonella.

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### (d)2.5 Registration of farms

#### (max. 32000 chars):

All commercial holdings for breeding flocks are registered in accordance with Article 137 of the law of the Veterinary activity. 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

### (d)2.6 Record keeping at farm

(max. 32000 chars) :

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

Each animal holding shall keep records with information provides details of sampling for Salmonella and the results. The records are kept at the farms and the owners are requested to made available them in case of official control. When a farm is inspected by an official veterinarian, the latter has also to perform a thorough check of all the records /logbooks/ kept in respective holding

### (d)2.7 Documents to accompany animals when dispatched

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#### (max. 32000 chars) :

During transport the live birds shall be accompanied with transport authorization, issued by the BFSA, according to the Council Regulation 1/2005 on the protection of animals during transport.

Operators wishing to export more than 20 birds or hatching eggs to another EU member state (or certain third countries) must comply with EU Directive 90/539/EC and ensure that the consignment is accompanied by a completed and signed Intra-trade Animal Health Certificate (ITAHC) for poultry breeding and production.

The ITAHC will also require the reference number of the operator's poultry health certificate. Animal health certificate has to be issued by the veterinarian servicing the farm of origin and completed on a pre-printed model form after an appropriate clinical examination performed by this veterinarian. All official veterinary health certificates issued for the export of poultry and hatching eggs are recorded on the Trade Control and Expert System (TRACES). This system allows tracking of exports of live animals and hatching eggs accompanied by veterinary health certification. The TRACES generates ITAHCs issued for intra-Community movements. A TRACE is an internet-based service which is owned and maintained by the Commission

### (d)2.8 Other relevant measures to ensure the tracebility of animals

#### (max. 32000 chars):

Each consignment of poultry or hatching eggs must be accompanied by information delivered by the veterinarian of the place of forwarding the consignment to the official veterinarian of their place of their destination.

The operators of hatcheries and the keepers of breeding flocks shall keep records of poultry or hatching eggs entering or leaving the premises. The records must contain information on the number, date, and origin or destination. These records must be retained for three years and be available to the Competent Authority for inspection.

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#### ANNEX II - PART B

### 1. Identification of the programme

Animal population : Breeding flocks of Gallus gallus

Request of Union co-financing for the period :

To 2014

#### 1.1 Contact

Name: Dr Aleksandra Miteva

Phone: +359 2 915 98 42

Fax.: +359 2 915 98 42

Email: a\_miteva@nvms.government.bg

### 2. Historical data on the epidemiological evolution of the disease

A concise description is given with data on the target population (species, number of herds and animals present and under the programme), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables, graphs or maps.

#### (max. 32000 chars) :

n Republic of Bulgaria, the Salmonella Control National Programme in breeding flocks has been in operation since 2008 and approved by Commission Decision 2007/873/EO.

The number of breeding flocks positive for Salmonella spp in total is as follow:

-In 2008 – No Salmonella positive serotypes

-In 2009 – 1 flock positive for Salm. Infantis; 1 flock - Salm. Bareilly; 2 floks-

Salm. Senftenberg; 1 flock -Salm. agona

-In 2010 - 3 flocks positive for S. Infantis, 2 flocks - S. hadar, 1 flock- S.Glostrup, 1. flock - S.Seftenberg, 1 flock - S. Corvallis.

-In 2011 – 1 flock positive for S. Typhimurium, 1 flock - S. Agona and S. Livingstone in hatchery.

-In 2012 - 1 flock positive for S.infantis, 2 flocks positive for S.corvalis and 1 flock positive for S.Lomnita.

The data shows that S.Infantis remains the most commonly isolated Salmonella serotype, followed by S.

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Hadar, S. Agona and S. Senftenberg in the Republic of Bulgaria as a whole.

The % Salmonella positive flock's prevalence for the Salmonella target serotypes included in the program decreased in 2011 and 2012 to 0.84%. The target of the SCNP in breeding flocks was achieved in 2011 and 2012, namely reduction to 1 % or less of the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for S.Enteritidis, S.Infantis, S.Hadar, S.Typhimurium and Salmonella virchow.

### 3. Description of the submitted programme

A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals, vaccination), the target animal population and the area(s) of implementation and the definition of a positive case.

(max. 32000 chars):

The target of the Program is to

- determine the health status of poultry of the hen's species in Republic of Bulgaria with regard to Salmonella enteritidis, Salmonella Hadar, Salmonella infantis, S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i), Salmonella virchow and all other types of Salmonella.

- reduction to 1 % or less of the maximum percentage of adult breeding flocks of Gallus gallus remaining positive for Salmonella enteritidis, Salmonella infantis, Salmonella hadar, S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) and Salmonella virchow (the relevant salmonella serotypes).

Duration of the programme: 01.01.2014-31.12.2014

Measures:

X Control

X Testing

X Slaughter of positive animals

X Killing of positive animals

X Vaccination

X Treatment of animal products

X Disposal of the products

X Monitoring or surveillance

### 4. Measures of the submitted programme

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Measures taken by the competent authorities with regard to animals or products in which the presence of Salmonella spp. have been detected, in particular to protect public health, and any preventive measures taken, such as vaccination.

(max. 32000 chars):

The measures taken by the competent authorities with regard to animals or products in which the presence of Salmonella spp. have been detected, in particular to protect public health, and any preventive measures taken, such as vaccination are described into the relevant veterinary legislation: 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 COMMISSION REGULATION (EC) No 213/2009 of 18 March 2009 amending Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Regulation (EC) No 1003/2005 as regards the control and testing of Salmonella in breeding flocks of Gallus gallus and turkeys. 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; 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 ORDINANCE 9/28.01.2006 on the monitoring of zoonoses in their prevention, limitation and eradication (Published in SG 15/17.02.2006), transposing DIRECTIVE 2003/99/EC 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

4	1	Summary	of me	pasures	under	the	nroc	ıramn	ne
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$Period\ of\ implementation\ of\ the\ programme:$	2014
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Measures
⊠ Killing of animals tested positive
Vaccination
☑ Disposal of products
Monitoring or surveillance

### 4.2 Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Descrive the responsabilities of all involved.

#### (max. 32000 chars):

Other, please specify

Bulgarian Food Safety Agency (BFSA) is the competent authorities for control of Salmonella and their zoonotic agents.

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 analyse 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 breeding hens
- 6. To send annual report to the European Commission containing the data referred to in points 3-6.

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 analyse the data on the poultry tested for salmonella in the region.
- 3. To summarize the data on positive animals.

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- 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 breeding hens.
- 6. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health and welfare" at BFSA.

The municipal veterinarian has the following responsibilities:

- 1. To control and to implement the programme for surveillance of salmonella in the relevant municipality.
- 2. To control the sampling of laying hens and the sending of samples to the laboratories.
- 3. To collect and analyse the data on the poultry tested for salmonella in the veterinary units located on the territory of the relevant municipality.
- 4. To summarize the data on positive animals from the veterinary units located on the territory of the relevant municipality.
- 5. To summarize the data on the salmonella surveillance costs incurred by the relevant municipality.
- 6. To keep a register in the database of all holdings with breeding hens
- 7. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health" at the relevant RFSD.

### 4.3 Description and delimitation of the geographical and administrative areas in which the programme is to be implemented

Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

(max. 32000 chars):

The programme shall be implemented on the territory of the whole country comprising 28 districts

### 4.4 Measures implemented under the programme

Where appropriate Community legislation is mentioned. Otherwise the national legislation is mentioned.

### 4.4.1 Measures and applicable legislation as regards the registration of holdings

(max. 32000 chars):

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

The owners of animal-breeding 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

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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.

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.

### 4.4.2 Measures and applicable legislation as regards the identification of animals

Not	appl	icab	le f	for	pou	ltry
-----	------	------	------	-----	-----	------

(max. 32000 chars):			
n/a			

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### 4.4.3 Measures and applicable legislation as regards the notification of the disease

(max. 32000 chars):

The Law on Veterinary Activities, Art.124 and Ordinance No.23 / 14.12.2005 on the order and the way of notification and registration of infectious diseases in animals, which is harmonized with Council Directive 82/894/EEC.

## 4.4.4 Measures and applicable legislation as regards the measures in case of a positive result

A short description is provided of the measures as regards positive animals (slaughter, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter

#### (max. 32000 chars):

In case of suspicion or conformation of Salmonella enteritidis or S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) the NRL shall notify immediately the BFSA. The positive result for target serovars confirmed by NRL is a condition to declare a flock as a positive for target serovars of the control programme.

4.4.9.1. When a breeding flock of Gallus gallus is suspected of being infected with Salmonella Enteritidis or S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) the flock is placed under official control by the Competent Authority following testing carried out according to Annex 2.2.2.2 of Regulation 200/2010/EC. If the flock is in the laying phase no further eggs may be sent for hatching and no birds or hatching eggs may leave the holding.

In the cases of positive results for S. Enteritidis or S.Typhimurium(including monophasic S. Typhimurium serotype with antigenic formula 1,4/5/,1 2:i) after own or official sampling the flock is placed under official control by the Competent Authority following sampling and testing of all flocks within the holding. The sampling and testing are carried out according to Regulation 200/2010/EC.

The flock with positive result obtained from own or official sampling and confirmed by NRL is considered as a positive flock for target serovars of the control programme.

In the cases of suspicion of infection the following measures shall be taken by the CA:

- prohibition of the bird and egg movement (movement restriction –if the flock is in the laying phase no further eggs may be sent for hatching and no birds or hatching eggs may leave the holding, except under licence issued by the Regional Food Safety Department.)
- epidemiological investigations
- sampling of other flocks within the holding (Annex 2.2.2.2 of Regulation (EC) 200/2010)
- checks the records keeping at the farms and bio-security measures,
- feed and water sampling,
- traceability of production 10-15 days back. All production on the market shall be placed under restrictive measures as far as possibly.

4.4.9.2.When infection with S. Enteritidis or S. Typhimurium has been confirmed, the owner is required to have the birds slaughtered in accordance with Community legislation on food hygiene according to the

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requirements of Annex II.C of Regulation 2160/2003/EC.

4.4.9.3. 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.

4.4.9.4. Hatching eggs present in the hatchery from the time the flock was suspected to be infected are removed and destroyed in accordance with Regulation (EC) No 1069/2009.

4.4.9.5. When a breeding flock is infected with S. Hadar, S. Infantis, or S. Virchow, the operator/owner of the flock will be required to draw up a plan in consultation with his/her veterinarian and the Competent Authority for the monitoring and control of the infection. The plan should include an epidemiological investigation, a review of biosecurity measures, any additional monitoring procedures, and measures to be taken to reduce or eliminate the infection. As appropriate the flock may be placed under official control.

4.4.9.6. Cleaning and dezinfection of the permises under official control followed by post cleaning and dezinfection sampling. Negative results is required to lift the restriction measures in the holding.

### 4.4.5 Measures and applicable legislation as regards the different qualifications of animals and herds

(max. 32000 chars):			
n/a			

# 4.4.6 Control procedures and in particular rules on the movement of animals liable to be affected or contaminated by a given disease and the regular inspection of the holdings or areas concerned

A short description of the control procedures and in particular rules on the movement of animals liable to be affected or contaminated by a given disease and the regular inspection of the holdings or areas is provided

(max. 32000 chars):

The Law of the veterinary activity requires the operators of hatcheries and the keepers of breeding flocks to keep records of poultry or hatching eggs entering or leaving the premises. The records must contain information on the number, date, and origin or destination.

These records must be available to the Competent Authority for inspection.

All official veterinary health certificates issued for the export of poultry and hatching eggs are recorded on the Trade Control and Expert System (TRACES).

This system allows tracking of exports of live animals and hatching eggs accompanied by veterinary health certification.

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### 4.4.7 Measures and applicable legislation as regards the control (testing, vaccination, ...) of the disease

National legislation relevant to the implementation of the programmes, including any national provisions concerning the activities set out in the programme.

#### (max. 32000 chars):

In Republic of Bulgaria 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.

Antimicrobial treatment may not be used for the control of Salmonella in the national control programme except within the limits set by Commission Regulation (EC) No. 1177/2006

### 4.4.8 Measures and applicable legislation as regards the compensation for owners of slaughtered and killed animals

Any financial assistance provided to food and feed businesses in the context of the programme.

#### (max. 32000 chars):

The 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 (Adopted by CoM decree No. 181 of 21.07.2006, publicised in the State gazette (SG), Issue No. 62 of 01.08.2006, in effect since the day of publicising).

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

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compensation costs or any financial assistance for food and feed busines 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.

## 4.4.9 Information and assessment on bio-security measures management and infrastructure in place in the flocks/holdings involved

(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 bio-security measures in industrial poultry farms, small farms, and private backyards are in accordance to the manual of Bio-security measures, issued by USAID Bulgaria and with the EC requirements.

Bio-security measures on holdings:

Health status 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

Rodent, insect and bird control

Cleaning and disinfecting of buildings

Recording of all events and operations

For each buildings must be applied self instruments

The verification of the bio- security measures or verification of disinfection has to be performed by Competent Authority. The relevant instructions and checklists are available and published on the following web-link:

http://babh.government.bg/bg/actualno-department-health&article\_id=108.html

### 5. General description of the costs and benefits of the programme

A description is provided of all costs for the authorities and society and the benefits for farmers and society in general

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(max. 32000 chars):

The financing of the 2014 Salmonella control programme shall be financed through the budget of the BFSA.

The necessary funds for compensation of the owners of the dead or killed in the context of the execution of this programme as well as the necessary financing for control and eradication measures in case of Salmonella outbreaks are provided by the state budget. The order and the conditions for providing the compensations are specified in Ordinance of the Council of Ministers of Republic of Bulgaria published by term of Art.109 of the LVA...

The benefits of the programme:

- Reducing the risk of spreading Salmonella within the European Union;
- Protecting the human health

Standard requirement for the submission of programme for eradication, control and monitoring	
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6. Data on the epidemiological evolution during the last five years	
Data already submitted via the online system for the years 2008 - 2011 : yes	
The data on the evolution of zoonotic salmonellosis are provided according to the tables where appropriate	
6.1 Evolution of the zoonotic salmonellosis	
6.1.1 Data on evolution of zoonotic salmonellosis for year: 2012	
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Region	Type of flock (d)	of flocks		flocks under the	Total number of animals under the programme	Number of flocks checked (b)	Serotype	Number of positive flocks (c)			( eggs	eggs	( eggs channelle d to egg		
Republic of Bulgaria	Breeding flocks o	208	1 696 5	208	1 696 52:	208	all relevant types of Salm	1	0	0	kg	0	kg	0	х
Total								1	0	0					
	•	•										ADD /	A NEW	/ ROW	

- (a) Including eligible and non eligible flocks for the programme
- (b) Check means to perform a flock level test under the porgramme for the presence of salmonella. In this column a flock must not be counted twice even if it has been checked more than one.
- (c) If a flock has been checked, in accordance with footnote (b), more then once, a positive sample must be taken into account only once.
- (d) Flocks or herds or as appropriate

### 6.2 Stratified data on surveillance and laboratory tests

### 6.2.1 Stratified data on surveillance and laboratory tests for year:

Region Test Type	Test Description	Number of samples tested	Number of positive samples	
------------------	------------------	--------------------------	----------------------------	--

2012

Republic of Bulgaria	microbiological test	feacal samples	617	1	Х
Republic of Bulgaria	other test	isolates	5	5	х
Total			622	6	
			ADD A NEW ROW		

### 6.3 Data on infection for year: 2012

Region	Number of herds infected	Number of animals infected	
Republic of Bulgaria	1	4 000	X
Total	1	4 000	
		Add a new row	

### 6.4 Data on vaccination or treatment programmes for year: 2012

Region	Total number of herds	Total number of animals		vaccinated or	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	
Republic of Bulgaria	208	1 696 523	51	51	239 400	363 800	х
Total	208	1 696 523	51	51	239 400	363 800	

Standard requirement for	the submission of progi	ramme for eradication,	control and monitoring
version: 2.3			

					Add a new row	
--	--	--	--	--	---------------	--

- 7. Targets
- 7.1 Targets related to testing

#### 7.1.1 Targets on diagnostic tests for year:

2014

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

Region	Type of the test (description)	Target population (categories and species targeted)	Type of sample	Objective	Number of planned tests				
Republic of Bulgaria	BACTERIOLOGICAL DETECTION TEST IN FRAME	Breeding flocks of Gallus gallus	Faeces	surveillance	650	x			
Republic of Bulgaria	SEROTYPING IN THE FRAME OF OFFICIAL SAMPL	Breeding flocks of Gallus gallus	isolates	surveillance	30	х			
	Total								
				Total AMR/BIH tests	0				
	Total BACTERIOLOG	SICAL DETECTION T	EST IN FRAME	OF OFFICIAL SAMPLING	650				
	Total SEROTYPING IN THE FRAME OF OFFICIAL SAMPLING								
Add a new row									

#### 7.1.2 Targets on testing of flocks for year:

2014

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

Region	Type of flock (d)	Total number of flocks (a)	Total number of animals	herds under the	Total number of animals under the programme	Number of flocks checked (b)	Serotype	Number of positive flocks (c)	Number of flocks depopulated	Total number of animals slaughtered or destroyed	Quantity of eggs destroyed (number)	Quantity of eggs channelled to egg product (number)	
Republic of Bulgaria	Breeding flocks	208	1 696 523	208	1 696 523	208	all relevant types of §	1	1	7 500	7 000	0	Х
Total		208	1 696 523	208	1 696 523	208		1	1	7.500	7,000	0	
										Add a new row			

- (a) Including eligible and non eligible flocks for the programme
- (b) Check means to perform a flock level test under the porgramme for the presence of salmonella. In this column a flock must not be counted twice even if it has been checked more than one.
- (c) If a flock has been checked, in accordance with footnote (b), more then once, a positive sample must be taken into account only once.
- (d) Flocks or herds or as appropriate

#### 7.2 Targets on vaccination or treatment

#### 7.2.1 Targets on vaccination or treatment for year:

2014

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

			Tarç	gets on vaccination o	treatment program	mme	
NUTS Region	Total number of herds in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Number of herds or flocks in vaccination or treatment programme	Number of herds or flocks expected to be vaccinated or treated	expected to be	Number of doses of vaccine or treatment expected to be administered	
Republic of Bulgaria	0	0	0	0	0	0	X
Total	0	0	0	0	0	0	
					Add a new row		

### 8. Detailed analysis of the cost of the programme for year: 2014

In case of multiannual programme, please provide an estimation on annual basis.

If your cost estimations differ between different implementation years please provide separate tables per year in attachment.

1. Testing						
Cost related to	<u>Specification</u>	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Cost of analysis	BACTERIOLOGICAL DETECTION TEST IN FRAME (	650	4	2600	yes	x
Cost of analysis	BACTERIOLOGICAL DETECTION TEST IN FRAME (	30 5		150	yes	X
				Add a	new row	
2. Vaccination (if you ask cofinancing f	or purchase of vaccins, you should also	fill in 6.4 and 7.2)				
Cost related to	<u>Specification</u>	Number of vaccine dosis	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Vaccination	Purchase of vaccine doses	0	0	0	no	X
				Add a	new row	
3. Slaughter and destruction (without a	ny salaries)					
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Slaughter and destruction	Compensation of animals	7 500	4	30000	yes	X
Slaughter and destruction	Compensation for the destruction of hatching eggs	7 000 0.2		1400	yes	X
				Add a	new row	

4.Cleaning and disinfection						
Cost related to	<u>Specification</u>	Number of units Unitary cost in EUR		Total amount in EUR	Union funding requested	
CLEANING/DESINFECTION	Test for verification of the efficiency of desinfection	30	5	150	yes	X
				Add a	new row	
5. Salaries (staff contracted for the pro-	gramme only)					
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
				Add a	new row	
6. Consumables and specific equipmer	nt					
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
				Add a new row		
7.Other costs						
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Other costs	collection and transport of samples	650 1		1 650 yes		X
				Add a	new row	
8. Cost of official sampling						
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Cost of official sampling	Cost of official sampling	650	0.5	325	yes	X
				Add a	new row	
	Total	2 010		3875		

#### **Attachments**

#### **IMPORTANT**:

- 1) The more files you attach, the longer it takes to upload them.
  2) This attachment files should have one of the format listed here: jpg, jpeg, tiff, tif, xls, doc, bmp, pna, pdf.
- 3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.

  4) IT CAN TAKE SEVERAL MINUTES TO UPLOAD ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!

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#### PROGRAMME for ERADICATION:

#### ANNEX II - PART A + B

Member States seeking a financial contribution from the Community for national programmes for the control and monitoring of salmonellosis (zoonotic salmonella), shall submit applications containing at least the information set out in this form.

The central data base keeps all submissions. However only the information in the last submission is shown when viewing and used when processing the data.

If encountering difficulties, please contact SANCO-BO@ec.europa.eu

Instructions to complete the form:

1) In order to fill in and submit this form you must have <u>at least</u> the ADOBE version

### Acrobat Reader 8.1.3

(example: 8.1.3, 8.1.4, 8.1.7, 9.1, 9.2,...), otherwise you will not be able to use the form.

Your version of Acrobat Reader is: 10.104

- 2) Please provide as much information as possible. If you have no data for some fields then put the text "NA" (Not applicable) in this field or 0 if it is a numeric field. If you need clarifications on some of the information requested, then please contact <a href="mailto:SANCO-BO@ec.europa.eu">SANCO-BO@ec.europa.eu</a>.
- 3) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page. If the form is not properly and completely filled in, an alert box will appear indicating the number of incorrect fields. Please use the "verify form" button untill all fields are correctly filled in. It is mandatory to fill in the box about Animal populations to make the rest of the questions visible. If you still have any difficulties, please contact SANCO-BO@ec.europa.eu.
- 4) When you have finished filling the form, verify that your internet connection is active and then click on the "submit notification" button below. If the form is properly filled in, the notification will be submitted to the server and a submission number + submission date will appear in the corresponding field.
- 5) IMPORTANT: Regularly save the pdf when you fill it out. After you have received the Submission number, DO NOT FORGET TO SAVE THE PDF ON YOUR COMPUTER FOR YOUR RECORDS!

Monday, April 29, 2013 12:07:34

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#### ANNEX II - PART A

#### General requirements for the national salmonella control programmes

Member state: BULGARIA

### (a) State the aim of the programme

(max. 32000 chars):

The target of the Program is:

- 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.

## (b) Animal population and phases of production which sampling must cover

Demonstrate the evidence that it complies with the minimum sampling requirements laid down in part B of Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council OJ L 325, 12.12.2003, p. 1. indicating the relevant animal population and phases of production which sampling must cover

It is mandatory to fill in the box about Animal populations to make the rest of the questions visible.

Animal population Laying flocks of Gallus gallus

pullets two weeks before moving to laying phase or unit

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#### (c) Specific requirements

Demonstrate the evidence that it complies with the specific requirements laid down in Parts C, D and E of Annex II to Regulation (EC) No 2160/2003

#### (max. 32000 chars):

Control measures and notification of positive results

In case of suspicion or conformation of Salmonella enteritidis or Salmonella In case of suspicion or conformation of Salmonella enteritidis or Salmonella typhimurium the NRL shall notify immediately the BFSA.

When a layer flock of Gallus gallus is suspected of being infected with Salmonella Enteritidis or Salmonella Typhimurium the flock will be investigated. The flock is suspected of being infected when S. Enteritidis or S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i) is isolated from a sample of faeces, boot swabs, tissue or organs from the birds in the flock, or from dust in the environment. This applies to layer flocks from day old through to end of production. In the cases of suspicion of infection the following measures shall be taken by the CA:

- prohibition of the bird and egg movement. The owner of the flock shall ensure that no eggs, poultry or poultry meat are moved from the premises where the flock is located.
- epidemiological investigations
- sampling all other flocks within the holding according to the sampling protocol as defined in Annex 2.2.2 in Commission Regulation (EC) No 517/2011 (two pairs of boot swabs per house (or equivalent faeces samples) plus one dust sample of at least 100 g (or equivalent faeces or boot swabs if dust is not available)
- checks the records keeping at the farms and bio-security measures,
- feed and water sampling,
- traceability of production 10-15 days back. All production on the market shall be placed under restrictive measures as far as possibly.

The Competent Authority takes samples for official control according to the sampling protocol as defined in Commission Regulation (EC) No 517/2011 (two pairs of boot swabs per house (or equivalent faeces samples) plus one dust sample of at least 100 g (or equivalent faeces or boot swabs if dust is not available)).

For the purposes of establishing the progress towards the target if S. Enteritidis or S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i) is isolated from any samples (feaces/dust samples; official/FBO sampling) the flock is classed as positive.

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

1. 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.

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- 2. 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
- 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:
- (a) 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;
- (b) 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;
- (c) prohibited access to packaging centres unless the competent authority is satisfied with the measures to prevent possible cross-contamination of eggs from other flocks.
- 3. 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.
- 4.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 by taking appropriate samples and having them analysed for the presence of Salmonella. Re-stocking may not take place until the cleaning and disinfection has been carried out and representative samples taken from the house after cleaning and disinfection have been shown to be negative for S. Enteritidis and S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i)).
- In order to exclude false-positive initial results, the competent authority may lift the restrictions mentioned above:
- (a) when the flock of layers is not the source of infection for humans by the consumption of eggs or egg products as a result of the epidemiological investigation of food-borne outbreaks in accordance with Article 8 of Directive 2003/99/EC;

and

- (b) where the flock is subjected to the national control programme and Salmonella serotypes for which a target for reduction has been set, is not confirmed by the following sampling protocol carried out by the competent authority:
- -7 samples (feaces and dust sample, which have to be tested separately) 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
- caecae and oviducts from 300 birds in the flock selected under supervision of the Competent Authority, or
- 4000 eggs

In addition to the sampling in point (b), the CA shall verify the absence of the use of antimicrobials, potentially affecting the result of the analyses of the sampling.

Confirmatory sampling may be carried out after FBO positive result as the official veterinarian shall use the sampling protocol in accordance with Annex II part D point 4 of Regulation 2160/2003. The

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confirmation sampling may be carried out in exceptional cases (in accordance with Annex II part D point 4 of Regulation 2160/2003), it is not implemented routinely after every FBO positive result.

### (d) Specification of the following points:

#### (d)1. General

## (d) 1.1 A short summary referring to the occurrence of Salmonellosis (Zoonotic Salmonella)

A short summary referring to the occurrence of the salmonellosis [zoonotic salmonella] in the Member State with specific reference to the results obtained in the framework of monitoring in accordance with Article 4 of Directive 2003/99/EC of the European Parliament and of the Council OJ L 325, 12.12.2003, p. 31., particularly highlighting the prevalence values of the salmonella serovars targeted in the salmonella control programmes.

#### (max. 32000 chars):

In Republic of Bulgaria the Salmonella Control National Programme in laying hens has been in operation since 2008 and approved by Commission Decision 2007/873/EO

The number of flocks with laying hens positive for Salmonella spp in total is as follow:

In 2008 – 2 flocks positive for S.Enteritidis

In 2009 – 2 flocks positive for S.Enteritidis, 1flock Salmonella Abovy, 1- Salmonella Corvallis, 1- S.

Agona ,1-S.Virchov

In 2010 - 2 flocks S.Enteritidis, 6 - S. Infantis, 1 - S Parkroyal

In 2011 – 4 flocks positive S.Enteritidis, 2-S. Agona, 1-S. Hadar, 3 - S. Kottbus, 4- S. Bareilly, 1-S. infantis.

In 2012 - 1 flock positive for S.Entereditis and 1 flock positive for S. Typhimurium.

In conclusion S. Enteritidis remains the most commonly isolated Salmonella serotype.

The % Salmonella positive flock's prevalence for the Salmonella target serotypes included in the program decreased in 2012 to 0.67% compared with the data in 2011. The target of the SCNP in laying flocks was achieved in 2012, namely a 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/EC.

## (d) 1.2 The structure and organization of the relevant competent authorities.

Please refer to the information flow between bodies involved in the implementation of the programme.

#### (max. 32000 chars) :

Bulgarian Food Safety Agency (BFSA) is the competent authorities for control of Salmonella and their zoonotic agents.

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-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 analyse 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 containing the data referred to in points 3-6.

-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 analyse 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 1-6 to Directorate "Animal health and welfare" at BFSA.

The municipal veterinarian has the following responsibilities:

- 1. To control and to implement the programme for surveillance of salmonella in the relevant municipality.
- 2. To control the sampling of laying hens and the sending of samples to the laboratories.
- 3. To collect and analyse the data on the poultry tested for salmonella in the veterinary units located on the territory of the relevant municipality.
- 4. To summarize the data on positive animals from the veterinary units located on the territory of the relevant municipality.
- 5. To summarize the data on the salmonella surveillance costs incurred by the relevant municipality.
- 6. To keep a register in the database of all holdings with laying hens
- 7. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health" at the relevant RFSD.

## (d) 1.3 Approved laboratories where samples collected within the programme are analysed.

(max. 32000 chars):

The samples collected within the National Control Programme are analysed by laboratories accredited for that purpose, designated and approved by BFSA.

As by 31.01.2012 accredited laboratories for Salmonellosis diagnostics are:

A. within the BFSA system:

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- 1. National Reference Laboratory for Salmonellosis diagnostics, Sofia (NRL);
- 2. the "Laboratory for bacterial diseases in poultry" at the National Diagnostic and Research Veterinary Institute, Sofia;
- 3. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Shumen;
- 4. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Blagoevgrad;
- 5. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Varna;
- 6. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Vratsa;
- 7. the testing "Laboratory Diagnostic Control" (LDC) Laboratory at the "Animal Health" (AH) Department with the Regional Food Safety Department (RFSD) of Haskovo
- B. Private laboratories:
- 1. the "Laboratory for testing food, feed and biological materials" "Regional Veterinary Station Ruse" SP Ltd.

Any positive isolates obtained within the tests performed therein must be sent for confirmation and typing in the:

National Reference Laboratory (NRL) for Salmonellosis diagnostics at the National Diagnostic and Research Veterinary Institute (within BFSA), 1606 Sofia, # 15 "Pencho Slaveikov" blvd.; ph. No. (00359 2) 952 3903.

Any results shall be considered as valid only if compliance with the requirements for testing demonstrated with the Commission Regulation (EC) No. 517/2011.

The official control samples shall be tested by the accredited laboratories listed in point A (state laboratories). The own-check samples could be tested by the accredited laboratories for detecting of Salmonella listed in point A and B (private or state laboratories).

All laboratories involved in the programme must participate in proficiency tests. The NRL has to participates regularly in proficiency tests (serotyping and Salmonella isolation) organised by the EU Reference Laboratory (EURL) for Salmonella. The NRL is responsible for training and organisation of proficiency tests for Salmonella isolation for other laboratories involved in the National Control Programme.

## (d) 1.4 Methods used in the examination of the samples in the framework of the programme.

(max. 32000 chars):

The method recommended by the Community Reference Laboratory for salmonella in Bilthoven, Netherlands shall be used: the method is a modification of ISO 6579 (2002) where a semi-solid medium (MSRV) is used as the single selective enrichment medium. The semi-solid medium should be incubated

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at 41.5 +/- 1°C for 2 x (24 +/-3) hours.

As regards the boot swab samples and other feacal material samples, referred to in paragraph 3.1, it is possible to pool incubated BPW enrichment broth for future culture. To do that, incubate both samples in BPW as normal. Take 1 ml of incubated broth from each sample and mix thoroughly, then take 0,1 ml of the mixture and inoculate the MSRV plates in the usual way.

## (d) 1.5 Official controls (including sampling schemes) at feed, flock and/or herd level.

(max. 32000 chars):

Official sampling at flock level:

Official sampling shall be carried out according to the sampling scheme of the Annex of the Regulation (EC) No. 517/2011.

Please see Part B, point 4.4.6

Official sampling on the feed stuffs from poultry:

Bulgarian Food Safety Agency performs sampling of feed stuffs as follow:

- 1. feed sampling done at producers of feed raw materials and wholesale traders in feed raw materials in bulk:
- 2. feed sampling done at farms.

The number of samples has been calculated on the basis of risk assessment in accordance with the provisions of Regulation 882/2004. This Plan involves also a minimum number of Salmonella samples taken from poultry feed consignments imported from third countries.

There have not been any positive results identified concerning this indicator.

If a positive result is to be identified, the measures and actions to be undertaken are pursuant to the provision of Article 396, Paragraph 2, Item 5 of the LVA.

Official control at the other stages of the food chain:

According to the National legislation (Law of veterinary activity and Food law) the establishments for production, storage and trade of animal products have to be approved registered by BFSA and entered into the national electronic database. The public registers of approved establishments are kept in the RFSDs and the BFSA.

The official inspections in establishments for production, storage, and trade of animal products are carried out by the official veterinarians at the BFSA/RFSD.

The official inspections in the establishments for production, storage and trade with food are carried out in accordance with the Regulation 882/2004 of the European Parliament and the Council Regulation 854/2004 of the European Parliament and the Council, laying down the specific rules for the organisation of official controls on products of animal origin intended for human consumption. The number of

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samples has been calculated by the official veterinarians on the basis of risk assessment and the type and quality of the materials included in the food processing and the results of the previous inspections. The samples from foods of poultry origin shall be taken and preceded as provided in Regulation 2073/2005. The frequency of sample taking could be increased and decreased on the basis of the results of the sample testing.

Annually the Regional Food Safety Directorates (RFSDs) draft a schedule for the number of inspections in the controlled establishments for production, storage, and trade of animal products.

The structure of the production of food:

Production, storage and trade with food of animal origin are carried out in:

- producing establishments
- establishments for hall -sailed
- establishments for retailed with food of animal origin
- restaurants

#### (d)2. Food and business covered by the programme

## (d)2.1 The structure of the production of the given species and products thereof.

(max. 32000 chars):

Totally there are 119 holdings with laying hens / 327 flocks / 2 779 951 laying hens in the country(data as by the end of 2012);

### (d)2.2 Structure of the production of feed

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(max. 32000 c	chars) :
n/a	
(d)2.3	Relevant guidelines for good animal husbandry practices or other guidelines (mandatory or voluntary) on biosecurity measures defining at least
(d)2.3.1	Hygiene management at farms
to approval I In the past se protection of country and measures ne The major po the hygien themeasur at farms, and	re obligated to have their individual Guidelines for good farmer practices, which are subject by the official veterinarian responsible for the control of the holding concerned. Everal informative brochures titled: "How to protect our poultry?; "Six requirements for f your poultry" and were distributed to all the 28 Regional Food Safety Directorates of the have been provided to the owners of all poultry holdings. This brochure lays down all the eded to protect poultry against infection. Dint for good farmer practices that should be follow by the farmers are concern to: the management at farms, ses to prevent incoming infections carried by animals, feed, drinking water, people working
(d)2.3.2	Measures to prevent incoming infections carried by animals, feed, drinking water, people working at farms
please see po	•

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#### (d)2.3.3 Hygiene in transporting animals to and from farms

(max. 32000 chars) :		
please see point 2.3.1		

### (d)2.4 Routine veterinary supervision of farms

(max. 32000 chars) :

Every year the 28th RFSDs on the base of risk assessment present plans for controls of poultry farms within the respective region. Those plans are annually approved by the BFSA.

To consider an inspection on farms as an official control in the frame of the salmonella control programme, the official veterinarian on behalf of the Competent Authority shall take official samples for detecting of Salmonella

### (d)2.5 Registration of farms

(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:

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- 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

### (d)2.6 Record keeping at farm

(max. 32000 chars) :

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

Each animal holding shall keep records with information provides details of sampling for Salmonella and the results. The records are kept at the farms and the owners are requested to made available them in case of official control. When a farm is inspected by an official veterinarian, the latter has also to perform a thorough check of all the records /logbooks kept in respective holding.

### (d)2.7 Documents to accompany animals when dispatched

(max. 32000 chars):

During transport the live birds shall be accompanied with transport authorization, issued by the BFSA, according to the Council Regulation 1/2005 on the protection of animals during transport.

Operators wishing to export more than 20 birds or hatching eggs to another EU member state (or certain third countries) must comply with EU Directive 90/539/EC and ensure that the consignment is accompanied by a completed and signed Intra-trade Animal Health Certificate (ITAHC).

The ITAHC will also require the reference number of the operator's poultry health certificate. Animal health certificate has to be issued by the veterinarian servicing the farm of origin and completed on a pre-printed model form after an appropriate clinical examination performed by this veterinarian.

All official veterinary health certificates issued for the export of poultry and hatching eggs are recorded on the Trade Control and Expert System (TRACES). This system allows tracking of exports of live animals

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and hatching eggs accompanied by veterinary health certification. The TRACES generates ITAHCs issued for intra-Community movements. A TRACE is an internet-based service which is owned and maintained by the Commission.

#### (d)2.8 Other relevant measures to ensure the tracebility of animals

(max. 32000 chars):

Each consignment of laying hens intended for slaughtering or to other holding must be accompanied by information delivered by the veterinarian of the place of forwarding the consignment to the official veterinarian of their place of their destination.

The operators shall keep records of poultry and eggs entering or leaving the premises. The records must contain information on the number of animals, date, and origin or destination. These records must be retained for three years period and be available to the Competent Authority for inspection.

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#### ANNEX II - PART B

#### 1. Identification of the programme

Animal population: Laying flocks of Gallus gallus

Request of Union co-financing for the period:

To 2014

#### 1.1 Contact

Name: d-r Aleksandra Miteva

Phone: +35929159842

Fax.: +35929159842

Email: a\_miteva@nvms.government.bg

### 2. Historical data on the epidemiological evolution of the disease

A concise description is given with data on the target population (species, number of herds and animals present and under the programme), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables, graphs or maps.

(max. 32000 chars) :

In Republic of Bulgaria the Salmonella Control National Programme in laying hens has been in operation since 2008 and approved by Commission Decision 2007/873/EO

The number of flocks with laying hens positive for Salmonella spp in total is as follow:

In 2008 – 2 flocks positive for S.Enteritidis

In 2009 – 2 flocks positive for S.Enteritidis, 1flock Salmonella Abovy, 1- Salmonella Corvallis, 1- S.

Agona ,1-S.Virchov

In 2010 - 2 flocks S.Enteritidis, 6 - S. Infantis, 1 - S Parkroyal

In 2011 – 4 flocks positive S.Enteritidis, 2-S. Agona, 1-S. Hadar, 3 - S. Kottbus, 4- S. Bareilly, 1-S. infantis.

In 2012 - 1 flock positive for S.Entereditis and 1 flock positive for S. Typhimurium.

In conclusion S. Enteritidis remains the most commonly isolated Salmonella serotype.

The % Salmonella positive flock's prevalence for the Salmonella target serotypes included in the

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program decreased in 2012 to 0.67% compared with the data in 2011. The target of the SCNP in laying flocks was achieved in 2012, namely a 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/EC.

### 3. Description of the submitted programme

A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals, vaccination), the target animal population and the area(s) of implementation and the definition of a positive case.

(max. 32000 chars) :

#### IThe target of the Program is:

- 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.

#### 4. Measures of the submitted programme

Measures taken by the competent authorities with regard to animals or products in which the presence of Salmonella spp. have been detected, in particular to protect public health, and any preventive measures taken, such as vaccination.

(max. 32000 chars):

The measures taken by the competent authorities with regard to animals or products in which the presence of Salmonella spp. have been detected, in particular to protect public health, and any preventive measures taken, such as vaccination are described into the relevant veterinary legislation: -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

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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

-ORDINANCE 9/28.01.2006 on the monitoring of zoonoses in their prevention, limitation and eradication (Published in SG 15/17.02.2006), transposing DIRECTIVE 2003/99/EC 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

#### 4.1 Summary of measures under the programme

Period of implementation of the programme: 2014
Measures
∑ Control
▼ Testing
⊠ Slaughter of animals tested positive
Vaccination
∑ Treatment of animal products
☑ Disposal of products
Monitoring or surveillance
Other, please specify

### 4.2 Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Descrive the responsabilities of all involved.

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#### (max. 32000 chars):

Bulgarian Food Safety Agency (BFSA) is the competent authorities for control of Salmonella and their zoonotic agents.

- 4.2.1 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 analyse 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 containing the data referred to in points 3-6.
- 4.2.2 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 analyse 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 1-6 to Directorate "Animal health and welfare" at BFSA.

The municipal veterinarian has the following responsibilities:

- 1. To control and to implement the programme for surveillance of salmonella in the relevant municipality.
- 2. To control the sampling of laying hens and the sending of samples to the laboratories.
- 3. To collect and analyse the data on the poultry tested for salmonella in the veterinary units located on the territory of the relevant municipality.
- 4. To summarize the data on positive animals from the veterinary units located on the territory of the relevant municipality.
- 5. To summarize the data on the salmonella surveillance costs incurred by the relevant municipality.
- 6. To keep a register in the database of all holdings with laying hens
- 7. To send annual reports containing the data referred to in points 1-6 to Directorate "Animal health" at the relevant RFSD.

### 4.3 Description and delimitation of the geographical and administrative areas in which the programme is to be implemented

Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

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(max. 32000 char	s)	:
------------------	----	---

The programme shall be implemented on the territory of the whole country comprising 28 districts

#### 4.4 Measures implemented under the programme

Where appropriate Community legislation is mentioned. Otherwise the national legislation is mentioned.

#### 4.4.1 Measures and applicable legislation as regards the registration of holdings

#### (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 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;

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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.

### 4.4.2 Measures and applicable legislation as regards the identification of animals

Not applicable for poultry

(max. 32000 chars):

n/a

## 4.4.3 Measures and applicable legislation as regards the notification of the disease

(max. 32000 chars):

The Law on Veterinary Activities, Art.124 and Ordinance No.23 / 14.12.2005 on the order and the way of notification and registration of infectious diseases in animals, which is harmonized with Council Directive 82/894/EEC.

## 4.4.4 Measures and applicable legislation as regards the measures in case of a positive result

A short description is provided of the measures as regards positive animals (slaughter, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter

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(max. 32000 chars):

Control measures and notification of positive results

In case of suspicion or conformation of Salmonella enteritidis or Salmonella In case of suspicion or conformation of Salmonella enteritidis or Salmonella typhimurium the NRL shall notify immediately the BFSA.

When a layer flock of Gallus gallus is suspected of being infected with Salmonella Enteritidis or Salmonella Typhimurium the flock will be investigated. The flock is suspected of being infected when S. Enteritidis or S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i) is isolated from a sample of faeces, boot swabs, tissue or organs from the birds in the flock, or from dust in the environment. This applies to layer flocks from day old through to end of production. In the cases of suspicion of infection the following measures shall be taken by the CA:

- prohibition of the bird and egg movement. The owner of the flock shall ensure that no eggs, poultry or poultry meat are moved from the premises where the flock is located.
- epidemiological investigations
- sampling all other flocks within the holding according to the sampling protocol as defined in Annex 2.2.2 in Commission Regulation (EC) No 517/2011 (two pairs of boot swabs per house (or equivalent faeces samples) plus one dust sample of at least 100 g (or equivalent faeces or boot swabs if dust is not available))
- checks the records keeping at the farms and bio-security measures,
- feed and water sampling,
- traceability of production 10-15 days back. All production on the market shall be placed under restrictive measures as far as possibly.

The Competent Authority takes samples for official control according to the sampling protocol as defined in Commission Regulation (EC) No 517/2011 (two pairs of boot swabs per house (or equivalent faeces samples) plus one dust sample of at least 100 g (or equivalent faeces or boot swabs if dust is not available)).

For the purposes of establishing the progress towards the target if S. Enteritidis or S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i) is isolated from any samples (feaces/dust samples; official/FBO sampling) the flock is classed as positive.

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

- 1. 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.
- 2. 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:

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- (a) 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;
- (b) 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;
- (c) prohibited access to packaging centres unless the competent authority is satisfied with the measures to prevent possible cross-contamination of eggs from other flocks.
- 3. 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.
- 4.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 by taking appropriate samples and having them analysed for the presence of Salmonella. Re-stocking may not take place until the cleaning and disinfection has been carried out and representative samples taken from the house after cleaning and disinfection have been shown to be negative for S. Enteritidis and S. Typhimurium (including monophasic S. Typhimurium serotypes with antigenic formula 1,4,/5/,1 2:i)).

In order to exclude false-positive initial results, the competent authority may lift the restrictions mentioned above:

(a) when the flock of layers is not the source of infection for humans by the consumption of eggs or egg products as a result of the epidemiological investigation of food-borne outbreaks in accordance with Article 8 of Directive 2003/99/EC;

and

- (b) where the flock is subjected to the national control programme and Salmonella serotypes for which a target for reduction has been set, is not confirmed by the following sampling protocol carried out by the competent authority:
- -7 samples (feaces and dust sample, which have to be tested separately) 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
- caecae and oviducts from 300 birds in the flock selected under supervision of the Competent Authority,
   or
- 4000 eggs

In addition to the sampling in point (b), the CA shall verify the absence of the use of antimicrobials, potentially affecting the result of the analyses of the sampling.

Confirmatory sampling may be carried out after FBO positive result as the official veterinarian shall use the sampling protocol in accordance with Annex II part D point 4 of Regulation 2160/2003. The confirmation sampling may be carried out in exceptional cases (in accordance with Annex II part D point 4 of Regulation 2160/2003), it is not implemented routinely after every FBO positive result.

4.4.5 Measures and applicable legislation as regards the different qualifications of animals and herds

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	x. 32000 chars) :
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# 4.4.6 Control procedures and in particular rules on the movement of animals liable to be affected or contaminated by a given disease and the regular inspection of the holdings or areas concerned

A short description of the control procedures and in particular rules on the movement of animals liable to be affected or contaminated by a given disease and the regular inspection of the holdings or areas is provided

#### (max. 32000 chars):

The Law of the veterinary activity requires the operators to keep records of poultry entering or leaving the premises. The records must contain information on the number, date, and origin or destination. These records must be available to the Competent Authority for inspection.

All official veterinary health certificates issued for the export of poultry and hatching eggs are recorded on the Trade Control and Expert System (TRACES).

This system allows tracking of exports of live animals and hatching eggs accompanied by veterinary health certification.

## 4.4.7 Measures and applicable legislation as regards the control (testing, vaccination, ...) of the disease

National legislation relevant to the implementation of the programmes, including any national provisions concerning the activities set out in the programme.

#### (max. 32000 chars):

In Republic of Bulgaria 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.

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

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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.

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. If the flock is under antimicrobial medication for animal health or animal welfare reasons the flock will be sampled again after the period of withdrawal for the product given in its Marketing Authorisation. Flock owners are required to keep records of antimicrobial use and to make these records available.

### 4.4.8 Measures and applicable legislation as regards the compensation for owners of slaughtered and killed animals

Any financial assistance provided to food and feed businesses in the context of the programme.

#### (max. 32000 chars):

The 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 (Adopted by CoM decree No. 181 of 21.07.2006, publicised in the State gazette (SG), Issue No. 62 of 01.08.2006, in effect since the day of publicising).

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 busines 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.

### 4.4.9 Information and assessment on bio-security measures management and infrastructure in place in the flocks/holdings involved

#### (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 bio-security measures in industrial poultry farms, small farms and private backyards are in accordance to the manual of Bio- security measures, issued by USAID Bulgaria and with the EC requirements.

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#### Bio-security measures on holdings:

Health status 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

Rodent, insect and bird control

Cleaning and disinfecting of buildings

Recording of all events and operations

For each buildings must be applied self instruments

The verification of the bio-security measures or verification of disinfection has to be performed by Competent Authority. The relevant instructions and checklists are available and published on the following web-link:

http://babh.government.bg/bg/actualno-department-health&article\_id=108.html

### 5. General description of the costs and benefits of the programme

A description is provided of all costs for the authorities and society and the benefits for farmers and society in general

(max. 32000 chars):

The financing of the 2014 Salmonella control programme shall be financed through the budget of the BFSA.

The necessary funds for compensation of the owners of the dead or killed in the context of the execution of this programme as well as the necessary financing for control and eradication measures in case of Salmonella outbreaks are provided by the state budget. The order and the conditions for providing the compensations are specified in Ordinance of the Council of Ministers of Republic of Bulgaria published by term of Art.109 of the LVA...

The benefits of the programme:

- Reducing the risk of spreading Salmonella within the European Union;
- Protecting the human health

Standard requirement for the submission of programme for eradication, control and monitoring	
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6. Data on the epidemiological evolution during the last five years	
Data already submitted via the online system for the years 2008 - 2011 : yes	
The data on the evolution of zoonotic salmonellosis are provided according to the tables where appropriate	
6.1 Evolution of the zoonotic salmonellosis	
6.1.1 Data on evolution of zoonotic salmonellosis for year: 2012	
$P_{\ell}$	age 25 of 35

Region		of flocks	Total number of animals	number of flocks	Total number of animals under the programme	Number of flocks checked (b)	Serotype	Number of positive flocks (c)	Number of flocks		( eggs	eggs	( eggs channelle d to egg	Quantity of eggs channelled to egg product	
Republic of Bulgaria	Laying flocks of G	305	3 231 3		297		salmonella enteritidis or	2	0	6 751	kg	0	kg	0	х
Total								2	0	6 751					
			•									ADD	A NEW	ROW	

- (a) Including eligible and non eligible flocks for the programme
- (b) Check means to perform a flock level test under the porgramme for the presence of salmonella. In this column a flock must not be counted twice even if it has been checked more than one.
- (c) If a flock has been checked, in accordance with footnote (b), more then once, a positive sample must be taken into account only once.
- (d) Flocks or herds or as appropriate

#### 6.2 Stratified data on surveillance and laboratory tests

#### 6.2.1 Stratified data on surveillance and laboratory tests for year:

			Number of samples	Number of positive	
Region	Test Type	Test Description	tested	samples	

2012

Republic of Bulgaria	microbiological test	fecal samples	473	2	Х
Republic of Bulgaria	microbiological test	isolates	9	9	х
Total			482	11	
			ADD A N	EW ROW	

#### 6.3 Data on infection for year: 2012

Region	Number of herds infected	Number of animals infected	
Republic of Bulgaria	2	6 751	X
Total	2	6 751	
		Add a new row	

#### 6.4 Data on vaccination or treatment programmes for year: 2012

Region	Total number of herds	Total number of animals		vaccinated or	Number of animals vaccinated or treated	Number of doses of vaccine or treatment administered	
Republic of Bulgaria	20	468 870	20	20	468 870	575 130	х
Total	20	468 870	20	20	468 870	575 130	

Standard requirement for the submission of programme for eradication,	control and monitoring
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					Add a new row	
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- 7. Targets
- 7.1 Targets related to testing

#### 7.1.1 Targets on diagnostic tests for year:

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

Region	Type of the test (description)	Target population (categories and species targeted)	Type of sample	Objective	Number of planned tests		
Republic of Bulgaria	BACTERIOLOGICAL DETECTION TEST IN FRAME	Laying flocks of Gallus gallus	Faeces	surveillance	500	X	
Republic of Bulgaria	BACTERIOLOGICAL DETECTION TEST IN FRAME	Laying flocks of Gallus gallus	isoaltes	surveillance	50	х	
				Total	550		
				Total AMR/BIH tests	0		
	Total BACTERIOLOG	SICAL DETECTION T	EST IN FRAME	OF OFFICIAL SAMPLING	550		
		Total SEROTYPING	IN THE FRAME	OF OFFICIAL SAMPLING	0		
Add a new re							

2014

#### 7.1.2 Targets on testing of flocks for year:

2014

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

Region	Type of flock (d)	Total number of flocks (a)	Total number of animals	herds under the	Total number of animals under the programme	Number of flocks checked (b)	Serotype	Number of positive flocks (c)	Number of flocks depopulated	Total number of animals slaughtered or destroyed	Quantity of eggs destroyed (number)	Quantity of eggs channelled to egg product (number)	
Republic of Bulgaria	Laying flocks of	305	3 231 308	305	3 231 308	297	salmonella enteritidi	2	2	15 000	25 000	0	Х
Total		305	3 231 308	305	3 231 308	297		2	2	15 000	25 000	0	
										Ad	d a new ro	ow	

- (a) Including eligible and non eligible flocks for the programme
- (b) Check means to perform a flock level test under the porgramme for the presence of salmonella. In this column a flock must not be counted twice even if it has been checked more than one.
- (c) If a flock has been checked, in accordance with footnote (b), more then once, a positive sample must be taken into account only once.
- (d) Flocks or herds or as appropriate

#### 7.2 Targets on vaccination or treatment

#### 7.2.1 Targets on vaccination or treatment for year:

2014

In case of multiannual programme, please provide an estimation on annual basis.

If your targets differ between different implementation years please provide separate tables per year in attachment.

			Targets on vaccination or treatment programme					
NUTS Region	Total number of herds in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Number of herds or flocks in vaccination or treatment programme	Number of herds or flocks expected to be vaccinated or treated	expected to be	Number of doses of vaccine or treatment expected to be administered		
Republic of Bulgaria	0	0	0	0	0	0	X	
Total	0	0	0	0	0	0		
					Add a			

### 8. Detailed analysis of the cost of the programme for year: 2014

In case of multiannual programme, please provide an estimation on annual basis.

If your cost estimations differ between different implementation years please provide separate tables per year in attachment.

1. Testing						
Cost related to	<u>Specification</u>	Number of tests	Number of tests Unitary cost in EUR		Union funding requested	
Cost of analysis	BACTERIOLOGICAL DETECTION TEST IN FRAME (	500 4		2000	yes	X
Cost of analysis	BACTERIOLOGICAL DETECTION TEST IN FRAME (	CTERIOLOGICAL DETECTION TEST IN FRAME C 50 5		250	yes	X
		Add a	new row			
2. Vaccination (if you ask cofinancing f	or purchase of vaccins, you should also	fill in 6.4 and 7.2)				
Cost related to	<u>Specification</u>	Number of vaccine dosis	cine dosis Unitary cost in EUR Total amount in EUR Union fun		Union funding requested	
Vaccination	Purchase of vaccine doses	0	0	0 no		
		Add a new row				
3. Slaughter and destruction (without a	ny salaries)					
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	
Slaughter and destruction	Compensation of animals	15 000	2	30000	yes	X
Slaughter and destruction	Costs from treatment of animal products (hatching eggs,.	25 000	0.04	1000	yes	x
	Add a	new row				

4.Cleaning and disinfection							
Cost related to	<u>Specification</u>	Number of units Unitary cost in		Total amount in EUR	Union funding requested		
CLEANING/DESINFECTION	Test for verification of the efficiency of desinfection	30 5		150 yes		X	
5. Salaries (staff contracted for the pro	gramme only)						
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested		
	Add a	new row					
6. Consumables and specific equipmer	nt						
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested		
		Add a new row					
7.Other costs							
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested		
Other costs	collection and transport of samples to the laboratory	500	1	500 yes			
		-		Add a	new row		
8. Cost of official sampling							
Cost related to	<u>Specification</u>	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested		
Cost of official sampling	Cost of official sampling Cost of official sampling		0.5	250	yes	X	
	Add a	new row					
	Total	1 580		3150			

#### **Attachments**

#### **IMPORTANT**:

- 1) The more files you attach, the longer it takes to upload them.
  2) This attachment files should have one of the format listed here: jpg, jpeg, tiff, tif, xls, doc, bmp, pna, pdf.
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