



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6734 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

UKRAINE

FROM 13 TO 17 MAY 2013

IN ORDER TO EVALUATE THE SALMONELLA NATIONAL CONTROL PROGRAMME FOR  
LAYING HENS

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office in Ukraine, from 13 to 17 May 2013.*

*The objective of this audit was to verify if the Salmonella national control programme for laying hens in place provides guarantees equivalent to those provided for in Regulation (EC) No 2160/2003, with a view to possibly admit Ukraine to the list of third countries from which Member States are authorised to import table eggs.*

*The report concludes that the Ukraine has a Salmonella National Control Programme for laying hens which is being implemented and under official supervision.*

*However there are some deficiencies related to the sampling frequency, record keeping and measures to exclude the possible use of antimicrobials.*

*Moreover laboratory results cannot be considered as fully reliable as laboratories at district level used for Salmonella testing are not accredited. Furthermore the analytical methods used are not within the scope of accreditation of the laboratories testing SNCP samples and alternative methods have not been validated against the EU/OIE reference method.*

*The Central Competent Authority acknowledged the deficiencies found and informed the audit team that immediate measures would be taken to rectify them.*

*The report addresses to the Ukrainian competent authorities a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.*

# Table of Contents

<b>1</b>	<b><u>INTRODUCTION</u></b> .....	<b>1</b>
<b>2</b>	<b><u>OBJECTIVES</u></b> .....	<b>1</b>
<b>3</b>	<b><u>LEGAL BASIS</u></b> .....	<b>1</b>
<b>4</b>	<b><u>BACKGROUND</u></b> .....	<b>2</b>
<b>5</b>	<b><u>FINDINGS AND CONCLUSIONS</u></b> .....	<b>2</b>
	5.1 <u>COMPETENT AUTHORITY</u> .....	2
	5.2 <u>CONTROLS AT FARM LEVEL</u> .....	3
	5.3 <u>SNCP FOR LAYING HENS</u> .....	5
	5.4 <u>LABORATORIES</u> .....	5
<b>6</b>	<b><u>OVERALL CONCLUSIONS</u></b> .....	<b>7</b>
<b>7</b>	<b><u>CLOSING MEETING</u></b> .....	<b>7</b>
<b>8</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>7</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>9</b>

#### ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
CA	Competent Authority
CCA	Central Competent Authority
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
NRL	National Reference Laboratory
OV	Official Veterinarian
SNCP	<i>Salmonella</i> National Control Programme

## 1 INTRODUCTION

This audit took place in Ukraine from 13 to 17 May 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme.

The audit team comprised one inspector from the FVO and one national expert. Representatives from the Competent Authority (CA) accompanied the audit team during the whole audit.

An opening meeting was held on 13 May 2013 with the Central CA (CCA), the State Department of Veterinary Medicine. At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for its satisfactory completion.

## 2 OBJECTIVES

The objective of this audit was to verify if the *Salmonella* national control programme (SNCP) for laying hens in place provides guarantees equivalent to those provided for in Regulation (EC) No 2160/2003, with a view to possibly admit Ukraine to the list of third countries from which Member States are authorised to import table eggs (Article 10(6) of Regulation (EC) No 2160/2003).

In order to achieve this objective the audit team evaluated the organisation of the CA, the controls performed at farm level, the implementation of the SNCP and the laboratory capacities.

The table below lists the sites visited and the meetings held in order to achieve the above objectives:

<b>Competent Authority</b>		
CCA	1	Opening and closing meeting.
Provincial CA	2	Documentation checked during visits in poultry farms.
<b>Laboratories</b>		
<i>Salmonella</i> National Reference Laboratory (NRL)	1	State Scientific Research Institute of Laboratory Diagnostic and Veterinary and Sanitary Expertise.
Official laboratory at provincial level	1	
<b>Primary production</b>		
Laying hen farms	2	

## 3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

EU legal acts quoted in this report are listed in Annex I and refer, where applicable, to the latest amended version.

## 4 BACKGROUND

As part of the procedure to admit Ukraine to the list of third countries from which Member States are authorised to import table eggs, the Ukrainian CA shall be in a position to attest the provisions reported on the veterinary certificate for eggs annexed to Regulation (EC) No 798/2008, in particular Part II.2.5 where it is indicated that the eggs shall fulfil the requirements in Article 10(6) of Regulation (EC) No 2160/2003, more precisely the implementation of a programme to reduce the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus*, as defined in Regulation (EU) No 517/2011.

A previous audit evaluating, among others, the implementation of SNCP for layers in Ukraine took place in 2009 (ref. DG (SANCO) 8334/2009) while the programme was in the early stages of implementation. One of the recommendations of this report concerned the *Salmonella* sampling (frequency and composition of samples) performed in laying hen farms. The report of this visit is published on the Health and Consumer Directorate – General Internet website: [http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=2293](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2293)

The Ukrainian SNCP for laying hens was approved by Order No 147 of the Chief Veterinary Officer dated 30 November 2009 and covers laying hen holdings comprising at least 1000 birds. This programme along with those for other poultry populations was sent for approval to Commission services and assessed by the SANCO zoonoses team which concluded that progress had been made compared with the draft programmes submitted earlier however there are still some concerns about the equivalency of provisions detailed under certain chapters.

According to the CA, there are currently 171 industrial size holdings of laying hens in Ukraine. In 2010 *Salmonella* Enteritidis was found in eight faecal samples in laying flocks. In 2011, for 88,700 samples taken (day-old chicks, faecal samples, eggs, feed, environmental samples) no *Salmonella* was found and in 2012 for 80,500 samples (types of samples as above) *Salmonella* serotypes had been found, however not targeted, in 40 samples.

## 5 FINDINGS AND CONCLUSIONS

### 5.1 COMPETENT AUTHORITY

#### **Legal requirements**

Article 46 of Regulation (EC) No 882/2004 specifies that official controls carried out in third countries by Commission experts shall have particular regard to the organisation of the third country's CAs, their powers and independence. This article refers also to other issues such as the training of staff in the performance of official controls, the existence and operation of documented control procedures and control systems based on priorities.

#### **Audit findings**

The CA has three levels: central, provincial (27 Veterinary Medicine Services) and district (486 district offices).

The CCA (the State Department of Veterinary Medicine) is responsible for drafting SNCPs, organisation of training, collecting and compiling data on *Salmonella* programme implementation.

Provincial levels are responsible for the collection of *Salmonella* sampling data from district level

and its assessment. Summaries of the results are sent both to the national *Salmonella* reference laboratory and CCA. The provincial services are also responsible for auditing the district offices as regards the implementation of the SNCP.

The SNCP is implemented by the district offices where Official Veterinarians (OVs) are responsible for taking the samples and reporting to the provincial offices about the number of samples taken.

*Salmonella* compiled data are reported every quarter by the district to the provinces from where summarised data are sent to the CCA using a standard reporting form. This form includes the number of samples initially planned and the number actually taken. The audit team found cases where the number of samples had been lower than scheduled but an explanation was always available and included in the report.

### Training

The audit team was provided with evidence (venue and list of participants) of training for officials dealing with the SNCP: training courses covered in 2011 the rules for *Salmonella* sampling, in 2012 SNCP implementation and in 2013 general procedures for export to the EU.

During the audit it was found that OVs involved in SNCP implementation had adequate knowledge as regards the sampling procedure.

### Audit

Internal audits are carried out by the provinces on the districts with a scheduled frequency where SNCP implementation is also assessed. The audit team reviewed the results of these controls in one province visited and found that the SNCP had been covered and that recommendations related to inadequate biosecurity conditions and minor deficiencies in SNCP implementation had been issued.

## **Conclusions**

The CA responsible for official controls within the scope of this audit is clearly designated.

There are procedures in place to collect and validate the data as regards SNCP's implementation.

Staff involved in the implementation of the SNCP had received training.

There are internal audits carried out which cover among others the implementation of the SNCP.

## **5.2 CONTROLS AT FARM LEVEL**

### **Legal requirements**

Article 6 of Regulation (EC) No 853/2004 concerning registration and approval of establishments.

Annex I to Regulation (EC) No 853/2004 sets out the general hygiene provisions for Food Business Operators (FBOs) involved in primary production.

### **Audit findings**

Laying hen farms are registered with a unique number given to each holding. The registration system is house-based and includes all farms without restrictions as to the number of birds. The audit team consulted this register in the two provinces visited and found that the information stored in this database was appropriate.

The frequency of official controls at poultry farms had been determined by Ukrainian Resolution No 884 from 2009. Under this resolution, official controls should take place at least once per year. A

standard check-list is used for verifying biosecurity conditions and implementation of the SNCP. Official controls are carried out mostly by a team comprising of officials from both district and provincial level.

In both farms visited the frequency of controls was respected and well documented. In one of these farms the CA issued recommendations with a deadline to rectify the deficiencies found and adequate follow-up had been performed.

However deficiencies found by the audit team had not been detected or recorded during official controls:

- in one instance the OV had failed to note an inadequate frequency of *Salmonella* sampling,
- in another case that sampling frequency was not auditable due to inadequate record keeping,
- deficiencies in biosecurity.

In both farms visited the records on treatment, mortality, pest control, sampling, etc. on flocks were kept. Information about practices and biosecurity measures in relation to the protection of flocks from *Salmonella* infection is included in the Instruction on Veterinary and Sanitary Rules for Poultry Establishments No 53 from 2001. This information is on the CCA's website and publicly available. However in the farms visited some requirements were not fulfilled e.g. inadequate biosecurity measures for entering the poultry houses (protective clothing done in incorrect place), poultry house not pest-proof (gap between wall and floor), disinfection mate not adequately covered by disinfectant.

#### Feed control

In Ukraine all feedstuffs must be certified as *Salmonella* free before it is fed to poultry. The audit team noted that feed batches delivered to the farm were certified as *Salmonella* free by the feed producers.

In Ukraine there is an official sampling programme for feed produced in the country which is regulated by the Order No 87 of 2003. Additionally, the SNCP requires that every fifth batch of feed delivered to the farm must be tested for *Salmonella*.

In both farms visited the audit team was provided with the test results for feed done in the framework of National Feed Sampling Programme and SNCP.

#### Cleaning and disinfection after depopulation

Under the Instruction on Veterinary and Sanitary Rules for Poultry Establishments No 53 of 2001 after each production cycles break of 21 days is required for cleaning and disinfection of poultry houses. The audit team was informed that environmental samples are to be taken after cleaning and disinfection. Restocking of the houses is allowed only if satisfactory results for *Salmonella* tests are obtained.

In one farm visited these rules were respected however in the second farm the audit team could not confirm fulfilment of this requirement because of inadequate records.

#### **Conclusions**

Farms are registered and under regular and well documented official supervision. Adequate tools to prevent *Salmonella* contamination are in place, such as effective cleaning and disinfection, controls on biosecurity conditions and on feedingstuffs.

However some deficiencies were noted in the performance of the official controls as deficiencies related to the biosecurity rules or *Salmonella* sampling frequency had not been detected or reported.



### 5.3 SNCP FOR LAYING HENS

#### Legal requirements

Both Regulations (EC) No 2160/2003 and (EU) No 517/2011 lay down rules for SNCP for laying hen populations. The requirements applicable until May 2011 were outlined in Regulation (EC) No 1168/2006.

Article 10(6) of Regulation (EC) No 2160/2003 requires third countries to provide guarantees equivalent to those provided for in this Regulation, including SNCP for laying hens.

#### Audit findings

In Ukraine the CA carries out all sampling (no FBO sampling in the programme). In the two farms visited the SNCP is being implemented. Sampling is done in compliance with the SNCP and in line with EU requirements i.e. each sample comprises 2 x 150 g of faeces. In one farm visited the sampling frequency was in general respected however in two cases the frequency had been 17 instead of 15 weeks. In the second farm although the audit team saw evidence that in general *Salmonella* sampling took place, sampling frequency was not auditable due to inadequate sampling records.

According to the SNCP OVs are required to check treatment records before sampling to exclude possible use of antimicrobials. However no documentary evidence was available to demonstrate that these checks had been done. Furthermore, no other check was performed to rule out the possible use of antimicrobials or bacterial growth inhibitors (laboratory tests for example).

The audit team was informed that in the case of *Salmonella* suspicion a restriction on movement of birds and eggs is imposed in accordance with Instruction No 316 of 2010. In point 1.8 of this Instruction a description of the restrictions and sanitary measures to be applied are described. The audit team was informed that if *Salmonella* Enteritidis or *Salmonella* Typhimurium is identified birds and eggs can be used only after heat treatment. The audit team was provided with the evidence that these measures were applied to a 2012 *Salmonella* positive flock even though the *Salmonella* serotype identified was a non-targeted one (*Salmonella* gallinarum).

The audit team was informed by the CCA that vaccination is not compulsory but in exceptional cases the birds can be vaccinated by using inactivated vaccine which has been approved by the CA. The audit team saw one example when the vaccination had been applied for a flock imported from the EU.

#### Conclusions

The SNCP for layers has been implemented however with some deficiencies related to the sampling frequency, record keeping and measures to exclude the possible use of antimicrobials.

### 5.4 LABORATORIES

#### Legal requirements

Article 46 of Regulation (EC) No 882/2004 indicates that Commission controls in third countries will have particular regard to the resources available to the CA, including diagnostic facilities.

Article 12 of Regulation (EC) No 2160/2003 lays down requirements for laboratories participating

in SNCPs, including the need to apply quality assurance systems and to participate in collaborative testing.

Article 12(3) of Regulation (EC) No 2160/2003 provides that alternative methods for *Salmonella* detection may be used if they have been validated in accordance with internationally recognised rules and offer equivalent results to those obtained by the relevant reference method.

Regulation (EU) No 517/2011 (point 3.2 and 3.3 of the Annex) lays down the reference analytical method (ISO 6579:2002/Amd.1:2007 – Annex D) and serotyping method (Kaufmann-White scheme) to be used in the context of SNCPs.

## **Audit findings**

State Scientific Research Institute of Laboratory Diagnostic and Veterinary and Sanitary Expertise is the national reference laboratory (NRL) for *Salmonella* and is accredited by a foreign accreditation body and the National Accreditation Agency of the Ukraine (NAAU) to ISO 17025.

The NRL participates in comparative tests for methods used for *Salmonella* isolation in Ukraine which are ISO 6579:2002/Amd.1:2007 (E), national method 4769:2007 and VIDAS method. The results of these tests are satisfactory and the frequency is at least once per year (FAPAS proficiency testing scheme); however poultry faeces were never used as matrix. This laboratory is responsible for the SNCP's data collection and its assessment and acts as arbiter when test results are disputed or suspect.

The method used for routine *Salmonella* detection in Ukraine is the national method 4769:2007 or VIDAS method (the latter used by seven provincial laboratories). Both methods have been validated by the NRL against ISO 6579:2002/Amd.1:2007 (E) which is the EU method for *Salmonella* detection in food and animal feedstuff. But these routine detection methods have not been validated against the EU and OIE reference method which is ISO 6579:2002/Amd.1:2007 – Annex D for the detection of *Salmonella* spp. in animal faeces and in environmental samples from the primary production stage.

There are 27 official laboratories at provincial level designated for *Salmonella* detection and serotyping. These laboratories are accredited to ISO 17025. The methods used are national method 4769:2007 or VIDAS for detection and Kaufmann-White scheme for serotyping. Other than in one provincial laboratory these methods are not in their scope of accreditation.

425 official laboratories at district level are authorised by the central laboratory for *Salmonella* detection in official samples but none are accredited.

All official laboratories are obliged, at least once per year, to participate in comparative tests organised by the NRL. The audit team saw evidence that the frequency of comparative tests is respected and results are satisfactory however faecal samples were never used as the matrix.

In the laboratory visited a standard procedure existed for the rejection of incorrect samples.

Templates for the sampling submission forms are created by the provincial laboratories. In the cases studied there was correct indication of the type and weight of samples and place of sampling (the number of the house).

In the provincial laboratory visited there are procedures in place for the notification of positive results. Under these procedures notification should be done immediately both for *Salmonella* spp and targeted *Salmonella* detected. At national level the notification requirement is regulated by Chapter 4 of Instruction No 316 from 2010 where *Salmonella* is included in the list of bacteria to be notified.

The audit team observed that the laboratory staff had received training. The analytical method applied in the framework of SNCP is the national method 4769:2007.

## Conclusions

Most of the laboratories involved in the SNCP analysis are not accredited and the methods they use are not within the scope of their accreditation.

The national methods used for *Salmonella* detection in official samples of animal faeces are not the EU/OIE reference one. These alternative methods have not been validated against the EU/OIE reference method for detection of *Salmonella* spp. in faecal samples.

## 6 OVERALL CONCLUSIONS

The *Salmonella* National Control Programme for laying hens is being implemented and under official supervision.

However the audit team found deficiencies related to biosecurity at farm level, sampling frequency, record keeping and measures to exclude the possible use of antimicrobials.

Moreover reliability of laboratory results is not guaranteed for several reasons (lack of accreditation of official laboratories at district level, non-inclusion of methods used for the *Salmonella* testing within the scope of accreditation, lack of validation of *Salmonella* detection methods used against EU/OIE reference analytical method).

The SNCP currently in place cannot provide guarantees equivalent to those provided for in Regulation (EC) No 2160/2003.

## 7 CLOSING MEETING

During the closing meeting held in Kiev on 17 May 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CAs.

During this meeting, the CCA acknowledged the FVO's findings and informed the audit team that immediate measures would be taken to rectify them.

## 8 RECOMMENDATIONS

The CCA should provide Commission services with guarantees and an action plan, including a timetable for its completion, within one month of receipt of the report in order to address all the deficiencies identified and in particular, the following recommendations:

N°.	Recommendation
1.	The CA should ensure that adequate biosecurity standards are in place in all laying hens farms in order to provide guarantees equivalent to the provisions laid down in EU legislation (point 4(h), Part A (II), Annex I to Regulation (EC) No 852/2004).

N°.	Recommendation
2.	The CA should ensure that the monitoring and sampling programme applied in laying hen flocks is in line with the requirements of Regulations (EC) No 2160/2003 and (EU) No 517/2011, in particular regarding frequency, record keeping and measures to exclude the possible use of antimicrobials.
3.	The CA should ensure that laboratories involved in the official controls apply the principles of internationally recognised quality assurance techniques, such as ISO/IEC 17025 or equivalent, and use internationally recognised quality assurance programmes /standards, where available, for standardising test methodologies and testing proficiency to ensure the reliability of analytical results.
4.	The CA should ensure that Salmonella detection methods is either the EU/OIE reference method or any alternative analytical method validated in accordance with internationally recognised rules and offering equivalent results to those obtained by the relevant reference method (point 3.2 and 3.4 of Annex to Regulation (EU) No 517/2011, Article 12(3) of Regulation (EC) No 2160/2003).

The competent authority's response to the recommendations can be found at:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2013-6734](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6734)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2160/2003	OJ L 325, 12.12.2003, p. 1-15	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
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 1168/2006	OJ L 211, 1.8.2006, p. 4-8	Commission Regulation (EC) No 1168/2006 of 31 July 2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 1003/2005
Reg. 517/2011	OJ L 138, 26.5.2011, p. 45-51	Commission Regulation (EU) No 517/2011 of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 798/2008	OJ L 226, 23.8.2008, p. 1-94	Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements