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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

GREECE

FROM 14 TO 23 SEPTEMBER 2009

IN ORDER TO EVALUATE THE SYSTEMS IN PLACE TO CONTROL THE SALMONELLA RISK IN THE TABLE EGG SECTOR

IN THE CONTEXT OF A GENERAL AUDIT

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an inspection mission carried out by the Food and Veterinary Office in Greece, from 14 to 23 September 2009.

The objective of this mission was to evaluate if the control system in place regarding the Salmonella risk in table eggs is in accordance with the relevant provisions of Community law relating to official food control. With this in mind, the mission team assessed the measures taken by the Greek competent authority in order to prevent possible outbreaks of Salmonella food poisoning due to the consumption of table eggs or foodstuffs prepared from table eggs.

In its overall conclusion, the report indicates that the Salmonella National Control Programmes for breeding and laying hen flocks have begun to be implemented with significant delays (up to two years). Implementation of the programmes improved in 2009 however, still not all breeder/layer flocks subject to the programmes have been tested. The efficiency and reliability of the Salmonella National Control Programmes is undermined by significant deficiencies in their implementation.

Results of analyses of laboratories participating in the Salmonella National Control Programmes were, in some cases, unreliable.

Concerning controls at establishment level, the situation is overall positive, however, some deficiencies were noted concerning reporting on official controls.

Although with some deficiencies, food-borne disease outbreak investigations were carried out by the Competent Authorities, there was not sufficient information available for the mission team to evaluate the correctness of actions taken by these authorities.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
EFET	Hellenic Food Authority
FBO/s	Food Business Operator
FDBO/s	Food-borne Outbreak/s
FVO	Food and Veterinary Office
GHP	Good Hygiene Practice
HACCP	Hazard Analysis and Critical Control Points
KEELPNO	Centre for Disease Prevention and Control
MRDF	Ministry of Rural Development and Food
MS	Member States
MT	Mission Team
NRL	National Reference Laboratory
OV	Official Veterinarian
PHD/s	Prefectural Health Directorates
PVD/s	Prefectural Veterinary Directorates
RASFF	Rapid Alert System for Food and Feed
SE	Salmonella Enteritidis
SNCP	Salmonella National Control Programme
ST	Salmonella Typhimurium

1 Introduction

The audit mission took place in Greece from 14 to 23 September 2009.

This specific audit forms part of the Food and Veterinary Office's (FVO) planned mission programme and was carried out as a component of a general audit, as defined in Article 45 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.

This report focuses the sector specific issues identified during the audit. It does not necessarily include aspects relating to Regulation (EC) No 882/2004 which will be addressed in the subsequent General Audit report.

The mission team (MT) comprised two inspectors from the FVO and one national expert from a Member State (MS).

2 Objectives Of The Mission

As part of the general audit, the objective of this mission was to evaluate if the control system in place regarding the *Salmonella* risk in table eggs is in accordance with the relevant provisions of Community law relating to official food control.

In order to achieve this objective the MT evaluated the organisation of the Competent Authority (CA) and its capacity for implementing the relevant Community requirements from the farm to the table.

In pursuit of this objective, the MT proceeded as follows:

- the MT assessed the measures taken by the CA in order to prevent possible outbreaks of *Salmonella* food poisoning due to the consumption of table eggs or foodstuffs prepared from table eggs;
- an opening meeting was held on 14 September 2009 with the CAs. At this meeting the MT confirmed the objectives of, and itinerary for the mission, and requested additional information required for the satisfactory completion of the mission;
- the following sites were visited:

Competent authority visits		
Central level	2	Opening and closing meeting
Regional level	3	Two Prefectural Veterinary Directorates and one Veterinary Field station
Laboratory visits		
National Reference Laboratory	1	
Official laboratories	2	
Private laboratory	1	
Primary production		
Farms	7	Only a documentary check was carried out in two of these.
Hatchery	1	
Food processing facilities		
Packing centres	3	In one of them only a documentary check was carried out

Catering services	1	Kitchen for hospitals and canteens
Egg Product establishments	1	

- representatives from the CA accompanied the MT during the whole mission.

3 Legal Basis for the Mission

The mission was carried out in agreement with the Greek Authorities and under the general provisions of Community legislation and, in particular:

- Article 45 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;
- Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States;
- Article 17 of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 April 2003 on the control of salmonella and other specified food-borne zoonotic agents;

Note: Legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the acts quoted in this report are given in the Annex to this report.

4 Background

4.1 Historical background

This mission was the first which was carried out in Greece regarding the controls on the *Salmonella* risk in table eggs.

4.2 Production and trade information

The MT was informed by the CA that 112,336 tons of table eggs were produced in Greece which covers 95-97 % of the egg consumption of the country.

5 Findings And Conclusions

5.1 Controls at farm level

Legal requirements

Article 3 of Regulation (EC) No 882/2004 of the European Parliament and of the Council requires MS to carry out regularly, on a risk basis and with appropriate frequency controls on feed or food businesses.

Chapter I of Annex II to Council Directive 90/539/EEC requires at least one inspection per year per holding by an official veterinarian (OV) in order to be approved by the CA for the purposes of intra-Community trade in poultry or hatching eggs.

Audit findings

The MT noted different positive elements in the control system, such as:

- The farms visited were appropriately registered and are subject to regular veterinary inspection by OVs of the competent Prefectural Veterinary Directorate (PVD). The checklist used for official controls forms part of the manual which was issued in May 2009 by the Central CA (CCA) for the uniform implementation of the Salmonella National Control Programme (SNCP) and covers a broad range of issues including the evaluation of biosecurity measures, sampling for Salmonella by Food Business Operators (FBOs), use of antimicrobials and vaccination against Salmonella.A draft version of the manual including this farm checklist was circulated to the PVDs in early 2008 by the CCA and was recommended for use by OVs.
- The annual frequency of official visits of poultry farms is determined by decisions of the Ministry of Rural Development and Food (MRDF): Decision No. 258685/07.06.2007 (GG B 1011), "Monitoring programme for salmonellosis in breeding hens of the species Gallus gallus" and Decision No. 260973/04.02.2009 (GG B 243), "Monitoring programme for salmonellosis in laying hens of the species Gallus gallus". These Decisions foresee mandatory official controls at poultry farms whenever official sampling of flocks or a hatchery (within the SNCPs) is carried out. The CA stated that additional official checks may be carried out when farms are visited for animal health issues (e.g. Avian Influenza, Newcastle disease, etc.). The operator of the farm is expected to sign the inspection report and is provided with a copy thereof.
- The MRDF decisions lay down detailed biosecurity requirements for breeding and laying hen farms and for hatcheries. The MT noted that the biosecurity measures were generally adequate in the farms and in the hatchery visited.
- The MRDF decisions require that all feedingstuffs must be confirmed as free from Salmonella before being fed to poultry. The MT was shown evidence that this requirement was ascertained either by a certificate from the feed supplier or by microbiological analysis of the feed concerned on behalf of FBO.

However, the MT also noted that:

- The checklist used contains no information for the identification of flocks.
- Although the shortcomings identified were outlined and corrective actions to remedy the situations were proposed in the official reports, the MT found that the reports contained no deadlines in the case of non-compliances found at farm level. A representative of the CA indicated that the lack of deadlines would hinder the enforcement of the requirements. The MT was informed by the CA that a follow-up of shortcomings is carried out during the next inspection. However, the MT found no any written evidence to confirm this.
- In one of the layer farms visited there was no written evidence that official controls had been carried out prior to May 2009.

Conclusions

Poultry farms are adequately registered, have adequate biosecurity measures and are under official supervision. However, inspections at farm level were not regularly carried out before May 2009. There is very limited evidence of official follow-up of shortcomings.

5.2 SNCPs FOR BREEDING AND LAYING HENS

Legal requirements

Regulation (EC) No 2160/2003 of the European Parliament and of the Council outlines how targets shall be established for the reduction of the prevalence of zoonoses, including *Salmonella*. The target for breeding hens was fixed by Commission Regulation (EC) No 1003/2005. To achieve the targets, MS have to implement a SNCP for breeding hens, including detailed sampling rules both for the FBO and for the official services. These sampling rules in the case of breeding hens are specified in Annex II.B to Regulation (EC) No 2160/2003 and in Regulation (EC) No 1003/2005.

The target for laying hens was fixed by Commission Regulation (EC) No 1168/2006. To achieve the targets, MS have to implement a SNCP for laying hens, including detailed sampling rules both for the FBO and for the official services. These sampling rules in the case of laying hens are specified in Annex II.B to Regulation (EC) No 2160/2003 and in Commission Regulation (EC) No 1168/2006.

Commission Decision (EC) No 2006/759 approving certain national programmes for the control of *salmonella* in breeding flocks of *Gallus gallus*.

Commission Decision (EC) No 2007/848 approving certain national programmes for the control of *salmonella* in flocks of laying hens of *Gallus gallus*.

Audit findings

The official sampling for breeding and laying hen flocks is carried out by OVs from the PVDs. Own check sampling is carried out either directly by the FBOs themselves or by private veterinarians on their behalf.

The MT was provided with details of the training courses provided for official and private veterinarians and FBOs on monitoring and control of *Salmonella* in poultry flocks, the correct application of biosecurity measures and the collection and transfer of the samples taken to laboratories carrying out *Salmonella* testing. A video is available on the MRDF website to demonstrate the proper sampling techniques. The manual for OVs referred to in 5.1. of this report contains detailed instructions on official controls to be carried out within the framework of the SNCP including forms for sampling and reporting.

All official samples within the framework of the SNCP are analysed in four official laboratories including the National Reference Laboratory (NRL). Serotyping of *Salmonella* positive samples are carried out exclusively in the NRL. The MT was informed by the CA that before taking official samples OV must contact the laboratory in advance before sending in samples to ensure that the laboratory has the capacity to receive and analyse the samples. Own check samples are sent for analysis to private laboratories only.

The MT noted that neither the official nor the own check sampling documents contained the weight of the samples taken.

FBOs, official or private laboratories are obliged to report positive *Salmonella* results both to the CA and to the CCA immediately. This is in line with Article 6 of Directive 2003/99/EC of the European Parliament and of the Council. However, when reviewing cases of positive flocks, the MT noted several cases when despite the fact that samples tested positive for *Salmonella* the official laboratory sent the results by regular mail which took at least one week for the CA to receive causing at least a week's delay in taking measures.

Detailed reports including official and own check results are sent to the CCA every six months by

PVDs involved in the programmes. A representative of the CCA informed the MT that own check results have been included in the report since May 2009 only.

SNCP provides financial compensation through co-financing from the European Commission for vaccination and for measures related to culling of birds. However, farmers are not compensated where they fail to comply with the provisions (e.g. biosecurity measures or own check sampling) of the SNCPs.

5.2.1 SNCP for breeding hens

- The national legislation (MRDF Decision No. 258685/07.06.2007 (GG B 1011), "Monitoring programme for salmonellosis in breeding hens of the species Gallus gallus") to implement the SNCP was issued on 07/06/2007 for breeding flocks covering the period of year 2007-2009. However, according to the data provided by the CA, only 29 breeder flocks were tested (official samples) out of 275 subjected to the programme in 2007, only 102 flocks out of 224 in 2008 and 162 out 223 by 30 June 2009. The MT was informed by the CA that the own check sampling for breeding flocks started at the end of 2008 only. The MT noted in one breeder farm visited that official sampling began in November 2007 while own check sampling started in January 2009. The MT was informed that a shortage of resources including laboratory capacity and official staff caused significant delay in the implementation of the SNCP.
- Vaccination is at the discretion of the operator and widely used. Only registered live or inactivated vaccines are permitted to be used. In the case of live vaccines the CA requires the manufacturer to provide an appropriate method to distinguish wild-type strains of Salmonella from vaccine strains which is in line with the requirements of Article 3 of Regulation (EC) No 1177/2006. The MT saw evidence that in November 2007 CCA sent a list of Salmonella vaccines complying with the aforementioned requirements to all PVDs.
- For adult breeding flocks routine sampling is carried out at the hatchery every second week by the FBO and every 16 weeks by the CA. Official confirmatory sampling is carried out in the holding, following detection of relevant Salmonella from sampling at the hatchery.
- According to the SNCP for breeding flocks in the case of confirmed positive to Salmonella enteritidis (SE) or Salmonella typhimurium (ST) the flock is slaughtered or destroyed, whereas for Salmonella hadar, Salmonella virchow and Salmonella infantis CA shall carry out traceability checks and make recommendations for improvement of biosecurity measures. Concerning the possibility of exceptionally authorising the use of antimicrobials to control Salmonella, by way of derogation from the general requirement in Regulation (EC) No 1177/2006, the SNCP lays down detailed requirements when this derogation may be granted by the CA.
- The MT was informed that to date no positive case of SE or/and ST have been found in breeding flocks during own check sampling, while during official sampling two flocks tested positive for SE and three flocks for Salmonella hadar in 2007. In 2008, no breeding flock tested positive for the relevant Salmonella (as listed in Article 1 of Regulation (EC) No 1003/2005).

The MT noted several shortcomings in the implementation of the programme in breeding flocks:

- The MT found that during official sampling at the holding the OV pooled all faecal samples taken to have one single result which is not in line with point 2.2.2.1. (a) of Annex to Regulation (EC) No 1003/2005 which states that faeces may be pooled for analysis up to a minimum of two pools. Moreover, the MT noted that the relevant MRDF decision allows pooling of samples into one composite sample. The CA admitted non-compliance and informed the MT that this discrepancy would be addressed during the next amendment of the relevant national legislation.
- In the hatchery visited the MT found that the interval between two official sampling was 22 weeks instead of 16 as required by point 2.1.2.1 (a) of Annex to Regulation (EC) No 1003/2005. In another flock no routine sampling was carried out at the holding towards the end of the laying phase which is in contrary to point 2.1.2.1 (b) of the same regulation.
- The MT reviewed a case where SE was detected by the NRL in a hatchery. The CA carried out confirmatory sampling in the holding. Faecal samples were pooled into one single sample. Two bird samples were taken eight days later and sent to the laboratory to exclude the use of antimicrobials. The delay in taking bird samples makes it difficult, if not impossible, to detect the use of antimicrobials. These actions are not in line with point 2.2.2.2. (b) of Annex to Regulation (EC) No 1003/2005.

5.2.2 SNCP for laying hens

An EU-wide *Salmonella* baseline study, under Commission Decision 2004/665/EC, was conducted in commercial large-scale laying hen holdings with at least 1,000 laying hens in the flock. The study was carried out in all MS and coordinated by the European Food Safety Authority -EFSA. The sampling of holdings took place between October 2004 and September 2005. The aim of the study was to estimate the prevalence of *Salmonella* in holdings at global EU-level as well as for each MS specifically.

According to this baseline study, the prevalence of zoonotic *Salmonella* in the Greek laying sector was a combined figure of 25.7 % for SE and ST in the clean dataset.

- The national legislation (MRDF Decision "Monitoring programme for salmonellosis in laying hens of the species Gallus gallus") to implement the SNCP was issued on 17/01/2008 and amended on 04/02/2009 for laying hen flocks covering the period 2008-2010. However, according to the data provided by the CA, of 357 laying flocks subject to the programme in 2008 only 112 were tested. The MT was informed by the CA that the own check sampling for laying flocks had started in a sporadic manner at the beginning of 2008. The MT noted in one layer farm visited that official sampling started in September 2008 while own check sampling began in February 2009 only. In another farm visited, the first official sample was taken in July 2008 whilst the own check sampling began in May 2009.
- The MT was informed that to date no positive case of SE or/and ST have been found in laying flocks during own check sampling, while during official sampling 16 flocks tested positive for SE/ST in 2008.
- Following the results of the baseline study of Salmonella prevalence in laying hen

flocks, vaccination against SE became mandatory in Greece in accordance with Regulation (EC) No 1177/2006. The relevant MRDF decision lays down the conditions to be met when the CA may grant derogation to FBOs. However, according to the CCA no such derogation has yet been granted.

The MT noted several shortcomings in the implementation of the programme in laying flocks:

- The MT reviewed a case where SE was detected in official samples from a laying hen house. The CA placed that house under restriction correctly i.e. the eggs were detained and sent for thermal processing, and the birds were sent for slaughter. However, not all of the other laying flocks on the holding were sampled although it is required by point 2.1. (d) of the Annex to Regulation (EC) No 1168/2006. Although the OV was aware of this requirement, due to other responsibilities and lack of time he did not complete the obligatory additional sampling tasks.
- When studying own check sampling in a laying flock the MT noted that the FBO took one faecal and one dust sample. This is not in line with point 2.2. (a) of the Annex to Regulation (EC) No 1168/2006 which requires two faecal samples. However, this non-compliance was not detected by the OV when he verified own check sampling. In another case the private veterinarian who was responsible to take samples on behalf of the FBO did not use any sampling document to send samples to the private laboratory. As a result insufficient information was available for the CA to verify the correctness of the sampling.

Conclusions: SNCPs on breeding and laying hens

SNCPs for breeding and laying hen flocks have begun to be implemented with significant delays (up to two years) due to insufficient laboratory capacity and lack of CA staff. Implementation of the programme improved in 2009 however, as of yet, not all breeder/layer flocks subject to the programme are tested. The efficiency and reliability of the SNCP is undermined by the significant deficiencies in its implementation. The data currently available does not allow for an adequate review and evaluation of the SNCP progress as required under Article 5.3.d of Regulation (EC) No 2160/2003.

5.3 Controls by the CA on foodstuffs

5.3.1 Controls in packing centres and egg-products establishments

Legal requirements

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls, including among other issues, rules on approval of establishments, and control and verification procedures, including sampling.

Annex II to Regulation (EC) No 852/2004 lays down the general hygiene provisions for FBOs, whereas Section X of Annex II to Regulation (EC) No 853/2004 lays down more specific criteria for eggs and egg products.

Audit findings

Egg packing centre

In the packing centres visited Hazard Analysis and Critical Control Points (HACCP) systems have been implemented. The sanitary conditions found by the MT were overall adequate. In accordance with the risk assessment system in place the egg packing centres visited were categorised as high risk establishments which involves at least one inspection visit per year from the PVD. The MT noted that this target was achieved in each egg packing centre visited. A uniform checklist issued by the MRDF is used for official inspections. Traceability and labelling of eggs where checked by the MT were in compliance with the relevant Community requirements.

Egg product establishment

The establishment visited had adequate layout and maintenance. It operated under a well-documented HACCP plan. As a part of the own check analyses, each production lot of egg products are tested for *Salmonella* and *Enterobacteriaceae*. Microbiological analysis is regularly carried out on products for *Staphylococcus aureus*, *Coliforms* and total plate count. Results of these analyses were available for the MT. An adequate traceability system is in place.

The establishment visited was under the supervision of the local PVD as that region is not covered by regional Hellenic Food Authority (EFET) directorate.

Based on EFET's 2007 guidelines the establishment was categorised as high risk establishment which requires one full audit or two targeted inspections per year. A detailed uniform checklist issued by EFET for inspection of egg product establishments is available to the inspectors. However, only one official inspection report was made available to the MT for the period 2005-2009 (a full audit, dated August 2009). Concerning the official inspections before that date, the MT noted that only the official sampling for microbiological and chemical analysis carried out in the establishment concerned was recorded in a logbook. The MT found records that official sampling was carried out from products for analysis of organic acids three times per year and for *Salmonella* and *Enterobacteriaceae* at least once a year.

The MT was informed that no guide to Good Hygiene Practice (GHP) has been developed so far for the egg processing sector.

Conclusions

Conditions in the establishments visited were broadly adequate. However, only very limited evidence was available that there had been regular official supervision of egg product establishments.

5.3.2 Controls at catering level

Legal requirements

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls, including among other issues, rules on approval of establishment, and control and verification procedures, including sampling.

Annex II to Regulation (EC) No 852/2004 lays down the general hygiene provisions for FBOs.

Audit findings

The MT visited one catering establishment which supplies meals for schools, hospitals and for canteens of large companies.

The MT was informed by EFET that catering establishments could choose to use a GHP guide or full HACCP system for their own checks. However, above a defined capacity a HACCP system is mandatory.

A GHP guide for the mass catering sector was issued in 2001 by EFET.

In the catering establishment visited the MT noted adequate structural and sanitary conditions and that the HACCP plan was being properly implemented. As part of the own check system sampling for microbiological analysis was regularly carried out with samples taken from surfaces, raw materials, meals and water.

In accordance with the relevant national legislation (Ministerial Decision 14708/2007) in place, employees of a catering establishment must undergo regular training (including induction training). The training should be carried out either by an approved trainer or by the FBO but in the latter case the curriculum has to be approved by EFET.

At present in Greece, there is no national requirement for retaining meal samples in public catering establishments. This is not a Community requirement, although in the case of outbreaks could facilitate their investigation. In the catering establishment visited a regular practice was to retain meal samples for up to ten days.

There is a risk assessment system in place to classify food-businesses into risk groups. Frequency of inspections depends on the risk group into which the establishment is listed. It takes into account several risk elements: type of food handled by the FBO, use of food by the consumer, operations that may influence food safety, reliability of own checks, past records of non-compliance, etc. Mass catering establishments are grouped into “high risk” category which requires at least one full audit (including HACCP audit) or two targeted inspections per year. A guideline was issued describing this procedure. A representative of EFET informed the MT that in the guideline, there are detailed criteria laid down as to when an OV may modify the frequency of inspection or alter the type of inspection (audit/inspection).

In the catering unit visited, the MT found that the target of inspection frequency was not fully achieved. There was one full audit in 2009 and only one targeted inspection in 2008. A detailed checklist is used during the routine official visits, which includes the evaluation of HACCP system. The MT noted that own check systems were adequately assessed by the CA during the full audit.

Conclusions

There is an adequate control system in place, based on risk assessment. However, the target of inspection frequency was not fully achieved. Conditions were generally adequate.

5.3.3 Outbreak investigations

Legal requirements

Article 8 of Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents outlines different rules for the CA epidemiological investigation of food-borne outbreaks. When this investigation succeeds in tracing back the source of a *Salmonella* outbreak due to eggs to the farm of origin, Regulation (EC) No 2160/2003 lays down certain

measures to be taken at that farm.

Article 4 of Regulation (EC) No 882/2004 indicates that adequate co-operation and co-ordination will be ensured between the different CAs involved in official controls.

Audit findings

According to the information provided by the CA the number of outbreaks of *Salmonella* food poisoning were 39 in 2006 (five linked to eggs), 21 in 2007 (three linked to eggs) and 39 in 2008 (15 linked to eggs). However, the information provided by the CA underlines that in the cases mentioned as "linked to eggs" the source of contamination (i.e. eggs) were not officially confirmed. These cases were ascribed by the patient to eggs or egg products.

Although requested, the MT was not provided with legal documents describing procedures to be followed during food-borne outbreak (FDBO) investigations.

The MT reviewed two cases of human outbreaks of *Salmonellosis*. In one case the epidemiological investigation was carried out by the competent Prefectural Health Directorate (PHD). They promptly responded to the notification from the hospitals, carried out an on-site visit to the establishment involved, took water and food samples. However, the MT was not provided with evidence that samples from kitchen personnel and samples from working surfaces had been taken. The PHD was not able to identify any potential cause for the outbreak.

In another FDBO reviewed by the MT, where EFET was responsible for the investigation, the MT was informed by the Centre for Disease Prevention and Control (KEELPNO) that the final report of this FDBO was not provided by EFET to KEELPNO even though it was requested. Therefore the MT was not able to assess the actions taken by CA during investigation.

Conclusions

Although it was requested, no written documents describing procedures to be followed by the CAs during FDBO investigations were provided for the MT. There was insufficient information available for the MT to evaluate the compliance of the actions taken by the CAs during FDBO investigations.

5.4 Rapid Alert System for Food and Feed (RASFF) follow up

Legal requirements

Article 50 of Regulation (EC) No 178/2002 lays down the scope and procedures of RASFF, intended to provide the CAs with an effective tool for exchange of information on measures taken to ensure food safety.

Audit findings

There has been no RASFF notification linked to table eggs since 2006. EFET is designated as a contact point for RASFF and has a written procedure in place to be followed after notification. (Circulars No. 6975/13-4-07, 9884/26-6-08 and 10473/4-7-08 explaining the implementation of the RASFF system and the role of the control authorities).

Conclusions

There is a written procedure in place for RASFF follow-up.

5.5 Laboratories

Legal requirements

Article 33 of Regulation (EC) No 882/2004 lays down the responsibilities and tasks of the NRLs designated by the MS.

Article 12 (2) of Regulation (EC) No 882/2004 requires CAs to only designate official laboratories that:

- Operate and are assessed and are accredited in accordance with an appropriate standard (*e.g.* EN ISO/IEC 17025), taking into account criteria for the different testing methods laid down in Community legislation (a derogation to these requirements is provided by Article 18 of Commission Regulation (EC) No 2076/2005, until 31.12.2009, under certain conditions),

Additionally, Article 12 of Regulation (EC) No 2160/2003 lays down requirements for laboratories participating in control programmes, including the need to apply quality assurance systems. This Article also indicates how laboratories shall regularly participate in collaborative testing organised or co-ordinated by a NRL.

Finally, Regulations (EC) Nos 1003/2005 and 1168/2006 lay down rules for the detection method (ISO 6579 Annex D) to be used in the context of SNCPs for breeding and for laying flocks, respectively.

Audit findings

- MRDF designated four national laboratories one of which was the NRL for official analyses of Salmonella within the framework of the SNCPs. The NRL and another laboratory visited are accredited by the Hellenic National Accreditation Body in accordance with ISO 17025. The MT was informed by the NRL that there are no immediate plans to have the other two laboratories accredited. This is neither in line with Article 12 (2) of Regulation (EC) No 882/2004 nor with Article 18 of Commission Regulation (EC) No 2076/2005.
- The MT was informed that a validated method (ISO 6579:2002 Annex D) is applied in all four official laboratories when carrying out Salmonella analysis within the scope of SNCPs. However, the MT noted in one of the official laboratories visited that the Salmonella analyses were completed within one or two days. A representative of the laboratory informed the MT that the incubation time of the media was reduced to 24 hours (instead of 2X{24+/-3} hours) at his own initiative. This was neither in compliance with point 3.2. of Annex to Regulation (EC) No 1003/2005 (version valid until 1 April 2009) nor with the method contained in EN/ISO 6579-2002/Amd1, referred to in point 3.2 of Annex to Regulation (EC) No 1003/2005 (version valid since 1 April 2009) and to in point 3.2 of Annex to Regulation (EC) 1168/2006. In the same laboratory, the MT noted that the template used to despatch the results of analysis did not indicate the method used for Salmonella analysis as required by the manual referred to in 5.1. in this report.
- The NRL participated regularly in proficiency testing organised by the Community Reference Laboratory with adequate results.
- The MT noted that the NRL's co-ordination role for laboratories participating in the SNCPs

was limited to recent on site visits. Minutes of the visits in the three official laboratories and in one private laboratory were provided to the MT by NRL. However, no specific findings or recommendations were contained in these minutes.[1]

- There have been no proficiency tests relevant to the SNCP organised or co-ordinated by the NRL since 2004. This is not in line with Article 12 of Regulation (EC) No 2160/2003.
- The MT was not provided with any evidence that the NRL organised any specific training related to the SNCPs for laboratories participating in the programme. The MT was informed however, that official and private laboratories participating in the programme often consult the NRL on SNCP specific issues.
- The MT was informed that according to the procedures in place official laboratories refuse to analyse those samples which do not respect the sampling requirements (e.g. underweight samples). In such a case, the laboratory should contact the competent PVD.
- All official laboratories visited by the MT claimed to be short staffed in relation to the variety and number of analyses to be carried out. In particular, it was apparent in one of the official laboratories visited by the MT where only two veterinarians and two temporary technical staff were responsible for carrying out analyses for Avian Influenza, Newcastle Disease and Salmonella. The head of the laboratory admitted that due to the lack of resources both human and financial, it is not possible to implement quality assurance system although it is required by Article 12 of Regulation (EC) No 2160/2003. In this laboratory, the MT did not find any written evidence that Salmonella samples had been analysed, other than records on the reception of samples and despatch of analyses results.
- The own check-analyses for Salmonella within the SNCP are carried out in private laboratories. The NRL is in the process of gathering information on compliance of these laboratories with the relevant standards. The Directorate-General for Veterinary Services under the MRDF stated that at present there are no laboratories formally designated to carry out own check analyses under the SNCP. This is not in line with Article 12 of Regulation (EC) No 2160/2003. The CCA informed the MT that once a list of designated private laboratories is available, it will be published on the MRDF website.
- The private laboratory visited by the MT was accredited to carry out microbiological analysis in foodstuffs. The scope of accreditation did not include Salmonella testing in faecal material or dust. The MT was informed that validated method which is ISO 6579:2002 Annex D is applied for Salmonella analyses. The MT noted that the laboratory had good facilities and qualified staff. The personnel participated in several training sessions including those organised by the CCA. The MT was provided with evidence that the laboratory participated in proficiency tests on Salmonella analysis in foodstuffs and in faecal material (May-June 2009), with adequate results. These proficiency tests were organised by UK laboratories. The MT reviewed cases of own check samples analysed in August 2008 and was not able to verify that the samples were analysed in accordance with the relevant ISO method, because apart from the data on sample reception and despatch of test results, there were no records available on the analysis. The MT was informed by the laboratory staff that these records had been accidentally destroyed. In the same laboratory the MT found a case when they began to analyse the incoming samples for Salmonella after two weeks of reception. However, the MT was informed that with new facilities available this practice was discontinued since the middle of 2009.

1 In their comments to the draft report the CA indicated that the report prepared after the NRL's visit to laboratories participating in SNCPs has been amended and now includes conclusions/observations from the visit and corrective measures to be taken, in addition to the subjects of the control/discussion.

Conclusions

Only two out of the four official laboratories within the framework of the SNCP are accredited. The reliability of results in some of these laboratories however, raises concerns, due to the fact that no proficiency tests were carried out, insufficient internal quality controls, shortage of sufficient staff and not properly implemented ISO method. The NRL does not fulfil sufficiently its co-ordination role over other laboratories as required in Article 33 of Regulation (EC) No 882/2004. T here are no laboratories formally designated by the CA to carry out own check analyses under the SNCPs.

6 Overall Conclusions

SNCPs for breeding and laying hen flocks have begun to be implemented with significant delays (up to two years). Implementation of the programme has improved in 2009 however not all breeder/layer flocks subject to the programme have been tested so far. The efficiency and reliability of the SNCPs are undermined by the significant deficiencies in their implementation.

Results of analyses of laboratories participating in the SNCPs were, in some cases, unreliable.

Concerning controls at establishment level, the situation is overall positive, however, some deficiencies were noted concerning reporting of official controls.

FDBO investigations have been carried out by the CAs and some of these were deficient. There was insufficient information available for the MT to evaluate the correctness of actions taken by the CAs.

7 Closing Meeting

During the closing meeting held in Athens on 23 September 2009, the MT presented the findings and preliminary conclusions of the mission to the CA.

During this meeting, the CAs acknowledged all the findings and preliminary conclusions presented by the MT and provided additional information requested by the MT during the mission.

8 Recommendations

The CCA should provide Commission services with guarantees and an action plan, including a timetable for its completion, within 25 working days of receipt of the report in order to address all the deficiencies identified in the report and in particular, the following**:**

N°.	**Recommendation**
1.	The sampling method applied in breeding flocks and laying flocks should comply fully with Community requirements in Regulations (EC) Nos 1003/2005 and 1168/2006, correcting all deficiencies mentioned in this report.
2.	The CA should ensure that a proper sampling protocol is applied in laying hen flocks when SE or ST is detected in a holding in accordance with point 2.1. (d) of the Annex

N°.	Recommendation
	to Regulation (EC) No 1168/2006.
3.	The CCA should gather the necessary information in order to carry out an adequate review and evaluation of the SNCPs in line with Article 5.3.d of Regulation (EC) No 2160/2003.
4.	The CA should ensure that the potential causes of the outbreaks are, as far as possible, studied and documented in the epidemiological investigations of outbreaks, as required by Article 8.2 of Directive 2003/99/EC.
5.	The CA should ensure that all laboratories involved in the SNCPs are designated by the CA, apply quality assurance systems and regularly participate in proficiency testing, particularly on faecal material, in line with Article 12 of Regulation (EC) No 2160/2003. This proficiency testing should be organised or coordinated by the NRL.
6.	The CA should ensure that official samples within the SNCPs are analysed in laboratories accredited in accordance with Article 12 of Regulation (EC) No 882/2004 and taking into account the derogation provided for in Article 18 of Regulation (EC) No 2076/2005.

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

http://ec.europa.eu/food/fvo/ap/ap_gr_2009-8067.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 2003/99/EC	OJ L 325, 12.12.2003, p. 31-40	Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC
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. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 1003/2005	OJ L 170, 1.7.2005, p. 12-17	Commission Regulation (EC) No 1003/2005 of 30 June 2005 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of Gallus gallus and amending Regulation (EC) No 2160/2003
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from

Legal Reference	Official Journal	Title
		Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
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. 1177/2006	OJ L 212, 2.8.2006, p. 3-5	Commission Regulation (EC) No 1177/2006 of 1 August 2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national programmes for the control of salmonella in poultry
Reg. 646/2007	OJ L 151, 13.6.2007, p. 21-25	Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in broilers and repealing Regulation (EC) No 1091/2005
Reg. 1234/2007	OJ L 299, 16.11.2007, p. 1-149	Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)
Reg. 589/2008	OJ L 163, 24.6.2008, p. 6-23	Commission Regulation (EC) No 589/2008 of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No

Legal Reference	Official Journal	Title
		1234/2007 as regards marketing standards for eggs