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FINAL REPORT OF A SPECIFIC AUDIT
CARRIED OUT IN
LITHUANIA
FROM 20 APRIL TO 29 APRIL 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

Executive Summary

This report describes the outcome of an inspection mission carried out by the Food and Veterinary Office in Lithuania, from 20 to 29 April 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 Lithuanian 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 before March 2009, the CA applied a Salmonella National Control Programme, that differed from that approved by the Commission. The programme now in place and approved by the Commission is well designed, although its efficiency and reliability is undermined by the deficiencies in its implementation.

Concerning controls at establishment level, the situation is overall positive, although some deficiencies found by the mission team had not previously been detected by the CA.

The human outbreaks of salmonellosis were generally correctly investigated.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CRL	Community Reference Laboratory
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
FBO	Food Business Operator
FVO	Food and Veterinary Office
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Points
MS	Member States
MT	Mission Team
NRL	National Reference Laboratory
OV	Official Veterinarian
PHC	Public Health Centre
PT	Proficiency Testing
RASFF	Rapid Alert System for Food and Feed
SE	<i>Salmonella Enteritidis</i>
SFVS	State Food and Veterinary Service
SNCP	Salmonella National Control Plan
SOP	Standard Operating Procedure
SOP	Standard Operating Procedure
ST	<i>Salmonella Typhimurium</i>

1 INTRODUCTION

The audit mission took place in Lithuania from 20 to 29 April 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; these aspects will be addressed in the subsequent General Audit report.

The mission team (MT) comprised two inspectors from the FVO and one observer from EFTA Surveillance Authority.

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 mission team (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 mission team 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 20 April 2009 with the CA. 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	4	County and district State Food and Veterinary Services (SFVS) offices
Laboratory visits		
National Reference Laboratory	1	
Primary production		
Farms	3	In one of them only a documentary check was carried out
Food processing facilities		
Packing centres	1	
Catering services	3	2 kindergarten kitchens and 1 hospital kitchen
Egg Product establishments	1	

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

[1] OJ L 165, 30.04.2004; corrected and re-published in OJ L 191, 28.05.2004, p.1.

3 LEGAL BASIS FOR THE MISSION

The mission was carried out in agreement with the Lithuanian 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;
- Decision 98/139 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 on the control of salmonella and other specified food-borne zoonotic agents;

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 Lithuania regarding the controls on the *Salmonella* risk in table eggs.

4.2 PRODUCTION AND TRADE INFORMATION

The MT was informed by the CA that around 700 million table eggs were packed and 60 million were processed in Lithuania in 2008. According to the CA most of them were for the national market.

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 Member States (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 adequately registered. Several programmes (e.g. cleaning and disinfection, pest control, use and disposal of animal by-products, etc.) must be presented and operational for the veterinary approval of the farm. Registration/approval procedure involves on-site visit(s) of the CA.
- There is a regular official supervision of poultry farms. Until 2009 the annual frequency of official visits of poultry farms was determined by an order of the SFVS Director which required such visits four times a year. Since 2009 this decision is delegated to the discretion of the county office. At the farms visited the MT found that the minimum target of inspection visits was twice or four times per annum.
- Detailed checklists are used when performing official controls at farm level that cover a range of issues including the evaluation of bio-security measures. The

checklist contains a section to cover the follow-up of shortcomings identified during previous inspection visits. The operator of the farm is expected to sign the inspection report and provided with a copy thereof. Where shortcomings are identified the farmer is obliged to submit a corrective action plan to the competent SFVS.

However, the MT also noted that:

- In farms with a large number of flocks the visits covered a small number of houses selected at random. In these cases the reports concerned did not identify the houses inspected, although there were deficiencies. This could hinder the follow-up of these shortcomings.
- No system based on risk assessment is used to determine frequency of official controls at farm level which is contrary to Article 3 of Regulation (EC) No 882/2004.
- The MT found shortcomings related to bio-security in the farms visited e.g. accumulation of rubbish and overgrown vegetation around houses of breeding flocks facilitating hiding of pests; dogs or cats were kept on the premises. In one of the farms visited the footbath was inadequate and egg trays were reused between different houses without being sanitised before reuse. At the same farm, where the disinfection procedure for poultry houses prior to restocking was explained to the MT, the MT noted that there was no disinfectant used in one of the houses "disinfected". Not all of these deficiencies had been addressed in the official inspection reports.
- In one district office visited the MT studied a case where an inspector had found two unregistered breeding hen flocks inside a laying hen farm. The CA reacted quickly detaining the eggs. The CA issued a registration five days later. Although the birds were well into the production age (approximately 600 days old), there was no evidence of investigation of the origin of the birds or the past destination of the incubated eggs. The farm was registered even though the programme for own checks submitted indicated the wrong frequency of sampling for *Salmonella* (sampling frequency of every three weeks instead of every fortnight as required by Part B point 1. column 3 of Annex II to Regulation (EC) No 2160/2003). No sanctions were imposed for this serious breach of sanitary rules and regulations.

Conclusions

Poultry farms are adequately registered and under regular official supervision. However, there are significant deficiencies related to bio-security and not all of them had been addressed in the official reports and therefore had not been corrected. The reports did not identify the houses inspected, although there were deficiencies. This could hinder follow-up of shortcomings.

5.2 SALMONELLA NATIONAL CONTROL PROGRAMME (SNCP) 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 *Salmonella* National Control Plan (SNCP) for breeding hens, including detailed sampling rules both for the food business operator (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.

Regulation 2160/2003 outlines how targets shall be established for the reduction of the prevalence of zoonoses, including *Salmonella*. To this end, MS have to implement national control programmes, 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 SNCP was submitted to and approved by the European Commission covering the period of year 2007-2009 for breeding flocks and 2008-2010 for laying flocks. The MT noted however, that this programme started to be implemented from March 2009 only. SFVS Director Order No. B1-62 of 12 February 2009, Standard Operating Procedure (SOP) of the quality system "Zoonosis control in poultry" put this programme into force. Formerly a national programme, which differed from the Community legislation, was applied. This programme was based on pooled samples of eggs and cloacal swabs, with different sampling protocols and frequency. This programme did not contain mandatory sampling both by FBO and CA (whereas this is mandatory in Community requirements), and this led in several cases to lack of official sampling.

An internal audit was carried out in February 2009 by Food and Veterinary Internal Audit Service. The scope of this audit was to evaluate the system in place to control the *Salmonella* risk in the table egg sector. The audit comprised visits of two county offices, two district offices and seven FBOs. The scope did not include the evaluation of official controls in the catering sector. The internal audit concluded that the national programme, which had been implemented until February 2009, was not in compliance with existing Community requirements.

In the SNCP newly applied official sampling is carried out by OVs. All official samples within the framework of the SNCP are analysed in the National Reference Laboratory (NRL). Sampling at the initiative of the operator is carried out by private veterinarians. Own check samples can be sent for analysis either to an official or a certified private laboratory.

FBOs are obliged to report positive *Salmonella* results to the CA. This is in line with Article 6 of Directive 2003/99/EC of the European Parliament and of the Council.

Reporting system: private veterinarians involved in sampling at the initiative of the operator at farms are obliged to report the results of the analysis to the competent district office on a monthly basis. In addition to the monthly reports on animal health issues from the district, city and county offices to SFVS headquarters, there is a quarterly report within the SNCP which provides the Central CA (CCA) with information on official tests carried out and the number of positives. A representative of the CCA explained to the MT that although the information on the own checks is available from the reporting system at central level, the responsibility to achieve the SNCP target remains with the respective county or district office.

Since March 2009 this new SNCP had been implemented in all the cases reviewed.

Concerning the new SNCP, the MT noted various positive points:

- In general, a correct sampling protocol was implemented at correct intervals.
- The MT saw evidence that several training sessions, meetings were held where issues on the SNCP were discussed with the OVs involved in SNCP. However, no training course on sampling in the context of *Salmonella* control has been carried out to date but one is planned for later in 2009.
- It was explained that, in principal, a compensation scheme is available to eradicate infectious diseases including *Salmonella* Enteritidis (SE) and *Salmonella* Typhimurium (ST) that may provide full compensation for the owner in the case of e.g. culling birds. The CCA indicated however, that there was no such case so far.
- The MT saw evidence that the SNCP had been presented and discussed at district level during staff meetings where the private veterinarians performing own checks at farm level were also present. CA representatives explained that private veterinarians involved in the sampling programme would be trained on the spot by an OV.

The MT however also noted different issues which are either a non-compliance with Community legislation or could compromise the efficiency of the Lithuanian SNCP:

- The MT saw one example when the OV responsible for official sampling at farm level, in his documentation, repeatedly referred to an incorrect legal basis and incorrect sampling method. However, the MT was told that in spite of this the sampling had been correctly carried out. In another case the OV interviewed by the MT appeared unfamiliar with the sampling requirements.
- In another case the MT noted that the sealing label number of the samples had never been registered at one of the district offices visited. This is neither in line with paragraph 6.2. of SFVS Director Order No. B1-62 of 12 February 2009 nor with point 7 Article 11 of Regulation (EC) No 882/2004. This practice might compromise the identification and therefore the legal validity of the sample concerned.

5.2.1 SNCP for breeding hens

- Routine sampling is carried out at the holding.
- Vaccination is at the discretion of the operator. Only registered live or inactivated vaccines are permitted to be used but SFVS has to endorse the request from the operator prior to any vaccination. 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 was informed that in the case of confirmed positive to SE or ST the flock is slaughtered or destroyed, whereas for *Salmonella* hadar, *Salmonella* virchow and *Salmonella* infantis CA might consider alternatives. Concerning the possibility of exceptionally authorising the use of antimicrobials to control *Salmonella*, by way of derogation of the general requirement in Regulation (EC) No 1177/2006, at the moment there are no guidelines on this issue, except that a decision would be taken on a case by case basis by the Deputy Director of SFVS.
- The MT was informed that to date no confirmed positive case of SE or/and ST have been found in breeding flocks.
- However, the MT noted in some cases that the samples from breeder flock were pooled to have one single result which is not in line with point 2.2.2.1. of the 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 EFSA. The sampling of the holdings took place during the period from October 2004 to 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 Lithuanian laying sector was a combined figure of 44.4 % for SE and ST in the clean dataset.

- The MT noted that in spite of the fact that the prevalence of *Salmonella* in the baseline study was over 10 % and Lithuania had not demonstrated a lower prevalence of SE based on the monitoring to follow up the Community target, no compulsory vaccination policy against SE was implemented, as it is required under point 3 Article 3 of Regulation (EC) 1177/2006. However, flocks in farms visited by the MT had been vaccinated.
- The CCA explained that if either an official or an own check sample tests positive, a confirmatory sample is taken by the OV applying the same sampling protocol used in routine official sampling. The flock concerned is placed under restriction and eggs produced may be marketed as class B eggs only. If the confirmatory sample proves negative restrictions are lifted but the competent SFVS district office may increase the frequency of official sampling of the flock concerned. If the confirmatory sample tests positive the flock is slaughtered or destroyed.

- The MT studied a case where SE was detected by the NRL in official samples from a laying hen house. The CA placed that house under restrictions i.e. the eggs were detained and sent for thermal processing. Then official confirmatory samples were taken that comprised of five faecal samples (150 g each) and two dust samples (25 g each) plus one pooled faecal sample and one pooled dust sample. The test results of these nine samples were negative. At the same time also two egg samples (containing ten eggs each) were analysed with negative results. Other laying flocks on the holding were not sampled although it is required by point 2.1. (d) of the Annex to Regulation (EC) No 1168/2006. The CA explained that the decision not to sample the other flocks had been based on the belief that the original results were false positive since the flock concerned never had a *Salmonella* history and there were no clinical signs of salmonellosis in the birds. Documentary review was carried out to verify the absence of use of antimicrobials without laboratory test. The MT noted however that in the majority of confirmed human *Salmonella* outbreaks due to the consumption of eggs in 2006 and 2007 and also in a Rapid Alert System for Food and Feed (RASFF) alert related to contaminated eggs in 2006, the eggs had originated from this farm. When visiting this farm the MT observed bio-security breaches, some of them significant. After the negative results of the confirmatory samples all restrictions were lifted. The CA did not carry out or foresee an increased sampling or surveillance.
- In another case the MT noted that the official sampling reports did not identify the house sampled.

Conclusions: SNCP on breeding and laying hens

Until March 2009, the CA applied a national programme that differed from the Commission-approved SNCP. The SNCP now in place contains correct sampling protocol and correct sampling intervals, although the efficiency and reliability of the SNCP is undermined by the deficiencies in its implementation.

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 establishment, 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 III to Regulation (EC) No 853/2004 lays down more specific criteria for eggs and egg products.

Audit findings

Egg packing centre

In the packing centre visited a Hazard Analysis and Critical Control Points (HACCP) system was implemented. The own-checks included periodic testing of eggs for *Salmonella* (60 eggs per month) and water analysis. The conditions were overall adequate. However the MT found minor deficiencies (e.g. the storage room for packaging material was not pest proof) which were not addressed in the inspection reports.

In accordance with the risk assessment system in place the egg packing centre visited was categorised as a medium risk establishment which involves at least one inspection visit per year from the district SFVS. In addition to this inspection, once a year the HACCP system is audited by a county SFVS inspector. The MT found that in this establishment, three inspection visits had already been performed by the CA in 2009.

The MT noted several cases where the labelling advised storing eggs, including those for the final consumer, at a temperature from 5 to 18° C, which is not in line with point 1. (f) of Article 12 of Regulation (EC) 589/2008, which specifies that the final consumer should be advised to keep eggs chilled.

Egg product establishment

The establishment had adequate layout and maintenance. It operated under a well-documented HACCP plan, and own-checks results were available for egg products and potable water. An adequate traceability system was in place. The establishment was categorised as medium-risk establishment and routinely inspected at least once a year. The MT was informed that the HACCP system was audited as a part of this routine visit when the district SFVS inspector was accompanied by a HACCP specialist from the county office.

- The MT found no evidence that official samples for microbiological analysis were taken in any of the establishments visited. As it is indicated in the horizontal part of the report, only in case of suspicion or human outbreaks are official samples taken.
- The MT was informed that no guide to Good Hygiene Practice (GHP) has been developed so far for the egg processing sector.

Conclusions

The SVFA control system at establishment level is overall adequate. The labeling of eggs is in some cases is not in compliance with Regulation (EC) 589/2008.

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 all FBOs.

Audit findings

The MT visited two kindergarten kitchens and a hospital kitchen.

The MT was informed that catering establishments could choose to use a GHP guide or full HACCP for their own checks. Most of the establishments opted for Good Hygiene Practices (GHP). The GHP guide was issued in 2004 and endorsed by the Ministry of Health (MoH) and the SFVS, however this guide has not been revised since Regulation (EC) No 852/2004 became applicable. In the catering establishments visited the MT noted that the GHP guide was properly implemented. The MT was informed by the CCA that the GHP guide concerned is being revised by the MoH and the SFVS.

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: Reliability of the HACCP system, consumer complaints, incidents of outbreaks and past records of non-compliance. Catering establishments supplying food to susceptible consumers (e.g. home for elderly, kindergarten or hospital kitchen, etc.) are also categorised into risk groups by applying this system however, the risk associated with these special consumer groups is not taken into account. All three catering establishments visited were categorised as medium-risk establishments obliging one official inspection visit per year.

In two catering units visited by the MT the target of inspection frequency was achieved but in one of them there was one visit less than planned in 2007. A detailed checklist is used during the routine official visits, which includes the evaluation of HACCP/GHP system. The MT noted that own check systems were adequately assessed in the cases studied.

At present there is no national requirement for systematically retaining meal samples of meals prepared in public catering establishments. This is not a Community requirement, although in the case of outbreaks could facilitate their investigation. In the hospital kitchen visited this was a regular practice.

There is a national law in place which makes cleaning and disinfection of eggs mandatory before they are broken in catering establishments. The MT observed that it was carried out properly in all the catering premises visited.

The MT noted that all kitchen staff should undergo training for six hours in good hygiene skills before they start working and then every two years. The employees must present a certificate which is valid for two years to testify that the training was completed. This system was well implemented but in one establishment, the MT found longer validity dates in all of these certificates. However, the MT was informed by the CCA that this national legislation restricting the validity of training certificates to two years is being revised and in the new provisions the validity will be extended to five years.

The conditions in catering premises visited by the MT were overall adequate but minor deficiencies were observed (e.g. poor maintenance of facilities and equipment, lack of fly-screens in the kitchen, potential cross-contamination due to inadequate layout). Some of these deficiencies were not addressed in the inspection reports. However, in one of the kindergarten kitchens visited the MT found structural deficiencies that had been detected

by the CA and reported to the municipality asking for corrective actions. The municipality in question explained that they had no budget for funding the corrective measures.

Conclusions

There is an adequate control system in place, based on risk assessment. Conditions were generally adequate in two of the three premises visited. However, the GHP guide broadly used in the public catering sector has not been revised in the light of the applicable Community legislation.

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 cooperation and coordination 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 23 in 2006 (three linked to eggs), 15 in 2007 (four linked to eggs) and 31 in 2008 (none linked to eggs).

There is a clear and effective system for notification. Most cases of salmonellosis are reported by doctors or hospitals to the county Public Health Centres (PHC). County PHCs have an obligation to inform, within two hours in oral form and within 12 hours in writing the respective district SFVS. The information reported contains: name of the disease, the name of the FBO suspected to be involved, number of persons affected and the suspected source of infection. County PHCs are also responsible to identify and locate potentially affected customers to arrange laboratory sampling of persons involved, suspend persons handling food from work if suspected to be infected.

Based on information received from county PHCs, officials of the county SFVS and the district SFVS must carry out a joint on-site inspection of the food businesses involved in the outbreak. An epidemiologist of the PHC can join the inspection team if required. This official control includes inter alia the evaluation of the own check system and GHP of the establishment concerned, sampling of products or raw materials and impose restrictions on products or activities if appropriate.

The MT noted several positive elements in the CAs investigations:

- Quick reaction, inspection with extensive sampling carried out on the same day as the notification in the suspect premises.

- There was quick and regular communication between SFVS and PHC.
- In the outbreaks studied by the MT the source of infection was traced back to the farm of origin and extensive sampling carried out on eggs. However, the MT also noted that although the majority of 2006 and 2007 *Salmonella* outbreaks related to eggs were traced back to the same farm, investigations carried out by the SFVS always failed to prove infection of flocks in that farm.
- The PHC had clear procedures when potential carriers were permitted to return work.
- The MT was informed that after the outbreaks studied a series of meetings were held between the CAs and the establishments involved in the outbreaks for training purposes.
- The MT saw evidence, in outbreak investigation documentation reviewed, that the CA suspended activities of the food businesses involved and also cases when financial sanctions were imposed by SFVS against kitchen employees. However, the MT was informed that in fully confirmed cases of *Salmonella* outbreaks in humans, the State Consumer Rights Protection Service is competent to impose financial sanctions.

Conclusions

The CAs have systems in place to co-operate and react quickly to notification of suspect food-borne outbreaks. Extensive testing is carried out, corrective measures and financial sanctions are imposed for the detected deficiencies. However, the flocks suspected as source of *Salmonella* infection in food-borne outbreaks were never proved to be positive.

5.4 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 control authorities with an effective tool for exchange of information on measures taken to ensure food safety.

Audit findings

Based on the information received from another Member State through RASFF, the SFVS responded very quickly and carried out an investigation at the farm of origin of the eggs. This investigation included an extensive sampling of feed, table eggs, cloacal swabs from hens, faecal material, dust and swabs from conveyor belts. All samples tested negative for *Salmonella*.

The result of the investigation and the measures taken were reported through the RASFF system.

Conclusions

The CA response to RASFF notification was overall adequate.

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),
- Take into account criteria for different testing methods laid down in Community feed and food law.

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

- The CA has sufficient laboratory capacity to perform official controls.
- The National Food and Veterinary Risk Assessment Institute Laboratory Department, bacteriology and food microbiology section has been designated as the NRL for *Salmonella* analysis. Under the SNCP official samples are analysed in the NRL only, which is accredited by the German Accreditation Council *Deutscher Akkreditierungs Rat*.
- The NRL visited had good facilities and qualified staff. The NRL participated regularly in proficiency testing (PT) organised by Community Reference Laboratory (CRL). The MT noted that in 2008 in one such test 6 out of 25 samples were not correctly tested. The MT was shown evidence that after the incorrect test results NRL contacted CRL and asked for assistance. Subsequently all 25 samples were correctly evaluated in the next such exercise.
- There is a network of laboratories in the SNCP involved in own-check testing. Private laboratories participating in SNCP must be certified by the NRL, which involves the need to use a simplified version of the ISO Standard 17025 as well as some documentary/onsite checks by NRL staff.
- The NRL has organised PT for laboratories, with satisfactory results in most cases. A NRL representative explained that where a participating laboratory obtained

unsatisfactory results, they would be willing to provide assistance and training, although in their view the initiative would lie with the laboratory that failed the proficiency test. The MT noted however that no PT have been organised yet on faecal material, which would be the most relevant to the SNCP. This is not in line with Article 12 of Regulation (EC) No 2160/2003.

- The MT was informed by a representative of the NRL that there was a Standard Operating Procedure (SOP) in place which provides instructions and criteria to accept or reject (e.g. non-compliant) incoming foodstuff samples. However, in the case of non-food samples (e.g. faecal material) the SOP foresees a case-by-case decision by the head of the department. A laboratory representative indicated that a more exhaustive SOP is being developed in this area.

Conclusions

There is a sufficient network of laboratories participating in SNCP. The NRL which is carrying out all official testing within the framework of SNCP is accredited. Those carrying out analyses on own check samples are either accredited or certified. Although several PT are organised by the NRL, no PT have been organised yet on faecal material, which would be the most relevant to the SNCP.

6 OVERALL CONCLUSION

Concerning the SNCP, until March 2009, the CA applied a national programme that differed from the Commission-approved programme. The programme now in place and approved by the Commission is well designed, although its efficiency and reliability is undermined by the deficiencies in its implementation.

Concerning controls at establishment level, the situation is overall positive, although some deficiencies found by the MT had not previously been detected by the CA.

The human outbreaks of salmonellosis were overall correctly investigated.

7 CLOSING MEETING

During the closing meeting held in Vilnius on 29 April 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 one month of receipt of the report in

order to address all the deficiencies identified in the report and in particular, the following:

No.	Recommendation
1	The CA should ensure that adequate bio-security standards are present in breeding and laying hen farms, according to the relevant SNCP.
2	The sampling method applied in breeding flocks and laying flocks should comply fully with Community requirements in Regulations (EC) Nos 2160/2003, 1003/2005 and 1168/2006, correcting all deficiencies mentioned in this report.
3	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 Regulation (EC) No 2160/2003 and in particular point 2.1. (d) of the Annex to Regulation (EC) No 1168/2006.
4	The CA should ensure that the vaccination policy implemented is fully in compliance with the requirements of point 3 Article 3 of Regulation (EC) No 1177/2006.
5	The CA should ensure that eggs are labelled and marked in accordance with criteria set in Regulation (EC) No 589/2008 concerning advice on storage of eggs by the final consumer.
6	The CA should ensure that the GHP guide used in the catering sector is in line with the applicable Community legislation in accordance with Article 8 of Regulation (EC) No 852/2004.
7	The CA should ensure that laboratories involved in the SNCP regularly participate in collaborative testing, particularly on faecal material, in line with Article 12 of Regulation (EC) No 2160/2003. This collaborative testing should be organised or coordinated by the NRL.

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

http://ec.europa.eu/food/fvo/ap/ap_lithuania_8069_2009.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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 Regulation (EC) No 852/2004 of the European

Reference	OJ Ref.	Detail
		Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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)
Regulation (EC) No	OJ L 163, 24.6.2008, p.	Commission Regulation (EC) No 589/2008 of 23 June 2008 laying down detailed rules for

Reference	OJ Ref.	Detail
589/2008	6-23	implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs