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FINAL REPORT OF A MISSION  
CARRIED OUT IN  
SPAIN

FROM 05 TO 14 JULY 2010

IN ORDER TO EVALUATE THE NATIONAL PROGRAMMES FOR THE CONTROL OF  
SALMONELLA IN SPECIFIC POULTRY POPULATIONS (BREEDERS, LAYING HENS,  
BROILERS, TURKEYS)

*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 Spain, from 5 to 14 July 2010.*

*The objective of the mission was to evaluate the actions taken by the Spanish competent authorities in order to control Salmonella, in particular concerning the implementation of the Salmonella National Control Programmes for various poultry populations.*

*The report concludes that the Salmonella National Control Programmes, which include a system of comprehensive, regular and well-documented biosecurity checks, are implemented in all Autonomous Communities. Significant efforts have been made in their implementation. However, their effectiveness is hindered by several weaknesses, in particular: the confirmatory sampling policy which is currently inadequate, the policy followed in the case of positive dust but negative faecal samples in laying flocks (to be changed in 2011) and own-check broiler sampling policy in some Autonomous Communities which is based on holdings instead of flocks. Although an electronic database and reporting system is available for the competent authorities in order to have an adequate review and evaluation of the Salmonella National Control Programmes' progress as required under European Union legislation, the deficiencies and inconsistencies found in particular in the sampling documents and official biosecurity check reports could undermine the reliability of competent authority evaluation in some cases.*

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

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
AC	Autonomous Community
CA	Competent Authority
CCA	Central Competent Authority
CRL	Community Reference Laboratory
EFSA	European Food Safety Authority
FBO	Food Business Operator
FCI	Food Chain Information
FVO	Food and Veterinary Office
GHP	Good Hygiene Practices
MARM	Ministry of the Environment, Rural and Marine Affairs
MS	Member State/s
MT	Mission Team
NRL	National Reference Laboratory
OV	Official Veterinarian
PT	Proficiency Test
RASFF	Rapid Alert System for Food and Feed
SE	<i>Salmonella enteritidis</i>
ST	<i>Salmonella typhimurium</i>
SNCP	<i>Salmonella</i> National Control Programme

## 1 INTRODUCTION

The mission took place in Spain from 5 to 14 July 2010 and was undertaken as part of the Food and Veterinary Office's (FVO) planned mission programme.

The mission team (MT) comprised two inspectors from the FVO and another DG SANCO official.

## 2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the actions taken by the competent authority (CA) in order to control *Salmonella*, in particular concerning the implementation of the *Salmonella* National Control Programme (SNCP) in the different poultry populations.

In order to achieve this objective the MT evaluated the organisation of the CA and its capacity for implementing the relevant Community requirements.

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

- an opening meeting was held on 5 July 2010 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 CA (CCA)	1	Ministry of the Environment, Rural and Marine Affairs (MARM)
Autonomous Community (AC) CA	3	The MT visited three CAs at AC level: Andalusia, Catalonia and Galicia and within two ACs, CAs at district and local level were visited.
Laboratory visits		
National Reference Laboratory (NRL)	1	
Regional official laboratory	1	(This laboratory also performs analyses on own-check samples)
Own-check laboratory	1	
Primary production		
Breeding hen farms	2	
Laying hen farms	2	
Broiler farms	2	

- representatives from the CCA and from the regional CAs accompanied the MT during the whole mission.

## 3 LEGAL BASIS FOR THE MISSION

The mission was carried out in agreement with the Spanish Authorities and under the general provisions of EU 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 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

## **4 BACKGROUND**

### **4.1 HISTORICAL BACKGROUND**

A previous mission to evaluate the system in place to control the *Salmonella* risk in the table egg sector took place in 2006 (ref. DG(SANCO)/8143/2006), and the report is published on the Health and Consumers Directorate-General's Internet site at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 COMPETENT AUTHORITY**

MARM, as the CCA, in particular the Directorate General for Agricultural and Livestock Resources is responsible for basic legislation in relation to *Salmonella* controls. MARM is responsible for coordinating SNCP implementation, including the drafting and the issuance of relevant guidelines. A great deal of information related to the SNCPs has been prepared by MARM and distributed throughout Spain and also published on the MARM's website.

MARM's coordination role is mainly realised through working group meetings with the ACs and with the laboratories (including NRL) involved in the programmes. At the request of the ACs, MARM can participate in epidemiological surveys (especially in complicated cases). MARM also cooperates in organising training courses on the SNCPs.

MARM has a key role in data collection and analyses. An electronic database and reporting system is in place to collect data from the ACs. This application facilitates MARM not only in collecting data but also in monitoring the implementation of the SNCPs (both own-checks and official controls) in the ACs. The MT saw numerous examples when in the case of discrepancies the CCA contacted the AC and requested clarification or further data. The MT noted that the CCA has limited power to go beyond its coordination and communication roles. The CCA has a role in liaising with the ACs or other Member States (MS) as required.

The ACs are directly responsible for the implementation of SNCPs. The SNCPs are translated into the languages of the ACs if relevant and the ACs may draft their own implementing legislation (e.g. more detailed implementing measures to the SNCP), as long as it is in line with the SNCP and with EU legislation.

A more detailed description of the CCA can be found in the country profile for Spain on the following website: [http://ec.europa.eu/food/fvo/last5\\_en.cfm?co\\_id=ES](http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=ES).

### ***Training***

Royal Decree No 1084/2005 stipulates that poultry keepers involved in poultry meat production must participate at least in 20 hours of training. This training covers poultry meat production including animal health, welfare and biosecurity measures. The MT was informed by the CCA that 80% of the poultry keepers in the meat sector had already participated in this training programme. Such training is not compulsory in the laying hen sector, however it is strongly recommended by the SNCP. In one of the ACs visited the MT saw evidence that during official farm inspection

compliance with the mandatory training requirement was checked. In all ACs visited the MT found documentary evidence on the training courses and also saw leaflets, guidance documents, CDs, etc prepared for the training of poultry producers.

In all ACs visited the MT noted evidence on several occasions that meetings, training courses (including e-learning courses) were held for veterinarians involved in the implementation of the programmes. However, the MT also noted in one AC visited that until recently (29 June 2010) no specific training had been organised on the implementation of the SNCPs for official veterinarians (OVs) since 2006.<sup>1</sup>

### Internal audits

According to the information received from the CCA, in 2008/2009 in seven ACs internal audits were carried out specifically on the implementation of the SNCPs. All three ACs visited were audited, in one of the ACs the audit was carried out by an external company. The MT noted that after the audits CAs drew up and implemented corrective action plans to correct the deficiencies.

The main findings/recommendations of these audits (some of them similar to those found by the MT) were:

- CA should improve coordination between different services/departments/units involved in the implementation of the SNCPs.
- There was a failure to complete the specific sections of the sampling form and protocols for checking compliance with biosecurity measures.
- There was inadequate follow-up of implementation of certain corrective measures for biosecurity of farms.

In one of the ACs visited the MT noted that corrective measures in response to the recommendations of the internal audit resulted in a revised AC control programme, valid from 2010.

## **5.2 CONTROLS AT FARM LEVEL**

### **Legal requirements**

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

Annex I to Regulation (EC) No 852/2004.

Chapter I of Annex II to Council Directive 2009/158/EC requires at least one inspection per year per holding by an OV in order to be approved by the CA for the purposes of intra-EU trade in poultry or hatching eggs.

### **Findings**

The farms visited by the MT were adequately registered in the “General Registry for Livestock Farms” database (REGA Registro General de Explotaciones Ganaderas) and were subject to regular official controls. A standard checklist was used for verifying biosecurity measures. Biosecurity measures are controlled and documented when official samples are taken for *Salmonella* analyses. In broiler flocks this biosecurity checks are also performed at least once a year even if only 10 % of the holdings are mandatory to be subject to official sampling annually. The MT noted that each SNCP contains a Guide to Good Hygiene Practices (GHP) for the control and prevention of

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<sup>1</sup> In their comments on the draft report the CA indicated that the OVs from this region had the possibility to access other training sessions on general topics related to poultry and *Salmonella*.

zoonotic *Salmonella* at farm level. These guides were drawn up by the CCA in cooperation with the relevant poultry organisations.

The MT noted that verifying biosecurity measures at farm level is a key point in the implementation of the SNCPs. Although this is not strictly a EU requirement, it can be a very useful tool. Information (e.g. general biosecurity measures, origin of the birds, feed control, cleaning and disinfection, pest control, use of veterinary medicinal products, veterinary supervision and own-check sampling) obtained and recorded on the checklist during these controls is entered into the electronic database by the ACs. In one of the ACs visited the MT noted that a special section was added to the checklist to cover follow-up of deficiencies.

- However, in the same AC when reviewing records of biosecurity checks, the MT noted that in some cases, although recurring deficiencies related to biosecurity were found by the OV, the CA did not carry out any enforcement action. The difficulty on enforcing certain requirements was also reported in other ACs.
- In one of the laying hen farms visited, which had several positive flocks in 2010, the MT found that there was garbage and overgrown vegetation (weeds) around the poultry houses (good hiding place for pests) and there was a pig farm in close proximity to the houses. A CA representative explained that it was their view that the adjacent pig farm could be linked to the repeated positives. However, the farmer considered these positives to be linked to laboratory problems and inadequate vaccines. The MT also noted that the farm veterinarian was not familiar with the rules concerning pest controls.
- In a broiler farm visited, which had positive cases the MT found that the farmer did not change working clothes between the houses, only shoes.
- In some cases the MT found inconsistencies and contradictions in the official reports on biosecurity measures, for example:
  - In the first report of a holding there had been no problem cited as regards the perimeter fence while in the subsequent report it was remarked that the holding had no perimeter fence at all.
  - Sometimes mutually exclusive options had been ticked on the checklist.
  - In some cases the own-check part of the report was left blank, while this should be a key element for verification of the implementation of own-checks.

Adequate records (animal treatment, mortality, vaccination, sampling, etc.) on flocks were kept at farm level in all ACs visited.

#### Water control

During the farm visits the MT found that water was analysed by the Food Business Operators (FBOs) regularly (at least once per year). However, in one of the breeding farms visited the MT noted that although the own-check analyses results showed the contamination of water with *E. coli*, no corrective action had been taken by the FBO.

#### Feed control

A comprehensive study was carried out on feedingstuff production (Coordinated study for determining the presence of *Salmonella* and other microbiological agents in feed-producing establishments) and concluded that, in general, feedingstuffs are safe in Spain. The SNCPs stipulate that control measures should be taken by the FBOs to avoid *Salmonella* contamination of flocks from feedingstuffs. The MT noted on several occasions that these controls amounted to a certificate supplied by the feed supplier to the FBO.



- However, the MT noted in one of the breeding farms visited that these certificates were out of date (three years old).

### Cleaning and disinfection

The SNCPs stipulate that after slaughter or destruction of an infected flock an effective cleaning and disinfection must be carried out by the FBOs. Poultry houses are not permitted to be repopulated unless the effectiveness of the cleaning and disinfection is confirmed by negative environmental sampling results. To evaluate the effectiveness of these procedures at least ten samples shall be taken from the environment. These samples may be pooled into a maximum of two pools.

- The MT noted in some cases that the number of environmental samples taken was not met and in other cases exceeded the requirements laid down in the SNCP.

### Epidemiological surveys

In all ACs visited the MT noted that in the case of positive flocks epidemiological surveys were carried out to identify the possible source of contamination. These surveys included the taking of official samples from water, feed and in some ACs from birds. In Catalonia, the emphasis was made on sampling to search for antimicrobials, in Galicia the emphasis was on sampling for *Salmonella* and in Andalusia this would be the discretion of the local inspector.

## **Conclusions**

Farms are appropriately registered, and under regular official supervision. Adequate tools to prevent *Salmonella* contamination are in place, such as effective cleaning and disinfection, controls on biosecurity conditions and on feedingstuffs. Although a significant effort is being made by the CAs, these tools are not yet fully effective due to some deficiencies in their implementation and some inconsistencies in reporting.

## **5.3 SNCP FOR BREEDING HENS**

### **Legal requirements**

Regulation (EC) No 2160/2003 outlines how targets shall be established for the reduction of the prevalence of zoonoses, including *Salmonella*. The target for breeding hens has been fixed by Regulation (EC) No 200/2010. To achieve the targets, MS have to implement a SNCP in breeding hens, including detailed sampling rules both for the FBO and for the official services. However, for those MS whose SNCP in breeding hens were approved in line with Regulation (EC) No 1003/2005, the provisions contained in the Annex of this Regulation are still applicable.

### **Findings**

Although there is no EU legal obligation for vaccination of breeding flocks, the CA informed the MT that the vast majority of breeder flocks are vaccinated. It was confirmed by the files reviewed by the MT.

Under the SNCP for breeders a flock is considered positive when *Salmonella* has been isolated during an official control and the serotyping carried out by an official laboratory (the NRL or an AC approved laboratory) is positive to any of the five relevant *Salmonella* serotypes.

The CCA explained that if a breeder flock tests positive in own-check analyses to any of the five relevant *Salmonella* serotypes, it is considered as a suspect case and then the CA carries out a routine official verification sampling by using the normal sampling protocol. *Verification sampling* is an official sample taking and analysis to verify the FBO's own-check positive results, as defined

by the CCA (no such term exists in the relevant EU legislation). No official restrictive measures are applied against the flock concerned until the initial positive own-check result is confirmed by the official verification result. Moreover, as the MT was informed, in exceptional cases the CA may decide to conduct further confirmatory analysis to exclude false results of the official sampling. The MT was informed by the CCA that the latter is restricted to exceptional cases and not recommended.

All this policy is not in line with point 1 of Annex II C to Regulation (EC) No 2160/2003, which stipulates that if the CA approved the method of own-check analyses then the CA may require that the measures specified in the Regulation should be taken. (See chapter 5.8 concerning the situation of laboratories performing analyses of own-check samples). Also, Regulations (EC) Nos 200/2010 and 1003/2005 indicate that sampling may be repeated in exceptional cases where there are suspicions of false results.

The MT noted that the SNCP for breeders was implemented in all of the ACs visited.

- However, when reviewing own-check and official control documents, in several instances the MT found that the number and volume/weight of samples taken were not clearly indicated in the sampling documents (e.g. instead of five pairs of boot swabs only five boot swabs). However, the MT also noted when the sampling data was entered in the electronic database system by the CA these unclear details were adjusted (e.g. from the database it appeared that five pairs of boot swab samples were taken although the sampling documents did not show this).
- In some cases the samples were pooled for analysis into one sample instead of the minimum of two pools which is not in line with point 2.2.2.1. of Annex to Regulation (EC) No 1003/2005.
- In one of the breeding farms visited only one pair of boot swab samples was taken instead of five pairs.

These deficiencies were not addressed in the official reports.

The MT noted that after a positive official sample result official restrictive measures were taken (e.g. movement restriction) following which the CA ordered the destruction of the flock and eggs and an epidemiological survey is carried out in accordance with the SNCP. Restocking of the houses was allowed only with the permission of the CA.

## **Conclusions**

The SNCP for breeders is being implemented however, with some deficiencies in sampling. The confirmatory sampling policy currently followed by the CA is not in line with EU requirements.

### **5.4 SNCP FOR LAYING HENS**

#### **Legal requirements**

Both Regulation (EC) No 2160/2003 and Regulation (EC) No 1168/2006 lay down rules for the SNCP in the laying hens population of the MS.

#### **Findings**

Vaccination of each laying hen flock is mandatory in Spain in line with EU legislation. The MT noted in all ACs visited that it was correctly applied.

According to the SNCP for layers a flock is considered positive when *Salmonella* has been isolated during an official control and the serotyping carried out by an official laboratory (the NRL or an AC approved laboratory) is positive to either *Salmonella enteritidis* (SE) or *Salmonella typhimurium*

(ST). The CCA explained that if a layer flock tests positive in own-check analyses, it is considered as a suspect case and then the CA carries out a routine official verification sampling by using the normal sampling protocols. Verification sampling is an official sampling and analysis to verify the FBO's own-check positive results, as defined by the CCA (no such term exists in the relevant EU legislation). According to the SNCP, no official restrictive measures are applied against the flock or the eggs concerned until the initial positive own-check result is confirmed by the official verification result, although in Catalonia the CA indicated that it would take restrictive measures after a positive own-check result. Moreover, as explained to the MT, after positive official results, an official confirmatory testing is routinely carried out by using one of the sampling protocols laid down in point 4(b) of Annex II D to Regulation (EC) no 2160/2003. These procedures are not in line with the provisions laid down in Annex II D to Regulation (EC) No 2160/2003, which stipulates that eggs shall not be used for direct human consumption if they originate from flocks that are suspected of being infected. The CCA informed the MT, that from 2011, confirmatory sampling in laying hen flocks would be allowed only in exceptional cases.

The MT was informed by the CCA that where only the dust sample tests positive (i.e. faecal sample tests negative) for SE/ST during official sampling, although it would be reported to the European Food Safety Authority (EFSA) as a positive flock, no restrictive measures would be taken against the flock or the eggs. The CA would impose restrictive measures only for the samples testing positive in faecal material. This is not in line with the objectives of EU legislation, especially with point 1 Article 1 of Chapter 1 of Regulation (EC) No 2160/2003. The aforementioned Article stipulates that the purpose of the Regulation is to ensure that proper and effective measures are taken to control *Salmonella* and other zoonotic agents in order to reduce the risk they pose to public health. The CCA indicated to the MT that this policy has already been brought in line with the EU requirements in the SNCP for 2011.

The MT noted that SNCP for layers was implemented in all the ACs visited and in general samples were correctly taken.

- However, the MT found some cases when samples were not taken in the appropriate timeframe (e.g. in the case of pullets more than two weeks prior to entering the laying phase), and sampling intervals as laid down in the SNCP are not always respected (e.g. in some cases of own-checks there were more than 15 weeks between sampling sessions).
- The measures taken after positive cases in general were in accordance with the relevant SNCP. However, the MT noted in one of the ACs visited that the time between the availability of positive own-check results and the first official restrictive measure was from two weeks to 1.5 months.

## **Conclusions**

The SNCP for layers is being implemented however, with some deficiencies in sampling. The confirmatory sampling policy and policy followed in the case of positive dust but negative faecal samples at the time of the mission is not in line with EU requirements.

### **5.5 SNCP FOR BROILERS**

#### **Legal requirements**

Both Regulation (EC) No 2160/2003 and Regulation (EC) No 646/2007 set rules for the SNCP in the broiler population of the MS.

#### **Findings**

The MT noted that the 10% target for official sampling of holdings has been implemented in all

ACs visited. In some cases this target has even been exceeded. Concerning the criteria for selecting holdings to be subject to official sampling, this differs among ACs. In Catalonia for instance official sampling was mostly attributed depending on census and random selection, and the workload of the district concerned. In Galicia risk criteria also included with the requirement to cover all integrators and possible information on public health risk.

The MT noted that once a positive was detected in an own-check, the CA carried out a follow-up of the case, conducting an epidemiological survey, taking samples of feed/water and ensured adequate cleaning and disinfection, which is a key measure. Also new official samples of the next round of birds were taken. In one of the ACs visited the farmer was required to communicate to the CA the results of the next two consecutive own-checks, and a dialogue was made with the integrator to discuss the case.

However the MT also noted some deficiencies:

- In one farm with positives only one pair of socks was being taken in the own-checks (and not the required two). This was indicated by the farmer and was supported by laboratory results documents. This non-conformity was not detected during official controls. Regarding this case the CA provided the MT with some contradictory information before the final meeting, as a veterinarian working for the integrator sent an electronic document indicating that the sampling in the farm was correct.
- The MT noted in one of the ACs visited that the own-check sampling was based on holdings and not flocks as required under EU legislation. According to point 3(b) of Article 2 of Regulation (EC) No 2160/2003 a flock, in the case of housed poultry, means all birds sharing the same airspace and point 1(a) of Annex to Regulation (EC) No 646/2007 stipulates that the sampling frame shall cover all flocks of broilers. The CCA confirmed to the MT that according to their opinion in the aforementioned case all houses constituted a single batch and therefore it is an acceptable policy, (provided birds are maintained under the same conditions) although in other ACs visited the own-check sampling was based on flocks.
- It is clearly indicated in the CAs' system that positives to *Salmonella* controls should be part of the Food Chain Information (FCI). Additionally in Andalusia positivity was highlighted in the sanitary movement certificate (guia). This was not the case in Catalonia. In this AC this positivity would be reflected only in the FCI. The MT requested information from the Catalonian CA concerning the FCI details for several movement certificates of positive flocks. However, these movement certificates (FCI) did not contain details of the *Salmonella* status of the birds as it was not mandatory under Catalonian implementing measures to report this information at the time the certificates were drafted. This became mandatory from September 2009 and therefore at the time of the mission this was already part of the CA's written procedures.
- According to information provided by the CA to the MT in some of the ACs there is a discrepancy in the positivity between own-checks and official controls in broiler flocks. In one of the ACs visited the discrepancy was significant (i.e. out of 2,227 own-check samples 0 tested positive, whilst out of 98 official samples 8 tested positive). The AC CA representative acknowledged the finding and indicated that they would investigate this.

## Conclusions

The SNCP for broilers is being implemented however, with some deficiencies in sampling. Own-check sampling policy based on holdings instead of flocks (in some ACs) is not in line with EU requirements.

## **5.6 SNCP FOR TURKEYS**

### **Legal requirements**

Both Regulation (EC) No 2160/2003 and Regulation (EC) No 584/2008 set rules for the SNCP in the turkey population of the MS.

### **Findings**

The MT noted that the AC CAs had distributed information to stakeholders on the SNCP for turkeys. The MT also noted that in all of the ACs visited and where relevant the programme is beginning to be implemented. However, according to the Catalan CA due to other priorities official testing has not yet started in this AC. Nevertheless, own-checks are already in place. In Galicia official testing has already started and the CA indicated that the target for official tests in 2010 will be met. The MT also noted that the data available on turkeys are preliminary and some data may not have yet been recorded in the electronic database.

### **Conclusions**

It is too early to evaluate implementation of the SNCP for turkeys as it is only mandatory from 1/1/2010. However, CA and farm operators are aware of their obligations and the programme is beginning to be implemented in the ACs where relevant.

## **5.7 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) FOLLOW UP**

### **Legal requirements**

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

### **Findings**

Between 2008 and the date of the mission there were eight RASFF notifications (six alerts and two information notifications) linked to Spanish eggs, either because of food-borne outbreaks of *Salmonella* which were claimed to be due to the consumption of Spanish eggs or because the bacteria was isolated from such eggs. In one of the ACs visited the MT reviewed a case when a SE positive result of a faecal sample taken during official controls from a laying hen flock also triggered a RASFF alert. The MT noted that adequate follow-up measures were taken (e.g. public health authorities were notified to take further measures with the eggs; the flock was culled; an epidemiological survey was carried out) by the CA in accordance with the SNCP.

### **Conclusions**

The CA response to RASFF notification was overall adequate.

## **5.8 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 meet certain quality standards.

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 and to participate in collaborative testing.

The relevant regulations for the different poultry populations lay down rules for the detection method (Annex D of ISO 6579) to be used in the context of SNCPs.

## Findings

The Spanish *Salmonella* NRL is accredited by the Spanish National Accreditation Body (ENAC) for identification/isolation of *Salmonella* spp. in accordance with EN ISO/IEC standard 17025. Since June 2010 the NRL has also been accredited for serotyping of *Salmonella* strains and it intends to seek accreditation for testing for antimicrobial resistance in 2011.

The NRL regularly participates in proficiency tests (PTs) organised by the Community Reference Laboratory (CRL) with consistently good results. At the moment, phagetyping is not carried out in the NRL, but in the Public Health Institute Carlos III.

The NRL has also the capability to carry out testing to distinguish the field strain of *Salmonella* from a wild strain, when needed.

Apart from its own role as a laboratory, the NRL plays a significant role in the organisation of the laboratory network in the context of the SNCPs. This is done through organisation of PTs and training courses.

PTs are organised on a regular basis and separately for official laboratories and for the own-check laboratories. The participation in PTs is a pre-requisite for participation in the SNCP tests. The PTs organised by the NRL are comprehensive, follow the same approach to those implemented by the CRL. PTs are organised also for serotyping. However, participation in these tests is not mandatory, as several ACs do not serotype or serotype only SE/ST. The vast majority of PT results were satisfactory with the few failing laboratories being mostly private laboratories (e.g. one in 2009). In the case of failing a PT, the MT noted that the NRL correctly took the appropriate follow up measures, such as submission of new set of samples to the laboratory concerned (then it was correctly tested) and training took place in the NRL.

The MT noted that the NRL staff regularly participated in training seminars organised by the CRL and other international institutions. NRL also organise training for the laboratories involved in the SNCP, for instance one yearly course on serotyping. In addition, the NRL in cooperation with the Health Programmes and Zoonosis Unit of MARM organised meetings with the laboratories (including laboratories performing own-check analyses) involved in the control programmes to discuss the relevant issues (e.g. electronic database application, PT results, sampling requirements of the different SNCPs, data required in sampling documents, notification of results, etc). The MT saw documented evidence that these meetings took place. The MT also noted evidence that the NRL and the Health Programmes and Zoonosis Unit, both departments of the MARM coordinate well.

According to information received from the CCA, all laboratories involved in the SNCP programmes use the reference method (ISO 6579) for *Salmonella* analyses. In the SNCPs there is a clear obligation on all laboratories to notify positive results to the CA and to reject non-compliant samples.

In addition to NRL the MT visited two AC laboratories (one own-check laboratory and one official one which also performs analyses of own-check samples). Both laboratories have good facilities and knowledgeable staff and are accredited to EN ISO/IEC standard 17025.

However, the MT noted:

- In the own-check laboratory, in earlier stages of the programmes, some inadequate samples had been accepted for processing, but since its accreditation improvements have been made

on this and also on reporting procedures.

- In the official laboratory visited (which also performs analyses of own-check samples) the MT found no documented evidence that non-compliant samples are rejected (apart from a blank form). Furthermore, from the sampling documents available, it was not possible to verify clearly what samples had been tested.
- According to the information received from the CCA out of 21 official laboratories involved in the SNCPs only eight are accredited (including the NRL). The rest are either not accredited or in the process of accreditation. This is not in compliance with Article 12 of Regulation (EC) No 882/2004 which requires that the CA only designate accredited laboratories to carry out the analyses of samples taken during official controls.

## Conclusions

Laboratories involved in the SNCPs are designated, use the reference method for analyses and regularly participate in PTs with adequate results. However, the majority of the official laboratories are not accredited which is not in line with EU requirements.

## 6 OVERALL CONCLUSIONS

The SNCPs, which include a system of comprehensive, regular and well-documented biosecurity checks, are implemented in all ACs. Significant efforts have been made in their implementation. However, their effectiveness is hindered by several weaknesses, in particular: the confirmatory sampling policy which is currently inadequate; the policy followed in the case of positive dust but negative faecal samples in laying flocks (to be changed in 2011); and own-check broiler sampling policy which is currently based on holdings instead of flocks in some ACs. Although an electronic database and reporting system is available for the CA in order to have an adequate review and evaluation of the SNCP progress as required under EU legislation, the deficiencies and inconsistencies found in particular in the sampling documents and official biosecurity check reports could undermine the reliability of CA evaluation in some cases.

## 7 CLOSING MEETING

During the closing meeting held in Madrid on 14 July 2010, the MT presented the findings and preliminary conclusions of the mission to the CA.

The CCA commented on the findings and insisted that their policy regarding routine confirmatory sampling in breeder and layer flocks, and the policy where only dust tests are positive, and own-check sampling policy based on holdings in broiler flocks (in some ACs) are in line with the EU requirements since the SNCPs were approved by the Commission.

## 8 RECOMMENDATIONS

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

Nº.	Recommendation
1.	The CCA should ensure that accurate official control reports are drafted covering all deficiencies including sampling errors in own-checks in accordance with the provisions of the SNCP and in order to fulfil the requirements of Articles 4.2 (a) and 9

N°.	Recommendation
	of Regulation (EC) No 882/2004.
2.	The CCA should ensure that the monitoring and sampling programme applied in breeding flocks complies fully with the requirements of Regulations (EC) Nos 2160/2003 and 200/2010, in particular regarding preparation of samples and confirmatory sampling policy.
3.	The CCA should ensure that the monitoring and sampling programme applied in laying flocks is fully compliant with the requirements of Regulations (EC) Nos 2160/2003 and 1168/2006, in particular regarding frequency of sampling, confirmatory sampling policy and the policy to be followed in the case of positive dust but negative faecal samples.
4.	The CCA should ensure that the monitoring and sampling programme applied in broiler flocks comply fully with the requirements of Regulations (EC) Nos 2160/2003 and 646/2007, in particular the sampling frame covers all flocks of broilers.
5.	The CCA should ensure that official laboratories designated under the SNCs are assessed and are accredited in accordance with an appropriate standard (e.g. EN ISO/IEC 17025) in line with Article 12 (2) of Regulation (EC) No 882/2004.

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

[http://ec.europa.eu/food/fvo/ap/ap\\_es\\_2010-8482.pdf](http://ec.europa.eu/food/fvo/ap/ap_es_2010-8482.pdf)



## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 2009/158/EC	OJ L 343, 22.12.2009, p. 74-113	Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs
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
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. 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. 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. 200/2010	OJ L 61, 11.3.2010, p. 1-9	Commission Regulation (EU) No 200/2010 of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of Salmonella serotypes in adult breeding flocks of Gallus gallus
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
Dec. 2006/759/EC	OJ L 311, 10.11.2006,	2006/759/EC: Commission Decision of 8

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
	p. 46-48	November 2006 approving certain national programmes for the control of salmonella in breeding flocks of Gallus gallus
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
Dec. 2007/848/EC	OJ L 333, 19.12.2007, p. 83-84	2007/848/EC: Commission Decision of 11 December 2007 approving certain national programmes for the control of salmonella in flocks of laying hens of Gallus gallus
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. 584/2008	OJ L 162, 21.6.2008, p. 3-8	Commission Regulation (EC) No 584/2008 of 20 June 2008 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 turkeys
Reg. 557/2007	OJ L 132, 24.5.2007, p. 5-20	Commission Regulation (EC) No 557/2007 of 23 May 2007 laying down detailed rules for implementing Council Regulation (EC) No 1028/2006 on marketing standards for eggs