



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO)/8143/2006 – MR Final

FINAL
REPORT OF A MISSION
CARRIED OUT IN
SPAIN
FROM 2 TO 6 OCTOBER 2006
IN ORDER TO EVALUATE
THE SYSTEMS IN PLACE TO CONTROL THE SALMONELLA RISK
IN THE TABLE EGG SECTOR

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Spanish Competent Authorities are given as footnotes, in bold, italic, type, to the relevant part of the report.



TABLE OF CONTENTS

1.	INTRODUCTION.....	3
1.1.	Background.....	3
1.1.1.	Production and trade patterns	3
1.1.2.	Rapid Alert System for Food and Feed (RASFF) notifications	3
1.1.3.	Baseline study on the prevalence of salmonella in laying hens	4
1.2.	Mission objectives and proceedings.....	4
2.	LEGAL BASIS FOR THE MISSION.....	5
3.	MAIN FINDINGS.....	6
3.1.	Legislation	6
3.2.	Competent Authority	6
3.2.1.	Central competent authority	6
3.2.2.	Competencies and powers of other CAs	8
3.2.3.	Coordination between the CA and the other authorities	8
3.3.	Laboratory services	9
3.3.1.	National Reference Laboratory	9
3.3.2.	Public laboratories	9
3.3.3.	Private laboratories.....	10
3.4.	Epidemiological situation in the table egg production sector and in humans 10	
3.4.1.	Situation in table egg sector	10
3.4.2.	Food poisoning outbreaks related to eggs	11
3.5.	Official control	11
3.5.1.	Monitoring and results of the monitoring programme in place for S. Enteritidis and S. Typhimurium in the egg laying sector	11
3.5.2.	Control measures taken in the event of flocks infected with invasive types of Salmonella	14
3.5.3.	Control of packing stations, catering facilities, processing establishments of egg products.....	16
3.6.	Guidelines on good hygiene practices	17
3.7.	Follow-up of food poisoning outbreaks	17
4.	CONCLUSIONS	17
5.	CLOSING MEETING.....	17
6.	RECOMMENDATIONS TO THE SPANISH COMPETENT AUTHORITIES.....	18
7.	COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS.....	18
	ANNEX.....	19

1. INTRODUCTION¹

The mission took place in Spain from 2 to 6 October 2006. The mission team comprised four inspectors from the Food and Veterinary Office (FVO), one national expert from a Member State and an observer from the EFTA² Surveillance Authority, ESA.

This mission was scheduled as part of the FVO's planned mission programme. This was the first mission undertaken to Spain for this specific purpose.

1.1. Background

1.1.1. Production and trade patterns

The Spanish egg sector is one of the most important ones in the EU with a large number of laying hens (+/- 49.9 million in 2005 – 13.4% of the EU total) producing 837,000 tonnes of eggs yearly. The production is concentrated in a small number of Autonomous Communities (ACs), such as Catalonia, Galicia, Castilla la Mancha and Castilla León. Many of the farms in these regions are large scale farms with more than 100,000 birds each. The following table provides some figures regarding egg production in Spain.

Table: Number of egg related establishments in Spain

Establishments	Number
Laying hen farms	1,056 *
Packing/Sorting Centres	803**
Egg Product establishment	35**

Note: * source: Registro de explotaciones ganaderas REGA del MAPA año 2006; ** source AESA, figures Sept 2006

While imports into, and export from, Spain are relatively insignificant in the egg sector, intra-Community trade in Spanish eggs is much more important. The following table gives an overview of commercial exchanges in this sector.

Table: Foreign trade regarding the Spanish egg sector

	Into Spain	From Spain
Intra-Community	12,144	115,767
Third countries	221	5,132
Total	12,365	120,899

Note: Figures 2005 in tonnes of eggs source: Customs Department

1.1.2. Rapid Alert System for Food and Feed (RASFF) notifications

In recent years, a certain number of RASFF notifications was raised by various Member States, 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. This even led to requests from

¹ A list of abbreviations and special terms is drawn up in the Annex to this report.

² EFTA = European Free Trade Association

certain Member States to ban the intra-Community trade in table eggs originating from Spain.

By way of example, the following notifications (either alert or non-alert information notification³), linked with the consumption of eggs and/or egg based food originating in Spain, were received in RASFF (in brackets the notifying Member State):

- 2005.554 (France)
- 2003/AEE (United Kingdom)
- 2002/361 (United Kingdom)
- 2002/082 (Italy)

1.1.3. *Baseline study on the prevalence of salmonella in laying hens*

An EU-wide *Salmonella* baseline study, under Commission Decision 2004/665/EC^{4 5}, was conducted on commercial large-scale laying hen holdings with at least 1,000 laying hens in the flock. The study was carried out in all Member States and coordinated by the European Food Safety Authority (EFSA), and the sampling of the holdings took place during the period from 1 October 2004 to 30 September 2005. The aim of the study was to estimate the prevalence of *Salmonella* at holding level at the global EU-level as well as for each Member State specifically.

In this baseline study, the prevalence of *Salmonella* of public health significance in the Spanish laying sector was one of the highest in the whole EU, namely a combined figure of 51.6% for *S. Enteritidis* (SE) and *S. Typhimurium* (ST) in the clean dataset, only surpassed by Poland, The Czech Republic and Lithuania.

1.2. **Mission objectives and proceedings**

The main objective of the mission was to investigate the actions taken by the competent authorities (CAs) in relation to outbreaks of *Salmonella* food poisoning due to the consumption of table eggs or foodstuffs prepared from table eggs. This included those outbreaks and findings reported in other Member States to which table eggs were sent, for which in a number of cases RASFFs were issued (see section 1.1.3).

In addition, further to the publication on 14 June 2006 by EFSA of "Preliminary Report on the Analysis of the Baseline Study on the Prevalence of salmonella in laying hen flocks of *Gallus gallus*", the various monitoring and control measures put in place by the CAs for *Salmonella* infections in eggs were also evaluated.

³ A non-alert information notification being issued when goods have not been distributed, so no action is needed in other Member States.

⁴ A list of legal references can be found in the Annex to this report.

⁵ It should be understood that for all legal texts quoted in this document, it is necessary to refer to the latest amended version.

In order to achieve these objectives the mission team evaluated also the organisation of the CA and its capacity for implementing the relevant Community requirements.

The mission team proceeded as follows:

- an opening meeting was held on 2 October 2006 with the Central CA, (CCA) at which also representatives from the Autonomous Communities (ACs) attended. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested;
- the following sites were visited:

COMPETENT AUTHORITY VISITS		
Central CA	3	AESA, MAPA and CNE Instituto de Salud Carlos III
Regional CA	3	ACs visited: Cast. la Mancha., Cast. León, Aragón. In each AC, meetings with the two CAs took place as well with the provincial and local CAs
Local CA	8	
LABORATORY VISITS		
National Reference Laboratory	1	Laboratorio Central de Veterinaria (MAPA, Algete- Madrid)
Regional laboratories	2	One public health and one animal health
PRIMARY PRODUCTION		
Laying hen farms	4	Large size farms with battery cages
ESTABLISHMENTS		
Packing stations	3	
Processing facilities (egg products)	1	
Caterers	2	Kitchen in an elderly people's home and another one catering mostly for schools.

- representatives of the different CAs accompanied the inspection team during the whole mission.

2. LEGAL BASIS FOR THE MISSION

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

- 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, in particular Article 17;
- 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, in particular Article 45;
- 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 Members states.

3. MAIN FINDINGS

3.1. Legislation

According to information received, Directive 2003/99/EC of the European Parliament and of the Council has been transposed into Spanish national legislation through Royal Decree 1940/2004.

For the implementation of Regulation (EC) No 2160/2003, a number of legal instruments have been adopted such as the Presidential Order (Orden PRE 1377/2005) laying down the measures for the control of *Salmonella* in laying hens. Its amendment Orden PRE 407/2006 of 14 February 2006 has further specified certain provisions regarding vaccination against *Salmonella* of public health significance, basically imposing vaccination of all pullet flocks, except those which have shown through official controls and by means of own checks to be at least for 6 months free from infection with SE or ST. However, all laying hen flocks which supply live birds or eggs for human consumption to the intra-Community trade, have to be vaccinated without exception.

Draft legislation has been prepared in order to provide a stronger legal basis for the *Salmonella* control programme. In this context, the team received, in the final meeting, draft Royal Decrees regarding the national *Salmonella* control programmes for breeding hens and for laying hens. The latter of the two drafts, based upon the Animal Health Act (*Ley 8/2003 de Sanidad Animal*), defines the minimum criteria the ACs have to apply for their programmes pending the entry into force of the first target for reduction of prevalence set in Article 1 of Regulation (EC) No 1168/2006 (1 February 2008). It stipulates also that the sanctions to be applied are those from the Animal Health Act.

In addition, the Royal Decree 328/2003 defines the general health plan for the poultry industry and is applicable throughout Spain. It concerns mainly provisions regarding animal health in particular for intra-Community trade of poultry and hatching eggs, including for salmonellosis (SE, ST and *S. pullorum-gallinarum*) as well as those regarding ante-mortem inspection.

As far as the risk posed by the use of fresh eggs is concerned, a Royal Decree (1254/1991) bans the use of raw eggs for the preparation of mayonnaise, sauces and food for immediate consumption in restaurants, collective kitchens, catering and similar food outlets.

3.2. Competent Authority

3.2.1. Central competent authority

3.2.1.1. Structure, competencies and power of the CCA

For the *Salmonella* control programme, the Ministry of Agriculture (MAPA) is the CCA while the Spanish Agency for Food safety (AESAs) deals with the food safety aspects in establishments, coordinates national zoonoses surveillance programmes and manages alert networks. The same distribution of tasks exists at the different levels, whereby each AC is responsible for the execution of the programme on its territory.

The CAs have a complex structure, and the details can be found in the Spanish country profile (Document SANCO/7733/2005) available on DG SANCO's website⁶.

In brief, the supervision of the farms is the responsibility of the MAPA and its counterparts at the different regional and local levels, while the food safety aspects are dealt with by AESA and their Animal Health or Food Safety counterparts at the various levels (i.e. AC, Provinces, Comarca/District).

3.2.1.2. Coordination between CCA and Regional or Local CA

Coordination between the different CAs and the ACs has taken place through an ad hoc working group with representatives from the relevant CAs and laboratories dealing with the different aspects of zoonotic *Salmonella*, as well as from the industry. Minutes of meetings of this working group were available to the team.

The involvement of the ACs in the elaboration of this programme was stimulated by delegating certain tasks for the preparation of the working group sessions to their representatives.

3.2.1.3. Written procedures for monitoring and official controls

Written procedures are in place or being prepared, such as those from the public health CA regarding the investigation of eggs suspected of transmitting salmonellosis and another one for the investigation of food borne outbreaks (*Procedimiento para el control de huevos sospechosos de transmitir salmonelosis* (draft) and *Procedimiento de trabajo oficial para las unidades administrativas de sanidad alimentaria ante brotes de toxoinfecciones alimentarias*). They describe in detail the steps to follow for these investigations, such as the sampling procedures.

3.2.1.4. Human resources (numbers of staff involved at different levels)

The team noted that sufficient staff is available at the different levels of the CA visited to deal with the *Salmonella* control programme and with the food safety aspects in relation to egg packing centres, egg product establishments or other premises preparing food using eggs. Nevertheless, certain tasks of the programme are delegated to TRASEGA, a public company with a contract with MAPA or their counterparts at regional and local level. These concern mainly the inspections for biosecurity.

3.2.1.5. Qualification/training of staff performing official controls

The mission team saw and received evidence of training of officials at the different levels (central and in the AC) concerning certain aspects of the programme, such as sampling procedures and biosecurity checks.

⁶ http://ec.europa.eu/food/fvo/country_profiles/CP_spain.pdf

3.2.2. Competencies and powers of other CAs

3.2.2.1. Authority/ies involved in the monitoring of the food chain

In each AC, the relevant services of the Department of Health and Consumption (*Departamento de Salud y Consumo*) depending from the Regional Government (*Gobierno*) have the power to supervise establishments of the food chain at all levels other than the primary production. Their provincial and local (district) services do the routine supervision, which is coordinated and audited by the AC level. For farms, the competence is with the Department of Agriculture and Livestock (*Departamento de Agricultura y Ganadero*), with similar structures at provincial and local (*comarca*) level.

3.2.2.2. Authority/ies involved in food poisoning outbreaks in humans

3.2.2.2.1 National Centre for Epidemiology (CNE)

The CNE collects information from food-borne outbreaks in Spain in order to constitute the annual report of trends of zoonoses for the EFSA, in accordance with Article 9 of Directive 2003/99/EC. It has a database in which the information received on-line from the different ACs is compiled.

The CNE is responsible for the National Network for Epidemiological Surveillance and got its legal authority by Royal Decree 2210/1995. It publishes a weekly bulletin, providing information on the situation regarding contagious diseases in humans, including on zoonoses.

During the visit, the team received further information regarding the organisation of the notification system. For human *Salmonella*, notification is only mandatory when it concerns an outbreak (i.e. more than one case, linked to the same source), not for individual cases. Apparently, more than 50% of the notifications concern individual cases (for which notification is not mandatory), or household restricted outbreaks. A multidisciplinary CNE team investigates all cases and outbreaks and provides feedback to the notifying entity.

When there is a risk that the outbreak will spread to several ACs (= *supra-comunitario*), urgent notification is mandatory.

Out of all food poisoning cases and outbreaks, approximately 50% are due to *Salmonella*.

3.2.2.2.2 ACs

Individual cases and outbreaks of foodborne disease, when reported by the general practitioners or hospitals are investigated by the Department of Public Health (*Departamento de Sanidad*) at AC level. The latter report such cases and outbreaks to the National Centre of Epidemiology (CNE). When food which is at the source of an outbreak has been distributed in several ACs, the CA which had the first information is obliged to provide the necessary information to those ACs and to the CCA.

3.2.3. Coordination between the CA and the other authorities

Evidence was available on existing contacts with the CA for human health. At the different levels, they belong to the same organisation, even if they are in different services.

3.3. Laboratory services

3.3.1. National Reference Laboratory

The Laboratorio Central de Veterinaria del MAPA (Central Veterinary Laboratory) in Algete (Madrid) is the National Reference Laboratory (NRL) for *Salmonella* in animals. It has good facilities and well trained staff, as well as sufficient capacities. It is not yet accredited but has started the process for accreditation.

It carries out sero-typing but not phage-typing. Controls for anti-microbial resistance are not carried out routinely, but such controls were included in the EFSA baseline study on all isolates. It receives all isolates from the official animal health laboratories from the ACs and has therefore a good overview of the situation.

It organises inter-laboratory proficiency testing for the official animal health laboratories from the ACs but not for private ones. In the last proficiency test, organised in 2005, 16 out of 18 regional laboratories participated of which only one had unsatisfactory results.

It has recently organised training regarding sero-typing for the regional laboratories.

3.3.2. Public laboratories⁷

National Microbiology Centre in the Carlos III Institute

The team did not visit this laboratory, but received some information on its functions during the visit to the CNE. It is the reference laboratory for infectious diseases in humans, including salmonellosis, and offers diagnostic services as well as research.

Regional Animal Health laboratories

Official samples taken in farms in the framework of the Salmonella control plan are tested in laboratories belonging to the relevant regional Agriculture CA of the AC. In ACs without an official laboratory dealing with poultry or carrying out *Salmonella* testing, samples are sent to a private laboratory specialised in poultry diseases (CESAC: Centro de Sanidad Avícola de Cataluña y Aragón, located in Catalonia, which functions as an official laboratory authorised and recognised by the ACs).

The capacity to cover for the territory appears to be adequate even if problems in official laboratories could arise from an increased number of official samples in the framework of an intensified control programme.

In view of the itinerary, it was only possible to visit one regional animal health laboratory. This laboratory had good records, used the right method for isolation of *Salmonella* and had obtained a good score in the proficiency tests organised by the NRL.

⁷ *In their comments of 08.05.2007, the Spanish CA reminded of the role of the Centro Nacional de Alimentación, answering to the AESA. This national food laboratory is the NRL for Salmonella isolated from foodstuffs. It was not visited during the mission.*

Public Health laboratory

The public health laboratory visited in one of the Regions, belonging to the relevant CA at AC level, was involved in testing of official samples taken in food establishments, mainly in catering and distribution. No private samples were received, except when results of a test in another laboratory were contested.

For *Salmonella* testing, only eggs were received and no egg-products or food produced with eggs. In 2005, 1,300 samples (each consisting of 30 eggs) were received, in which both shell and contents were tested separately. Pooled samples of three eggs were used.

Although the laboratory had good standards for registering the samples using a unique laboratory number, the system used for registration did not permit the generation of an overview of the results. However, the head of the laboratory estimated that some 4% of the shell analyses were positive, while *Salmonella* was never isolated from the contents. Although the laboratory had received accreditation from the National Entity for Accreditation (ENAC) for many of the tests it carried out, including for microbiology, the method used for *Salmonella* isolation was not yet accredited even though it had been validated.

Evidence was available of the participation of the laboratory in an international inter-laboratory proficiency test with satisfactory results.

3.3.3. Private laboratories

As the team did not visit any private laboratory involved in the *Salmonella* control programme or in own checks in food establishments, an assessment of their functioning and capacities was not possible. The laboratories carrying out analyses on samples collected in the framework of own checks in accordance with the *Salmonella* control plan, should be authorised for this purpose in accordance with Article 9 of the Orden PRE 1377/2005.

In one of the ACs visited, the CA had foreseen to organise the supervision of private laboratories, but had not yet done so.

Although own checks at farm level are compulsory in Spain and in case of a positive result, notification is mandatory, the mission team found no evidence of any positive result having been notified following an own check.

3.4. Epidemiological situation in the table egg production sector and in humans

3.4.1. Situation in table egg sector

3.4.1.1. Community surveys (EFSA)

As indicated in point 1.1.2, the EFSA organised baseline study indicated a combined prevalence figure of 51.6% for *S. Enteritidis* (SE) and *S. Typhimurium* (ST) in the clean dataset.

3.4.1.2. National surveys

The team did not receive an up-to-date overview for Spain of the current situation after the start of the reinforced control plan (see section 3.5.1)⁸. Also at local level, in one region, it was not possible to receive precise figures for the specific area covered. In the regions where figures were provided, they seemed to be lower than the ones from the study, without any clear explanation for the differences being provided. In one region the figures were 17.3% and 28.5% of flocks and holdings respectively. In another AC, the figure for farms was 17%, while in the third one, it was respectively ca. 30% in the official checks. Here, the explanation provided was that figures were improving following the introduction of compulsory vaccination in the new control programme (see point 3.5.1)⁹.

3.4.2. Food poisoning outbreaks related to eggs

As far as the numbers of food-borne outbreaks and individual cases caused by *Salmonella* are concerned, the figures can be considered as relatively low (some 300 individual cases of SE per month in 2004, but not necessarily all of them being linked to eggs¹⁰). This might be due to the prohibition of the use of raw eggs for the preparation of mayonnaise and certain sauces in catering establishments (Royal Decree 1254/1991). Two yearly peaks usually exist however, one in month of May and one in the summer months. According to the explanation received, these are linked to an increase of temperatures and an increase in catering activities in those periods.

Interesting to note is that according to the Spanish annual report to EFSA, 1,686 samples of eggs in shell, taken in egg packing centres, were tested in 2004, 24 of which were positive for *Salmonella* (13 for SE).

3.5. Official control

3.5.1. Monitoring and results of the monitoring programme in place for *S. Enteritidis* and *S. Typhimurium* in the egg laying sector

The control plan for *Salmonella* in laying hens was originally based upon the Orden PRE 1377/2005. Following a number of Rapid Alerts in which Spanish eggs were indicated as being at the source of food-borne outbreaks in different Member States and the publication, by EFSA, of the results of the baseline study in which a high prevalence in the Spanish laying sector was revealed, some Member States urged the Commission to take action against eggs coming from flocks which were not covered by an official control programme and found to be negative for SE and ST. In order to avoid the imposition of heavy restrictions on intra-Community trade in Spanish eggs, and in light of the publication, by EFSA of the preliminary results of the

⁸ *In their comments of 8.05.2007, the Spanish CA commented that this was due to the fact that the figures in the database created for this purpose had not been collated yet at national level.*

⁹ *In their comments of 8.05.2007, the Spanish CA noted that the improvement was due to the implementation of biosecurity checks and the reinforcement of these checks, the vaccination of all replacement flocks and the fact that the Spanish data refer to the sampling was representative for the total population of laying flocks and not just taken at the end of the production period as was the case in the baseline study.*

¹⁰ Source: Annual report EFSA.

baseline study, the CA decided to start, as from June 2006, a programme of additional measures for surveillance, control and eradication in which official controls would play a more important role.

Orden PRE/1377/2005

On the basis of Orden PRE/1377/2005, the minimum requirements were in place to start a national surveillance programme, mainly focused on own checks combined with a high level of biosecurity and vaccination. For this national surveillance programme, official sampling only took place when the sampling in the framework of own-checks and/or the level of biosecurity was considered inadequate. These considerations were based on the results of the compulsory annual inspection or on information otherwise received.

No guidelines were available to the officials involved in these inspections regarding the interpretation of these provisions. However, a checklist was used in order to establish a specific score for each production unit.

The amendment 407/2006 of this Order has put certain additional provisions to the vaccination namely to impose vaccination against *Salmonella* on all flocks from which birds or eggs go into intra-Community trade as well as in those flocks for which own checks did not provide a negative result for SE and ST (for more details see section 3.1).

Intensified programme

As explained above, the CA adopted, as from June 2006 an additional programme¹¹ with the aim of achieving a significant reduction of the prevalence of *Salmonella*. This programme should result in an almost total eradication of the bacteria in laying hen farms supplying their eggs to the table egg market.

In this programme, which takes into account the provisions of Article 5 of Regulation (EC) No 2160/2003 and two recent Regulations¹², less exceptions on the compulsory vaccination of laying hen flocks are possible than before. One AC adapted this programme by a Resolution dated 18 August 2006, which intended to harmonise the implementation of this programme in its provinces. But this Resolution was drafted in a way that farm owners could decide whether to participate in the programme or not, i.e. the programme was voluntary rather than compulsory, while provisions in Orden PRE 1377/2005 would be mandatory in any case. The CCA did not comment on this issue in the final meeting¹³.

The programme will be followed up by means of an on-line database, developed by MAPA, or through the MAPA intranet website, to coordinate the results of surveillance and control measures, which was not completely operational at the time of the visit, as data had still to be collated and "cleaned". The team were given a demonstration of the functioning of this

¹¹ *Plan Nacional de Medidas adicionales para la Vigilancia y control de la Salmonella en gallinas ponedoras de la especie Gallus gallus, Año 2006* (National plan of additional measures for the surveillance and control of *Salmonella* in laying hens of the *Gallus gallus* species, Year 2006).

¹² Commission Regulations (EC) No 1168/2006 and (EC) No 1177/2006.

¹³ *In their comments of 8 May 2007, the CA noted that anyhow the Autonomous Regions have no legal power to take measures going against national standards.*

system, in which the ACs directly enters data regarding monitoring and vaccination of flocks in their territory.

The official sampling in the intensified programme is based upon the provisions of Article 1, Paragraph 2 of Commission Regulation (EC) No 1168/2006, meaning that no longer only faeces are collected, but also dust is sampled.

All farms supplying eggs to egg packing centres as table eggs are subject to the programme. Flocks producing only for household consumption or producing small quantities of eggs only delivered to the local trade are exempt, but the latter are still to be checked regarding their surveillance for zoonotic *Salmonella*, by the relevant AC.

The team saw differences in the practical implementation of this programme. In one AC, all flocks would undergo two official samplings, while in another one only one official sampling would be carried out in one flock of each farm. In one AC, the flock would be considered only as suspected of being infected when dust samples would be found positive, while in another one either positive dust or faeces samples would lead to the flock being considered as infected¹⁴.

Vaccination

According to the explanation received, all laying pullets have to be vaccinated in accordance with Article 8.1 of the Orden PRE 1377/2005, as amended. The only exception was for flocks in which biosecurity requirements were completely respected and official controls had shown freedom of infection for at least six months. This derogation has however now been further restricted in the intensified programme, bringing the period of freedom to eight months for the official controls and to twelve months for the own checks.

In one of the farms visited not all flocks were vaccinated as some of them had been introduced into the farm before this Order came into force.

Salmonella vaccines used in laying hens have to comply with the provisions of Commission Regulation (EC) No 1177/2006/EC, i.e. for live vaccines there should be a method to distinguish isolates from the field strains. This was the case for the vaccine used in one flock where the team was able to check this.

Feedstuffs

The team did not visit feed mills as feedstuffs were not explicitly covered by the scope of the mission. It was however noted during discussions at different levels that neither in farms nor in feed mills there was any official sampling for microbiological checks on feedstuffs taking place at the time of the mission. The reason for this was, according to the explanation received, due to the lack of established microbiological criteria at Community level, which still have to be established, by the Commission, in accordance with

¹⁴ *In their comments of 8 May 2007, the CA added further details to explain the reason of these differences, such as level of biosecurity and the previous health situation (antecedents) of the farm.*

Regulation (EC) No 882/2004 of the European Parliament and of the Council¹⁵.

Official controls in farms

These concern biosecurity checks and official sampling in accordance with the *Salmonella* control programme.

During a documentary check, the team noted that the prescribed form of Annex II to Orden PRE 1377/2005 had been used in the farm where this was specifically checked. The TRASEGA inspectors had indicated most of the deficiencies regarding biosecurity, but not all of them as some existing deficiencies (noted by the mission team during the visit) such as the fact that the egg conveyor belt passed from one house into the next one¹⁶, were not reported. The score which should have been zero on the basis of the first TRASEGA inspection findings, as one of the exclusion requirements was not respected (namely the lack of evidence that the flock was vaccinated), was not reported in the document seen. Subsequently, the CA notified the reported deficiencies to the owner who was given a fixed deadline to correct them. Following a new inspection, it appeared that most of the deficiencies reported in the first TRASEGA report had been corrected indeed, and a score was granted allowing the farm to remain in business¹⁷.

3.5.2. Control measures taken in the event of flocks infected with invasive types of Salmonella

Restrictions in infected flocks

Both in the original programme and in the intensified one, restrictions in case of a positive faeces sample concern only the positive flock while no measures apart from sampling would be taken in other flocks on the same farm. The reasoning behind this is that, legally speaking, each flock is an epidemiological unit and that, therefore, measures do not apply to other flocks, even if they are in the same farm as long as they are negative. The restrictions comprise a stand-still, both for the eggs produced and the birds present in the flock. Eggs are only allowed to go for heat treated egg products or for destruction, while the hens can only leave the house for slaughter or destruction.

The team noted that restrictions were properly supervised and that the necessary documentation on the consignments of eggs produced during the stand-still was available. This included feedback from the receiving egg product establishment. In one case, the team was informed by the CA that the owner had not observed the restrictions and that distribution of table eggs, which were under restriction, had taken place in different regions of Spain. The relevant CA had issued a national rapid alert, thus informing the relevant

¹⁵ *In their comments of 8 May 2007, the CA noted that feed samples were analysed in the framework of own checks as well as in accordance with AC requirements.*

¹⁶ *In their comments of 8 May 2007, the CA noted that this is not a legal requirement in Orden Pre 1377/2005.*

¹⁷ *In their comments of 8 May 2007, the CA added further details on the procedure for providing the score.*

CA in the different ACs concerned, and was investigating the case in view of recalling those eggs, and possibly prosecuting the owner.

In one case, the team observed that a positive result had been found for *S. Infantis* and in another case a positive one for *S. Altona*. In spite of the fact that these serotypes have a potential zoonotic impact and that this had been communicated by the CA responsible for food safety to those dealing with farm supervision in the same AC, the relevant flocks were not subject to any restriction as the results for SE and ST were negative. It is worth noting, however, that neither Community rules nor Spanish legislation on zoonoses would provide a specific provision to impose action, unless the general principle of Regulation (EC) No 178/2002 (Article 14¹⁸) of the European Parliament and of the Council would be applied.

According to the explanation received in the final meeting, compulsory slaughter of infected flocks was one of the control means provided for in the existing programme for which significant budgetary provisions were available¹⁹; this would be based on the Animal Health Act rather than on a specific Decree for *Salmonella* control. However, the team did not find any reference to support this, nor did they see any case in which compulsory slaughter of positive flocks took place²⁰. In the intensified programme, this is an explicit provision.

According to the explanation provided during the mission, two draft Royal Decrees²¹, which were only provided to the team at the final meeting, would give a stronger legal base to impose compulsory slaughter of infected flocks as the Orden PRE 1377/2005 does not explicitly foresee such measures. The team did not manage to find any specific reference to compulsory slaughter in the draft Decree regarding the *Salmonella* control programme for laying hen flocks.

In one particular farm, for which epidemiological inquiries in relation to several food-borne outbreaks in other Member States indicated that it might have been the source of these outbreaks, a first official sampling carried out in July 2005, revealed that three out of six flocks were positive for SE.

Following the confirmation of the infection, the owner decided to treat all infected flocks with colistin after which the flocks showed negative in an official sampling.

In June 2006, new positive results were noticed in four flocks out of the five remaining ones, two of which had been infected before. In view of this result, the owner decided to treat the feed with protected acidifiers and to add acidifiers (propionic and formic acids) to the drinking water. After three weeks of this treatment, the flocks turned negative again.

No specific antibiotic residue testing was considered by the CA for the flocks which turned negative. No explanation was available why *Salmonella* was

¹⁸ Stating that food shall not be put on the market if it is unsafe.

¹⁹ According to the explanation received, funds are available for compensating the transport, slaughter and destruction costs, but not for compensation of the value of the animals.

²⁰ *In their response of 8 May 2007, the CA commented on this point.*

²¹ One of them however, concerns breeding flocks.

repeatedly isolated. Although some weaknesses regarding biosecurity existed in the farm (see point 3.5.1), culling of the birds was not considered by the CA who claimed that no budget was foreseen for compensation. No restrictions on the negative flock were in place, in spite of the biosecurity weaknesses. This is due to the fact that the legislation only prescribes measures in flocks in which *Salmonella* of public health significance was isolated.

3.5.3. *Control of packing stations, catering facilities, processing establishments of egg products*

In general, the egg sorting and packing centres were in compliance with food safety requirements as laid down in Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council. A HACCP plan was in place in all those visited by the team, even if in one of them, certain questions were raised regarding the definition of the various critical control points.

In one of the centres visited, linked to a farm in which SE had been found, the owner had installed special equipment with UV light to lower any risk of shells being infected. Traceability in all centres was well organised.

In another centre, breaches of the indication of the best before dates (BBD²²) were noted as the BBD was for some of the boxes set at 30 instead of 28 days after the date of laying. This constitutes an infringement of Commission Regulation (EC) No 2295/2003, Article 9 (2)²³.

A problem existed in the egg products establishment visited, as the prescribed tests for certain organic acids were not carried out at all. This constitutes an infringement of Regulation (EC) No 853/2004 of the European Parliament and of the Council, Annex III, Section X, Chapter II, Part IV²⁴.

The team also visited two caterers' premises. The inspectors from the local CA paid great importance to various food safety aspects. For the table eggs, they checked storage conditions, BBD and labelling, while also commercial documents were available allowing traceability. Neither the mission team nor the local inspectors noted any breach of the requirements regarding the use of table eggs for the preparation of mayonnaise or other sauces. The mayonnaise used was industrially prepared.

In two out of three ACs visited²⁵, the CA included in their official inspections in food processing establishments the random sampling of eggs. The results showed contamination with *Salmonella* percentages varying from year to year and between ACs (between 4% and 25%).

²² In the relevant legislation referred to as date of minimum durability.

²³ It should be noted, however, that this was outside the scope of the mission.

²⁴ It should be noted, however, that this was outside the scope of the mission.

²⁵ In the third one, sampling had been abandoned in view of a re-organisation of the CA.

3.6. Guidelines on good hygiene practices²⁶

The team noted that in all ACs visited, the regional CA had disseminated a number of guidelines regarding different kinds of food processing establishments, such as bakeries, catering egg product establishments and egg packing centres. Other guidelines were issued at central level in cooperation between MAPA and the inter-professional organisation of the egg and products thereof (INPROVO) representing, as well as with CESAC, regarding biosecurity in farms.

3.7. Follow-up of food poisoning outbreaks

The team investigated one particular file in depth from which it appeared that the relevant CA had gone in great depth to investigate the source of the infection, in accordance with article 8 Paragraph 2 of Directive 2003/99/EC. In addition, a central on-line database allows for a good overview of the situation.

4. CONCLUSIONS

In the EFSA baseline study, the prevalence of *Salmonella* in laying hen flocks in Spain was found to be one of the highest in the EU.

Although some efforts had been made to reduce this prevalence, the mission team found a number of weaknesses in the system which could be partially responsible for the limited progress in improving the situation.

The CCA appeared to be aware of the problems this could cause both to consumer safety and to trade. Therefore, they started in the summer of 2006 an intensified *Salmonella* surveillance and control programme, in consultation with the different authorities involved, both at central and regional level, and the poultry industry.

If the CA maintain the thorough supervision which is currently in place in infected flocks, in particular regarding the restricted use of eggs produced, the risk of food-borne outbreaks originating in flocks under control could be strongly reduced.

The considerable decrease of food poisoning related to egg preparation is mainly due to the prohibition of the use of raw eggs for the preparation of mayonnaise and certain sauces in catering establishments (Royal Decree 1254/1991).

Certain infringements of Community rules, which were not explicitly covered by the scope of the mission, were found in some of the establishments²⁷.

5. CLOSING MEETING

A closing meeting was held on 6 October 2006 with the CCAs and representatives from a number of ACs (not only from those visited during the mission). At this meeting, the main findings and conclusions of the mission were presented by the inspection team. During this meeting, the CCA acknowledged the findings and preliminary conclusions presented by the mission team and provided some additional information, such as a copy of the new official surveillance and control programme in laying hens (2006).

²⁶ Implementation of Article 7 and 8 of Regulation (EC) No 852/2004.

²⁷ The mission team received, after completion of the mission, written assurances from one the CA from one of the ACs visited that corrective action was already taken.

6. RECOMMENDATIONS TO THE SPANISH COMPETENT AUTHORITIES

Despite the fact that the following issues were not specifically included in the scope of the mission but are related to this production sector, the Spanish authorities should provide the Commission services, within one month of receipt of the report, an action plan, including a timetable for its completion, in order to address the following recommendations:

- 1) The CA should ensure that in packing centres the provisions related to the indication of the best before dates for table eggs, as defined in Commission Regulation (EC) No 2295/2003, Article 9 (2), are respected;
- 2) The CA should ensure that in egg product establishments the prescribed tests for certain organic acids are carried out in accordance with Regulation (EC) No 853/2004, Annex III, Section X, Chapter II, Part IV;
- 3) The CA should ensure that laboratories, including NRL, performing analyses taken during official controls are assessed and accredited in accordance with the requirements of Article 12 of Regulation (EC) N° 882/2004 - taking into consideration the requirements of Article 18 of Commission Regulation (EC) N° 2076/2005, especially because of its paramount importance for the analysis and testing of *Salmonella* as in Article 11 of Regulation (EC) No 2160/2003.

7. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

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

http://ec.europa.eu/food/fvo/ap/ap_spain_8143_2006.pdf

ANNEX

1. Abbreviations and special terms

AC	Autonomous Community
AESA	Spanish Food Safety Agency (<i>Agencia Española de Seguridad Alimentaria</i>) ²⁸
BBD	Best Before Date or Date of minimum durability
CA	Competent Authority
CCA	Central Competent Authority
EC	European Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
ENAC	National Entity of Accreditation (<i>Entidad Nacional de Acreditación</i>)
ESA	EFTA Surveillance Authority
EU	European Union
FVO	Food and Veterinary Office
HACCP	Hazard Analyses Critical Control Point
MAPA	Ministry of Agriculture, Fisheries and Food (<i>Ministerio de Agricultura, Pesca y Alimentación</i>)
RASFF	Rapid alert system for food and feed
SANCO	Health and Consumers Protection Directorate General
SE	Salmonella Enteritidis
ST	Salmonella Typhimurium

2. Community Legislation quoted in the report

European legislation ²⁹	Official Journal (OJ)	Title
Regulation (EEC) 1907/90	L 173, 6.7.1990, p. 5	Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs
	62, 15.3.93, p. 38	
Regulation (EC) 178/2002	L 31, 1.2.2002, p.1	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Regulation (EC) 2160/2003	L 325, 12.12.2003 p. 1	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.
Directive 2003/99/EC	L 325, 12.12.2003, p. 31	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) 852/2004	L 139, 30.4.2004, p. 1 Corrigendum L 226, 25.6.2004, p. 1	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Regulation (EC) 853/2004	L 139, 30.4.2004, p. 55 Corrigendum 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) 882/2004	L 165, 30.4.2004, p. 1 Corrigendum 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.

²⁸ Currently named AESAN (Agencia Española de Seguridad Alimentaria y Nutrición)

²⁹ Community legislation (Internet): http://europa.eu.int/eur-lex/en/search/search_lif.html

Decision 98/139/EC	L 38, 12.2.98, p. 10	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 Members states.
Decision 2004/665/EC	L 303, 30.9.2004, p. 30	Commission Decision 2004/665/EC of 22 September 2004 concerning a baseline study on the prevalence of salmonella in laying flocks of <i>Gallus gallus</i> .
Regulation (EC) 1168/2006	L 211, 1.8.2006, p. 4	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 <i>Gallus gallus</i> and amending Regulation (EC) No 1003/2005.
Regulation (EC) 1177/2006	L 212, 2.8.2006, p. 3	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) 2295/2003	L 340, 24.12.2003, p. 16	Commission Regulation (EC) No 2295/2003 of 23 December 2003 introducing detailed rules for implementing Council Regulation (EEC) No 1907/90 on certain marketing standards for eggs