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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ARGENTINA

FROM 22 APRIL TO 03 MAY 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF EGG PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

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 audit carried out by the Food and Veterinary Office in Argentina, from 22 April to 03 May 2013.

The objective of this audit was to assess the performance of the competent authority with regard to supervision of public health conditions of the production of egg products destined for export to the EU.

The report concludes that the system of official controls in place is based on regular controls at establishment level, including permanent presence of official veterinarian services at establishments during production.

However, the effectiveness of this system is compromised by the several deficiencies detected by the audit team, the main ones being as follows:

- *There is no documented evidence that the competent authority assesses all EU requirements during EU approval procedures (notably HACCP plan and its implementation).*
- *Deficiencies in establishments visited (related to sanitary conditions and hygiene practices) had not previously been detected or recorded in any official control report, demonstrating that monitoring of ongoing compliance with initial approval conditions is not entirely effective.*
- *Weaknesses in the certification procedures in place (date and language).*
- *Deficiencies in both official and own-check sampling of egg products in the approved establishments (for microbiological analyses and organic acids).*

The report includes recommendations addressed to Argentinian competent authority aimed at rectifying the identified shortcomings and enhancing the control system in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CCP	Critical Control Point
EC	European Community
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organization for Standardization
OAA	Argentinian Accreditation Body
OV	Official Veterinarian
RASFF	Rapid Alert System for Food and Feed
RENSPA	National Health Register for Agricultural Farmers
SENASA	National Animal Health and Agro-food Quality Service

1 Introduction

The audit took place in Argentina from 22 April to 3 May 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme.

The audit team comprised two inspectors from the FVO. Representatives from the Competent Authority (CA) accompanied the audit team during the whole audit.

An opening meeting was held on 22 April 2013 with the Central CA (CCA). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for its satisfactory completion of the audit.

2 Objectives

The objective of the audit was to assess the performance of the CA with regard to supervision of public health conditions of the production of egg products destined for export to the European Union (EU).

In order to achieve this objective the audit team evaluated the organisation of the CA and its capacity for implementing the relevant EU requirements.

The table below lists the sites visited and the meetings held in order to achieve the above objective.

Competent authority visits		
CCA	1	Opening and closing meeting
Regional CA	1	Certification office
Laboratory visits		
Laboratory	2	Belonging to SENASA laboratory network
Food processing facilities		
Egg processing establishments	5	

3 Legal Basis

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

Full legal references are provided in ANNEX I. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 Background

4.1 Historical background

Argentina is included in the list of third countries from which egg products may be imported into the EU laid down in Part 1 of Annex I to Regulation (EC) No 798/2008.

This was the first audit of the official control system for Argentinian egg product exports to the EU.

There has been no Rapid Alert System for Food and Feed (RASFF) notifications linked to egg products from Argentina since 2009.

4.2 Production and trade information

The table below was provided by the CCA and indicates the quantity (in metric tonnes) of egg products exported to the EU market in 2011 and 2012:

	2011		2012	
	Egg Powder	**Liquid Egg**	**Egg Powder**	**Liquid Egg**
Total (in tonnes)	**2,797**	**0**	**3,753**	**0**

Austria, Germany, Denmark, Italy and Sweden were the main importing member states.

5 Findings And Conclusions

5.1 Legislation and implementing measures

Legal requirements

Article 46 of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in third countries in order to verify the compliance or equivalence of third-country legislation and systems with the relevant EU legislation.

Findings

The main piece of national legislation used by the CA for the official control of egg products is Decree 4238/68 and its amendments. In addition to requirements for the national market, Chapter I, Section 1.1.4.1 of this decree states that in the case of export products and the establishments that manufacture them shall meet the conditions and requirements of the country of destination or those accepted as equivalent.

Several resolutions, circulars and service orders have been issued (many of them recently amended in 2012 and 2013) to ensure a proper implementation of the legislation concerning the production of egg products intended for export to the EU.

Conclusions

While a comprehensive analysis of Argentinian legislation was not carried out by the audit team, the national legislation and implementing measures applicable for export to the EU are broadly in line with EU requirements related to the scope of this audit.

5.2 Competent authority

Legal requirements

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

Findings

The CCA is SENASA (National Animal Health and Agro-food Quality Service). The Directorate for Inspection of Products of Animal Origin is responsible for management control, training and legislation. Within the above-mentioned Directorate, for the egg products sector these tasks are under the responsibility of the Co-ordination Office for Poultry, Egg Products, Minor Species and Game Products.
At central level there is a specific auditing service directly attached to the president of SENASA which is in charge of internal audits.

The CCA is responsible for elaborating the norms, for assigning approval numbers to establishments eligible for EU export and for the general supervision of the control systems.

SENASA regional offices are in charge of the overall supervision of the EU approved establishments and have coordinators supervising food producing establishments including those of the egg products sector. Under each coordinator there are supervisors who are in charge of carrying out inspections in egg processing establishments.

Each egg product establishment is under permanent supervision of a veterinary inspection service headed by an official veterinarian (OV) assisted by official auxiliaries. The audit team noted in the establishments visited that the OV's performance is evaluated during regional supervisor's visits on site which consist of an inspection of the premises and a review of official records kept by the OV.

Control by the CCA over the SENASA regional offices is based on internal audits and a management control system which includes visits to different establishments. In four egg processing establishments visited the audit team noted that the reports of management control visits were available. These reports included a specific section regarding the recommendations for CA staff. Internal audits were performed on different subjects (including on slaughterhouses exporting to the EU and on export certification) but none so far have concerned egg product establishments exporting to the EU. Internal audit reports are drafted but are only dispatched to a restricted number of addressees: SENASA president, the National Controllers Office directly attached to the Argentinian Presidency and the SENASA management concerned by the audit.

The audit team was informed by the CA that different training sessions are organised for OVs assigned to egg processing establishments. Evidence was provided to the audit team that a workshop that covered specific EU requirements for egg products intended for EU export, was organised in February 2013. However the audit team noted that CA staff knowledge of certain EU requirements was questionable (for more see sections 5.3.2 and 5.3.3 below on own-check and official sampling).

Conclusions

The CA has appropriate structures, legal powers and a sufficient number of qualified staff to perform official controls on egg products intended for export to the EU. However, the knowledge of certain EU requirements (in particular regarding sampling of egg products on microbiological criteria and organic acids compliance) by the CA staff is limited.

5.3 Official controls of production and placing on the market

5.3.1 Procedures for EU approval

Legal requirements

Article 12(1) and 12(2) of Regulation (EC) No 854/2004 establish certain requirements for establishments involved in exports of products of animal origin into the EU, namely to appear on lists drawn up and updated by the CA in accordance with this Article.

At present there is no harmonised EU list of egg product establishments approved for EU exports.

Findings

Approval of establishments

To be approved for EU export, establishments should first get national approval followed by specific approval to export to the EU.

The current system of approval of establishments for the domestic market is based on Food Business Operator (FBO) compliance with national requirements concerning structure and equipment but without reviewing that in operation the FBO complies with sanitary and hygiene requirements. The CA informed the audit team that when approval is given to an FBO, a SENASA approval number is attributed and the official veterinary service is provided to the establishment. First consignments of egg products can leave the establishment and be put on the domestic market only when all hygiene and sanitary conditions are met. According to the CA compliance with those requirements is ensured by the on-going inspection activities of the OV and regional supervisor. However in documents available to the FVO team there was no evidence that from a set date, an FBO is deemed compliant with the relevant hygienic and sanitary conditions.

The audit team noted that according to current national legislation a Hazard Analysis and Critical Control Point (HACCP) plan is not mandatory for obtaining SENASA national approval and thereafter for placing egg products on the national market.

An FBO wishing to export to any foreign market, either to EU member states or other destinations, must comply with Resolution No 108/2010, which provides the administrative procedures to be followed by an FBO and the CA regarding export approval. In case of egg products an approval is required for each EU member state to which FBO wishes to export.

An FBO must apply in writing to the CA for export approval. Following receipt of this application, the regional CA may carry out an on-site visit to verify compliance with requirements of the importing country or may simply rely on the outcome of previous official controls. The opinion of the regional CA is communicated to the CCA. The CA informed the audit team that for EU exports the CCA informs the member state of destination that an FBO complies with EU requirements and requests updating of the list of approved establishments for this specific member state. When the reply from the member state is received, accepting the proposed establishment for export, the CCA issues the final approval.

The audit team noted that:-

- For each member state, individual approval documents were available in all establishments visited. The documents indicated the type of products for which the establishment had been approved for export.
- There was no documented evidence that the CA assesses all specific EU requirements as part of its approval procedure for EU listing. This particularly concerns evidence of

assessment of HACCP plans and their implementation.

- In two establishments visited the reevaluation of approval was carried out by the CA respectively in 2012 and 2013 (based on national rules: a re-approval evaluation should be carried out every two years). In both instances before re-approval was given to the FBO, an on-site visit was carried out by the CCA (including a general HACCP assessment). However the CA informed the audit team that these on-site visits before re-approval is given are not mandatory and re-approval can be given based on a regional CA opinion that concludes that the FBO complies with all requirements of the importing country.
- In one establishment visited export to the EU took place before EU approval was granted to the FBO. The CA explained that while awaiting the reply of the importing EU member state accepting the establishment for export, the FBO can export as long as he/she submits a letter of commitment to bear all responsibilities if the exported consignment is rejected at the EU border.
- Argentinian legislation provides the CA with legal powers to suspend certification or withdraw approval if serious non-compliances are detected by the CA and not corrected by the FBO. The CCA informed the audit team that no such enforcement action has been needed so far in the egg processing sector.

Conclusions

While procedures exist for the approval of EU exporting egg product establishments, no documented evidence can be provided demonstrating that during the approval procedures the CA assesses all specific EU requirements and therefore it cannot be guaranteed that the establishments at time of approval meet all EU requirements, in particular requirements as regards HACCP plans and their implementation.

5.3.2 Controls at establishment level

Legal requirements

The export health certificates for the relevant commodities contained in Regulation (EC) No 798/2008 requires foods business operators to implement a programme based on HACCP principles.

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

Chapter II of Section X of the Annex III to Regulation (EC) No 853/2004.

Article 4 and 10 of Regulation (EC) No 852/2004.

Findings

General findings

Requirements applicable to raw material used in the production of egg products intended for export to the EU are established by Decree 4238/68. Under this decree , imported raw material may be used (such as food additives).

The audit team noted that specific raw materials (e.g. fresh shell egg) must originate from farms approved by SENASA. Fresh eggs sent to egg processing establishment must be accompanied by a commercial document ("shipment order") that bears the RENSPA (National Health Register for Agricultural Farmers which is only attributed to SENASA approved farms) number and eggs laying dates.

According to the FBOs visited, no liquid eggs had been used as raw material in these EU exporting

establishments.

Official supervision of the establishments is carried out by the regional supervisor who completes a "Supervision Report" form (in place since December 2012 when the previous Service Order was replaced by Service Order 08/2012 "Supervision Report for Egg Product Establishments"). On site visits are made to the establishments on a monthly basis (pursuant to Circular Letter 4056 SENASA, replacing previous provisions). These visits cover, amongst other, the establishment's facilities, general and specific hygiene conditions, export procedures and certain issues related to HACCP system (no full audit of HACCP is carried out). Furthermore supervisory visits assess the performance of OV activities. A report of each visit is given to the FBO, including the evaluation of the in-house OV.

In addition, the CCA has management control programmes in place, and also visits the establishments based on an annual inspection plan. This annual visit covers, amongst other, the establishment's facilities, documents related to official controls and certification, hygiene practices, manufacturing processes, HACCP system, sampling, staff training and preventive maintenance.

Furthermore, each establishment has a permanent Official Veterinary Inspection Service that carries out daily control activities (e.g. checks on raw material, pre-operational and operational hygiene, presence of the HACCP monitoring records, some general and specific hygiene requirements and pre-certification). In the establishments visited, daily activities were evidenced on different documents such as a log book and signatures on FBO documentation. In one visited establishment in addition the OV had drafted and used a specific checklist detailing her daily activities and pointing out deficiencies detected; this can be considered as good practice as the daily activities are better organised and assessment of the OV work is made easier.

In all establishments visited records of the official controls carried out by all levels of the CA were available. Where reports contained observations and recommendations for their correction, a plan for corrective actions was required with a deadline. Evidence of follow-up of corrective actions was also available.

In two establishments visited the audit team noted that CCA reports (dated 2012 and 2013) highlighted several deficiencies in these establishments, which had neither been reported in the monthly reports by the Regional Supervisor nor in the records of daily inspections. Amongst them deficiencies regarding sampling and tests required under Regulation (EC) No 853/2004 were mentioned (no samples taken for 3-OH-butyric acid and lactic acid).

A copy of the official reports is always provided to the FBO. Nevertheless, the evaluation of the FVO audit team in the establishments visited differed in some instances from the results of CA official controls, in that certain deficiencies had not been noted or reported by any level of official supervision.

Specific findings in egg product establishments

Out of the five establishments visited, four were found by the audit team to meet EU equivalent requirements. Only some minor deficiencies were observed (not all present in each establishment) in four sites. For example: -

- Surfaces of walls and equipment in some cases were not maintained in a sound condition and not easy to clean or disinfect in contravention of point 1 (b) and (f), Chapter II of Annex II to Regulation (EC) No 852/2004.
- Ceilings in some localised areas (including egg powder packing room, egg breaking room) were not constructed to prevent the accumulation of dirt and the shedding of particles in contravention of point 1 (c), Chapter II of Annex II of Regulation (EC) No 852/2004.
- Inadequate hygiene practices were noted: e.g. the same person handles both cardboard boxes

and wrapping material in dried egg product packaging room.

- Some areas were not protected against condensation (egg breaking room) in contravention of paragraph 2(b), Chapter I of Annex II to Regulation (EC) No 852/2004.
- Presence of some rusty equipment in production areas.
- Inadequate sorting of eggs at candling point was noted during FVO visit (single worker manning an ovoscope without a mirror). As a consequence several partially dirty and broken eggs were not discarded and therefore used for production of liquid eggs in contravention of point 1, Part II and point 1, Part III, Chapter II, Section X of Annex III to Regulation (EC) No 853/2004.
- Inadequate ducting of water in some areas with pooling in a room with exposed product (e.g. egg breaking room).
- Unclean fittings (lamp cable) over exposed liquid egg.
- Partially damaged insulation of pipe used for external transport of pasteurised egg product between two production buildings that leads to increased temperature of already cooled product due to excessive sun exposure.
- No RENSPA approval number and / or egg laying date on shipment orders accepted in two establishments despite FBO instructions and national requirement in place.

The fifth establishment visited presented several non-compliances with EU requirements such as:-

- Establishment not pest proof (flies were present in several production rooms) which is not in line with point 2(c), Chapter I, Annex II to Regulation (EC) No 852/2004.
- Wall surfaces in some areas not maintained in a sound condition (presence of paint flakes) and not easy to clean or disinfect in contravention of point 1 (b), Chapter II of Annex II to Regulation (EC) No 852/2004.
- Ceilings in egg breaking room not constructed to prevent the shedding of particles (loose silicon) in contravention of point 1 (c), Chapter II of Annex II of Regulation (EC) No 852/2004.
- Location of air vents above egg breaking machine blowing air directly on liquid eggs.
- The shell eggs, which underwent washing and disinfection with chlorinated water, were not rinsed with potable water and were delivered to an egg breaking machine without adequate drying. Dripping from the shells contaminated the liquid egg in contravention with point 1, Part III, Chapter II, Section X of Annex III to Regulation (EC) No 853/2004.
- No egg laying date on document accompanying eggs accepted in the establishment.
- Potential contamination of packaging and wrapping material with forklift hydraulic oil leak. This is not in compliance with provisions of Chapter X of Annex II to Regulation (EC) No 852/2004.
- High temperature (about 30ºC) in the storage room for raw material (not adjusted by the FBO although according to his instruction the maximum temperature should be 25ºC).
- Presence of food additive (used for product intended for domestic market) in storage room with ambient temperature in contravention of manufacturer’s instructions under which it should be kept between 10 and 15ºC.
- Presence of equipment with paint flakes in production areas including those where unprotected egg powder is handled.

Although these deficiencies had not been detected during previous official controls, the audit team noted that for some of them immediate corrective actions were ordered by the OV and taken by the FBO in the FVO team's presence.

HACCP

HACCP plans were present in all visited establishments and covered all productions. Critical Control Points (CCPs) were properly identified.

HACCP plan implementation was generally satisfactory and properly documented.

However, some shortcomings were noted by the audit team in two establishments which had not been mentioned in the CA inspection reports:

- Incorrect setting of the critical limit for one CCP (flow rate to ensure appropriate time of pasteurisation was set as minimum value instead of as maximum value and as a result there was no assurances that heat treatment was achieving its HACCP objective).
- Flow chart not fully updated to reflect the current production process (step for washing and drying of eggs still in the flowchart but not being carried out any more).

Own-check sampling

The audit team found a comprehensive own-check sampling programme in place for egg products. The audit team noted in all establishments visited that each batch of egg products is sampled by the FBOs and parameters for testing include among others microbiological criteria such as *Salmonella* and Enterobacteriaceae. Samples are generally analysed in in-house laboratories and in some instances in external ones.

FBO methods used for *Salmonella* detection in egg/ egg products are either rapid tests validated against the EU reference method ISO 6759 or, in one laboratory, the EU reference method itself was used.

However in four establishments visited the audit team noted that instead of five individual samples from each batch collected and analysed individually, only one composite sample was tested. This practice is not equivalent to EU rules (Regulation (EC) No 2073/2005). This deficiency had not been detected during official controls. In the case where ISO 6579 method is used and according to this standard, pooling of samples at laboratory level may be accepted provided that there is evidence that this procedure does not affect the quality of the test result.

In all establishments visited water was chlorinated (target 0.5 to 1 ppm) and daily tests on the free residual chlorine content were performed and recorded. In one establishment visited the FBO carried out sampling and tests for all the physical chemical parameters listed in Council Directive No 98/83.

In four of the five EU exporting establishments visited, the audit team noted that no results of tests for the presence of 3 OH-butyric acid in egg products was available although some samples had recently been taken. The CA informed the audit team that for the time being no laboratory in Argentina has a test to analyse this parameter. In one establishment visited some samples taken on already exported product (in the destination country) were tested in 2011 and 2012 and the results were available and below the EU maximum limit.

Furthermore, the audit team noted that only in two establishments visited were the results for lactic acid content available (all results below EU maximum limit). However in one of these establishments instead of testing lactic acid in raw material (as per EU requirements) the lactic acid content was tested in the final product. The CA informed the audit team that all shell eggs used as raw material in egg processing establishments exporting to the EU come only from SENASA approved farms and their freshness is monitored during official controls (laying egg date is required on the shipment document).

Extraneous material quantity (egg shell, egg membrane and other particles) was measured only in two of the establishments visited. In one of these establishments the quantity of eggshell remains,

egg membranes and any other particles was analysed in liquid eggs but not in the processed egg product as required under EU legislation. No results for this analytical test were available in other establishments visited.

In all establishments visited the audit team was informed by the FBOs that since 2010 all laboratory microbiological analyses results for products were compliant.

Traceability

The CCA informed the audit team that egg product establishments must have a traceability system in place, pursuant to the provisions of Chapter I, Paragraph 1.1.4.1 to Decree 4238/68. In addition, Circular Letter 3958, issued by the CCA, is in place and deals with Product Traceability and Recall.

Each establishment implements its own traceability system, which is evaluated by the CA.

The audit team noted that in all the establishments visited traceability systems were in place and records were properly kept.

However in one establishment visited full traceability could not be ensured as the official approval (RENSPA) number was not always on the shipment order for fresh eggs coming from the farm.

Moreover in one establishment visited the audit team noted a shortcoming concerning labeling. The production date on one box of final egg product did not match with the production date on other boxes of the same batch (although batch was defined by the FBO as "one day's production").

Conclusions

There is a regular and documented system of official controls of egg product establishments exporting to the EU. However, shortcomings in the performance of the official controls found by the audit team (non-compliances in establishments as regards maintenance and good hygiene practices, washing and drying eggs, deficiencies in own-check monitoring programmes and shortcomings related to traceability) compromise the effectiveness of the control system in place.

There were HACCP plans present in the establishments visited which were, in general, well implemented.

5.3.3 Official sampling

Legal requirements

The statements contained in sections II.2.4 and II.2.6 of the egg products certificate included in Commission Regulation (EC) No 798/2008, imply that the CA should take samples for laboratory analysis.

Findings

Water potability is regulated by the Argentine Food Code. Sampling procedure in food producing establishments is described in Decree 4238/68. In addition Circular Letter No 2731 provides more details on water potability and sampling.

In the establishments visited the water samples were taken for microbiological and physical-chemical parameters. Microbiological parameters, in line with the requirements of Council Directive 98/83/EC, were tested fortnightly. Physical and chemical parameters were tested every six months. However, not all the chemical parameters listed in this Directive were monitored (as already mentioned in FVO inspection report DG(SANCO) 2012-6347).

There is no written sampling programme so far established at national level for egg products but in all establishments visited the OV takes at least monthly sample of egg products (one sample from

one batch randomly selected) for microbiological criteria, including *Salmonella* and Enterobacteriaceae. The samples are analysed in SENASA approved laboratories. Results were available in the establishments visited. However in four establishments visited only one sample per batch had been taken and tested instead of the five required under EU legislation. As already mentioned, if ISO 6579 method is used, pooling of samples at laboratory level may be accepted provided that there is evidence that this procedure does not affect the quality of the test result.

The audit team noted that a "Control Plan for Food Residue, Contaminants and Hygiene in Foods of Animal Origin" is in place and implemented by the Coordinating Office for Surveillance and Alerts on Residues and Contaminants.

In all establishments visited the audit team was informed by the OVs that since 2010 all laboratory analyses results were compliant (below EU limits).

Conclusions

There is a comprehensive official sampling programme for water and for *Salmonella* analyses in egg products. However, the sampling protocol used for *Salmonella* detection is not fully equivalent to EU rules.

5.4 Laboratories

Legal requirements

Article 46 of Regulation (EC) No 882/2004 indicates how Commission controls in third countries will have particular regard to the resources available to the CA, including diagnostic facilities. The Codex Alimentarius Guidelines require adequate quality controls and the use of validated analytical methods.

Findings

Laboratories performing the analysis of official samples shall be approved by the CA to become part of the SENASA network of official laboratories. The requirements for approval are in Resolution No 246/2010, established by the SENASA and include general requirements and specific requirements (by analyte).

The CA informed the audit team that one of the conditions to become an official laboratory is to be accredited according to ISO 17025 standard. The current SENASA requirement is that at least one test method for pathogens in foodstuff should be within the scope of accreditation.

Laboratories within the SENASA National Network are regularly audited by SENASA specialists.

The audit team visited two laboratories belonging to SENASA laboratory network.

The audit team noted that the method used by the SENASA network for *Salmonella* detection in egg products intended for EU export is the EU analytical reference method ISO 6579.

The laboratories visited have knowledgeable staff and regularly participate in proficiency testing for *Salmonella* detection (organised by the National Reference Laboratory, the National Institute for Industrial Technology, and also by external providers) with satisfactory results.

Both laboratories are accredited to ISO 1725 standard by the Argentinean Accreditation Body, (OAA). The *Salmonella* method used is within the scope of accreditation.

The audit team noted that both laboratories visited are regularly audited by OAA and the reports were available. In the case of non-compliance detected, corrective actions were taken and assessed by OAA. The audit team was provided with evidence of training for laboratory staff.

However in one laboratory visited the staff informed the audit team that official samples in unsealed containers are being transported to the official laboratory by FBOs despite national procedures in place intended to prevent tampering with official samples.

Conclusions

Laboratories involved in egg products analyses for EU exports meet the relevant EU requirements.

5.5 Official certification

Legal requirements

Council Directive 96/93/EC lays down several certification principles.

Annex VI to Regulation (EC) No 854/2004 lays down requirements for certificates accompanying imports.

The model certificates for egg products are outlined in Part II, Annex I to Commission Regulation (EC) No 798/2008.

Findings

Certification of egg products intended for export is regulated in Disposition No 5/2003, approving the Manual for Final Export Certification. To obtain health certification, FBOs follow the procedures set forth in Circular Letter No 3510.

The system in place for certification is based on the issuing of interim certificates covering the movement of EU eligible products from the exporting establishment to the Argentinean port/airport where the consignment leaves the country for export to the EU.

An establishment must apply for health certification to the Official Veterinary Service of the establishment, by submitting a sworn statement (affidavit). The sworn statement contains information on the product, manufacturing conditions, net weight, gross weight, batch number, destination, etc.

The preliminary certificate is signed only after the OV has:

- verified that the information on the application is correct;
- verified that the conditions of the container to be used are met;
- verified the cleanliness of secondary packaging;
- verified the labeling;
- checked packing list.

In all cases reviewed by the audit team the EU export health certification procedure had been correctly followed.

However the audit team noted that the final certificates, in particular for consignments sent by ship, were only issued by the certification office (part of Regional CA) when the ship had already left for several days. However the date stated on the final certificate is the date when the consignment was loaded on board of the transport vessel (day when it left from CA control).

The language of the certificates was not always in line with the requirements of Regulation (EC) No 854/2004 (e.g. Spanish and French used for a consignment sent to Italy via a Border Inspection Post in Belgium: the certificate should have been in French/Dutch and Italian).

Conclusions

There is a procedure in place for issuing of EU export health certificates and it is adequately implemented. However full effectiveness of the certification system is compromised by some

weaknesses noted, in particular as regards date certified and language used.

6 Overall Conclusions

The system of official controls in place is based on regular controls at establishment level, including permanent presence of official veterinarian services at establishments during production.

However, the effectiveness of this system is compromised by the several deficiencies detected by the audit team, the main ones being as follows:

- There is no documented evidence that the CA assesses all EU requirements during EU approval procedures (notably HACCP plan and its implementation).
- Deficiencies in establishments visited (related to sanitary conditions and hygiene practices) had not previously been detected or recorded in any official control report, demonstrating that monitoring of ongoing compliance with initial approval conditions is not entirely effective.
- Weaknesses in the certification procedures in place (date and language).
- Deficiencies in both official and FBO sampling of egg products in the approved establishments (for microbiological analyses and organic acids).

7 Closing Meeting

During the closing meeting held in Buenos Aires on 3 May 2013, the audit team presented the findings and preliminary conclusions to the CA.

During this meeting, the CA acknowledged the findings and informed the audit team that they will reflect on them upon receipt of the draft report.

8 Recommendations

The CCA should provide Commission services with an action plan, including a timetable for its completion, within one month, in order to address the following recommendations for egg products exported to the EU.

N°.	Recommendation
1.	The CCA should ensure that CA staff carrying out official controls in EU egg product export establishments has adequate knowledge of EU legislation, in particular with the relevant requirements laid down in Section X of Annex III to Regulation (EC) No 853/2004 and Regulation (EC) No 2073/2005 (in particular regarding sampling of egg products on microbiological criteria and organic acids compliance).
2.	The CCA should demonstrate that only establishments with all standards equivalent to those of the EU, notably HACCP plan and its implementation as required under Regulation (EC) No 852/2004, are approved for export of egg products to the EU.
3.	In order to be in line with the relevant EU requirements, the CA should ensure that the deficiencies recorded by the audit team are corrected in the establishments visited and are not present in other approved ones (see: Annex II to Regulation (EC) No

N°.	Recommendation
	852/2004,and Section X of Annex III to Regulation (EC) No 853/2004).
4.	The CCA should ensure that disinfection of eggs for production of egg products for export to the EU is carried out avoiding any contamination in line with EU requirements laid down in Point III.1. of Section X of Annex III to Regulation (EC) No 853/2004 (disinfected eggs shall be rinsed with potable water and adequately dried before breaking).
5.	The CCA should ensure that egg product samples taken within own-checks and by the CA staff for official microbiological analyses are in line with EU requirements laid down in Regulation (EC) No 2073/2005 (in particular regarding the sampling protocol).
6.	The CCA should ensure that when certifying egg products to be exported to the EU, rules and principles of certification equivalent to those laid down in Council Directive 96/93/EC and Regulation 854/2004 are respected (in particular regarding date and language used in certificates).
7.	The CCA should ensure that egg product samples are taken and analysed for organic acids and quantity of extraneous materials in line with Part IV, Section X of Annex III to Regulation (EC) No 853/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6722

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 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. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 798/2008	OJ L 226, 23.8.2008, p. 1-94	Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin