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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
SPAIN
FROM 04 TO 15 JUNE 2012
IN ORDER TO EVALUATE COMPLIANCE OF BORDER INSPECTION POSTS WITH
APPROVAL REQUIREMENTS

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 (FVO) in Spain from 4 to 15 June 2012.

The overall objective of the audit was to assess the national system in place to ensure that approved Border Inspection Posts (BIPs) were constructed, equipped, maintained and operated in line with approval requirements. In terms of scope, the audit concentrated on the ability of the Competent Authorities to ensure that operating BIPs maintain compliance with approval requirements for the categories approved.

The report concludes that there is a variation in the level of compliance of the facilities in the BIPs. Meanwhile most of them comply with the minimum structural and operational requirements of Decision 2001/812/EC and Directive 91/496/EEC, others do not do so for all their approval categories (Málaga BIP (port), Huelva BIP (port), Marín port (IC Protea Productos del Mar), Vilagarcía-Ribeira-Caramiñal port (IC Ribeira and IC Caramiñal) and Vigo port (IC Puerto Vieira and IC Frig. Morrazo). The severe deficiencies in Sevilla BIP (airport) and IC Laxe (under A Coruna-Laxe BIP) indicate the need for an immediate suspension of the activity. The situation in A Coruna-Laxe BIP, where new facilities in full compliance are available for use but the controls are carried out in a facility where the adequate hygiene and temperature controls cannot be ensured, requires immediate action by the Competent Authorities.

While the current system of supervision and audits is effective at detecting structural and hygienic deficiencies at BIPs, the absence of documented actions plans and deadlines allied with a failure to enforce timely corrective actions, compromises the ability of the Competent Authorities to ensure that all operating BIPs maintain compliance with approval requirements. This situation was already noted in the previous 2011 FVO audit.

The availability of resources appears sufficient to support the import controls system. However, the inefficient co-ordination between the functional Ministries, the MINHAP and the Public Bodies involved in the import controls and facilities management undermines the effectiveness of the controls (reduction of the verification activities, inadequate facilities) which increases the risk for a failure of the system.

The report makes a number of recommendations aimed at pursuing the outstanding shortcomings.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AENA	Spanish Airports and Air Navigation (<i>Aeropuertos del Estado y Navegación Aérea</i>)
AENOR	Spanish Association for Standardization and Certification (<i>Asociación Española de Normalización y Certificación</i>)
Approval categories	Categories of live animals and animals products for the receipt of which BIPs are approved in accordance with Commission Decision 2001/881/EC, as follows:
	HC Products fit for human consumption
	NHC Other products (Products not fit for human consumption)
	U Live animals: ungulates (cattle, pigs, sheep, goats, wild and domestic solipeds)
	E Live animals: registered equidae (as defined in Council Directive 90/426/EEC)
	O Live animals: other animals (including zoo animals)
	(2) Packed products only
	(3) Only for fishery products
BIP	Border Inspection Post as defined in Council Directives 97/78/EC and 91/496/EEC
Central Competent Authorities	The functional Ministries, MSSSI and MAGRAMA
EU	European Union
FVO	Food and Veterinary Office
IC	Inspection Centre
MSSSI	Ministry of Health, Social Services and Equity (<i>Ministerio de Sanidad, Servicios Sociales e Igualdad</i>)
MAGRAMA	Ministry of Agriculture, Foodstuffs and Environment (<i>Ministerio de Agricultura, alimentación y Medio Ambiente</i>)
MINHAP	Ministry of Finance and Public Administrations (<i>Ministerio de Hacienda y Administraciones Públicas</i>)

1 INTRODUCTION

This audit took place in Spain from 4 to 15 June 2012. The audit team comprised three auditors from the Food and Veterinary Office (FVO). The audit team was accompanied throughout the audit by at least one representative of each of the Central Competent Authorities.

An opening meeting was held on 4 June 2012 with the representatives from the Ministry of Health, Social Services and Equity (*Ministerio de Sanidad, Servicios Sociales e Igualdad* - MSSSI) and the Ministry of Agriculture, Foodstuffs and Environment (*Ministerio de Agricultura, alimentación y Medio Ambiente* -MAGRAMA) which are the Spanish Central Competent Authorities for the scope of this audit.

Also present at the meeting were representatives of the Ministry of Finance and Public Administrations (*Ministerio de Hacienda y Administraciones Públicas* - MINHAP) and representatives from the Public Body for State's Ports (*Organismo Público Puertos del Estado*) and Spanish Airports and Air Navigation (*Aeropuertos del Estado y Navegación Aérea*, AENA).

At this meeting, the objectives of and the itinerary for the audit were confirmed. Additional information required for the satisfactory completion of the audit was provided by the Central Competent Authorities.

2 OBJECTIVES

The objective of the audit was to assess the national system in place to ensure that approved Border Inspection Posts (BIPs) are constructed, equipped, maintained and operated in line with approval requirements.

In terms of scope, the audit included BIPs listed in Commission Decision 2009/821/EC. The audit team evaluated the compliance of listed BIPs with EU requirements and the ability of the Central Competent Authorities to ensure that operating BIPs maintain compliance with approval requirements for the categories approved. In particular, the audit evaluated the system of supervision/audit and follow-up (regarding the mentioned scope) within the framework of Regulation (EC) No 882/2004, as well as facilities, personnel, equipment and operating procedures in individual BIPs in the framework of Council Directives 91/496/EEC and 97/78/EC and Commission Decision 2001/812/EC.

3 LEGAL BASIS

The audit was carried out 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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Other relevant EU legislation was taken into consideration during the audit, in particular:

- Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries; Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC, and in particular Article 19;
- Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of border

inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in TRACES;

- Commission Decision 2001/812/EC of 21 November 2001 laying down the requirements for the approval of Border Inspection Posts responsible for veterinary checks on products introduced into the Community from third countries.

A full list of the legal instruments referred to in this report is provided in Annex 1 and refers, where applicable, to the last amended version.

4 BACKGROUND

At the time of the audit, there were 275 BIPs listed in Commission Decision 2009/821/EC, as last amended. When a Member State requests approval listing of a BIP, the Commission ascertains that facilities, equipment and staff comply with EU legislation before the BIP is listed. EU legislation does not stipulate when BIPs are to be revisited, and it is up to the Competent Authority of the Member State to ensure that approval requirements are maintained at listed BIPs.

The European Court of Auditors, in its Special Report No 14/2010 (“The Commission’s management of the system of veterinary checks for meat imports following the 2004 hygiene legislation reforms”) pointed out that around 17% of the EU BIPs had not been inspected by the FVO since before Decision 2001/812/EC was adopted.

Although the unvisited BIPs had low throughput and, thus, limited control activities, on-the-spot checks to the four Member States with a higher number of unvisited BIPs were planned for 2012 with the aim to assess compliance of BIP facilities with EU requirements.

The previous FVO audit in Spain covering different aspects of BIPs and import controls took place in May 2011 (audit report ref. DG(SANCO) 2011-8926- MR FINAL). The report (hereinafter, the 2011 report) can be found in the internet at

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2792.

The 2011 report made two recommendations (Nos. 10 and 11) to the Spanish Competent Authorities relevant to the scope of the current audit. The actions proposed to address one of those recommendations were considered not satisfactory.

At the time of the audit, Spain had 42 BIPs listed (three of them suspended) in Commission Decision 2009/821/EC, as last amended.

5 FINDINGS AND CONCLUSIONS

5.1 PROVISION OF FACILITIES

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the Competent Authority to ensure that they have access to appropriate and properly maintained facilities and that adequate equipment is available.

The requirements for BIP facilities, their equipment and hygiene are laid down in Directive 91/496/EEC concerning live animals and in Directive 97/78/EC and Decision 2001/812/EC concerning products of animal origin.

Findings

The current audit evaluated a total of eleven BIPs and part of their Inspection Centres (ICs).

5.1.1 BIP Sevilla (port): HC, NHC

During 2011, the BIP received around 160 consignments, all packed products for HC products.

The audit team noted:

- Facilities were shared for handling both categories HC and NHC, with different equipment available to perform veterinary checks. Procedures were in place to minimise cross-contamination, for cleaning and disinfection and records.
- The facilities were built and maintained to a high standard. In the unloading area, a door opens directly to the outside and it is used as access for non-inspecting personnel and forklifts.
- The equipment to perform veterinary checks was complete and adequate. However, there was no equipment, nor procedures, to handle unpacked products, for which the BIP is also approved, even though it has never received such commodities.
- The last audit from the MSSSI covering facilities was carried out in 2007. In 2010, AENOR (the Spanish Association for Standardization and Certification - *Asociación Española de Normalización y Certificación*) carried out an audit on behalf of the MAGRAMA, which included facilities. The outcome was communicated also to the MSSSI. After the audit, the State's Port body presented an action plan to address the deficiencies identified.

5.1.2 BIP Sevilla (airport): HC(2), NHC(2), O

The BIP has received one consignment of products in 2009 and one in 2011. Live animals have never been arrived.

At the time of the audit, the airport was not receiving any flights from outside the EU. According to the information provided by the Director of the airport, cargo flights from outside the EU are very unlikely to arrive in the future. However, he expressed the intention to build new facilities.

The audit team noted:

- The facilities for products are shared for HC and NHC consignments. The three storage areas for the different temperature regimes open to the hangar and, although they could be locked, BIP staff did not have the key for two of them.
- The design does not provide sufficient separation of the flows for personnel and products.
- The facilities for live animals consisted of three rooms aligned in a hangar. The layout and the building materials are not adequate to minimise the animal health risks (e.g. surfaces are not easy to clean and disinfect, animals and personnel would have to enter the hangar to go to the housing area).
- The last audits were carried out in March 2007 (by the MSSSI) and 2010 (AENOR on behalf of the MAGRAMA). No significant deficiencies were reflected on the reports.

5.1.3 BIP Huelva (port): HC-T(CH), HC-T(FR), NHC-NT

5.1.3.1 IC Puerto Interior: HC-T(FR), HC-T(CH)

The IC for HC received 16 consignments in 2011, all frozen fish and fishery products packed in boxes.

The audit team was informed that a project to substitute the existing facilities was in its third draft and would be sent shortly to the functional Ministries to be forwarded to the FVO for further evaluation.

The audit team noted:

- The facilities are approved for packed and unpacked products. There was an unloading area suitable for receiving containers, but the area of unloading ships was not enclosed or covered by a roof. The gate at the unloading area left an open gap to outside in its upper part.
- Due to the type of consignments (cargo in bulk) the facilities are very seldom used.
- Consignments arrived packed in bulk in big ships, and unloading takes several days. There are no facilities to store all the cargo in the port, so for this purpose a documented procedure was put in place by the MSSSI that foresees the detention of the consignments in authorised warehouses until they are released from the veterinary point of view. The boxes are loaded in lorries, which are sealed by BIP staff to go to an establishment approved for this warehousing. There, the operator unseals the lorries and fills a document that is returned to the BIP. BIP staff may carry out checks on-the-spot but those are not documented. Customs also supervise the procedure.
- BIP facilities had acceptable building standards. The chiller was out of use for two days before the visit, according to BIP staff.
- The inspection room had fabric chairs and a porous ceiling. The door frames in many areas of the BIPs were made of non-washable wood.
- The last audit on facilities was carried out by the MSSSI in June 2008. After different communications with the Port Authorities, an action plan was presented in 2011 and modification of the facilities started in May 2011. All structural deficiencies detected were addressed in the action plan presented.

5.1.3.2 IC Puerto Exterior: NHC-NT

The IC has not received NHC consignments in the last three years.

The audit team noted:

- There is no storage area/room for the consignments.
- The materials used on the walls of the inspection room cannot be easily cleaned.
- The gate in the unloading area leaves several openings to the outside.
- The MAGRAMA carried out the last audit on facilities in 2009. The important structural deficiencies noted during the FVO audit were already present and reported. No action plan with deadlines had been presented, but a project for new facilities was mentioned in the documentation reviewed. Despite that, the date of completion of the works was 2010, no

enforcement actions had been taken by the MAGRAMA. At the time of the FVO audit, most of the deficiencies detected by the Competent Authorities persisted.

5.1.4 BIP Málaga (port): HC, NHC, U, E, O

According to the information received during the audit, the traffic at the port had been seriously affected by the recession. In general terms, the Port Authorities indicated that more transshipments take place than imports.

The BIP received 85 consignments of HC products during 2011, and 94 consignments in 2012 until the FVO audit.

NHC consignments were not received.

Live animals had not been received in the last three years.

The audit team noted:

- The BIP staff include three veterinarians and one assistant staff working for the MAGRAMA and three veterinarians, three inspection technicians and one assistant working for the MSSSI.
- The BIP has a contract with a company located in the port for supplying all necessary support staff and equipment needed for veterinary checks.
- Facilities for HC consignments:
 - All areas and rooms required were available and were built and maintained to adequate standards. There was no saw to cut frozen products that were often received. This had been requested to the MINHAP.
 - The HC facilities had been last audited by the MSSSI in April 2012. The deficiencies detected had been solved by the Port Authority.
- Facilities for NHC consignments:
 - Although facilities were approved for three temperature regimes, only one storage room at ambient temperature was available.
 - Surfaces were built with materials which are not easy to clean and disinfect in most areas (e.g. walls, floors and ceilings in the storage room, the unloading and inspection room and the wooden cupboard doors in the inspection room).
- Facilities for live animals:
 - There was no procedure to move arrival animals from ships to the BIP.
 - The corridor that animals should enter through was not suitable for bovine and equidae.
 - There was no inspection area for E and U animals and the layout and equipment in the room for detention presented problems to ensure animal welfare.
 - There was no equipment to check live animals.
- The facilities for NHC products and live animals had been last audited in January 2012 by MAGRAMA. In the audit report, the serious structural deficiencies were reflected and a deadline of 30 days was given to the State's Port body to present an action plan, including deadlines for completion. However, this reply was not yet provided at the time of the FVO audit and no enforcement measures had been used by the MAGRAMA.

- Representatives of MAGRAMA stated that it was decided to withdraw the approvals for E and U, but this had not yet been communicated to the Commission services. The Public Body for State's Ports indicated their intention to keep approval for categories NHC and O and indicated that a project was under development.

5.1.5 BIP Almería (port): HC, NHC-NT

Facilities were new and started to operate on 4 June 2012. Approval for “O” had been granted by the MAGRAMA and communicated to the Commission to put it to a vote on the SCOFCAH in July 2012.

The BIP received 318 consignments in 2011, all packed HC products.

The BIP staff included two veterinarians who were working for both functional Ministries, one veterinarian on maternity leave and three technicians. There was a vacant post for a veterinarian.

The audit team noted:

- Facilities for HC, NHC and O were built to a very high standard and had all necessary rooms and areas. The equipment to perform veterinary checks was adequate and complete. There was equipment to handle hygienically unpacked products in case they arrive (e.g. Aerial rails for carcasses).
- Hygienic procedures were in place to avoid contamination due to a flow of people or goods. Documentation on internal supervision for facilities and cleaning procedures was well kept.

5.1.6 BIP Almería (airport): HC(2), NHC(2), O

Facilities were temporarily suspended until May 2011 when new facilities were finished. No consignments were received during 2011. At the time of the audit, the airport did not receive flights from third countries and no cargo flights from outside the EU were expected to arrive in the following years. The BIP personnel was the same as those working at the Almeria port BIP.

The audit team noted:

- Facilities had all necessary rooms and areas for the categories approved. The equipment was also adequate and the layout allowed adequate flows of personnel and goods.
- There was evidence that rodents could enter the ambient temperature room adjacent to the BIP (in the same hangar).

5.1.7 BIP Vigo (port)

The BIP at Vigo port is an important high throughput BIP with 12,459 consignments in 2011 handling big amounts of different fishery products. It includes seven ICs, of which three were visited during the current audit.

5.1.7.1 IC Pescanova: HC-T(FR)(2)(3)

The audit team noted:

- The layout of the IC complies with the minimum requirements for the category approved.
- The last audit from the MSSSI took place in 2009. The report included some

recommendations but there was no action plan provided by the operator. There was no documented follow-up or enforcement measures from the Competent Authority.

- Wooden pallets used for handling the frozen packed fish are used by the operator. Staff are instructed to avoid entering them into the inspection room of the IC.

5.1.7.2 IC Puerto Vieira: HC-T(FR)(3)

The audit team noted:

- The IC only partially complies with the requirements laid down in the EU legislation.
- The unloading area is open to the harbour and there is no protection (e.g. plastic slat curtains) against birds, that are walking around on the surfaces where the frozen unpacked fish is handled.
- The facilities of the inspection room had a door of inadequate material (bare wood), the window opens to the outside area without protection against insects.
- Procedures for cleaning and disinfection are not documented and some parts of equipment and facilities were not sufficiently clean.

5.1.7.3 IC Frig. Morrazo HC-T(FR)(3)

The audit team noted:

- The facility had been built a long time ago, and the layout of the IC does not fulfil the current requirements on design and separation of flows. The issue was discussed in detail with the operator during the FVO visit and a simple reconstruction to fulfil the EU requirements was proposed and agreed with the Competent Authorities. The operator provided guarantees that the works would be done immediately, eliminating the deficiencies in the flow design.
- The facilities are kept at an optimal hygiene standard and the equipment was very well cleaned and maintained, including calibration of gauges.

5.1.8 BIP Marín (port) HC, NHC-T(FR), NHC-NT

The BIP received 829 consignments in 2011.

The audit team noted:

- Overall the BIP has the necessary rooms and areas required for the categories included in the approval. However, the ceiling is made of a material not easy to clean in the inspection room.
- The changing room shared between HC and NHC did not have cupboards and protective

clothes.

- Equipment was adequately clean, but some deficiencies in equipment were noted: based on the statement of one of the officials, the spear to sample bulk materials (e.g. fish meal) was not used because there was no budget/arrangements in place to adequately clean and disinfect after use; protective clothing was not available in the BIP, and staff met explained that they bring their clothing home to be cleaned.
- Structural deficiencies noted during the last verification visit from MAGRAMA had been corrected.

5.1.8.1 IC Protea Productos del Mar: HC-T(FR)(3)

The audit team noted:

- The flows of personnel and consignments are not adequate to reduce the risk of cross-contamination. During the visit, the operator representative agreed to upgrade the facilities to make them fully compliant in a very short time.
- Equipment necessary for the checks was present in the inspection room. In the changing room there were no cupboards with proper clothes for the staff.
- The operator is an importer and was recently approved for handling products of non-animal origin. At the time of the audit, the former cold store for POAO had been used for vegetables and there was no cold store allocated for fish or fishery products, therefore the facilities at the time of the audit were approved for handling both POAO and products of non-animal origin.
- It was noted that the approval for handling products of non-animal origin had been granted by the services of the Autonomous Community, who did not inform the Competent Authorities in charge of the IC. Staff of the MSSSI learnt about the new activity during the preparation of the FVO audit, but were unaware that the cold store for fish had been used for vegetables. The Competent Authority guaranteed that an action plan will be immediately implemented to rectify the irregular situation.

5.1.9 BIP Vilagarcía–Ribeira–Caramiñal (port)

5.1.9.1 IC Vilagarcía HC(2), NHC(2)(11)

The BIP received 118 consignments in 2011 for HC and no consignments for NHC.

The audit team noted:

- The BIP is newly built and constructed in line with all the EU requirements in relation to layout and proper materials.

5.1.9.2 IC Ribeira: HC

During 2011 this IC received 20 consignments of frozen tuna in bulk (a total of about 11,000 tonnes intended for further processing).

The audit team noted:

- Facilities had all rooms and areas for the approval. Minor problems such as wooden doors, non-washable ceiling or dirty drains were observed.
- Large bulk consignments of fish for further processing were received, and there were no suitable storing facilities available for storage in the port. The control of the consignments is similar to the description for the BIP at Huelva port.
- There was no mechanism to ensure that only consignments cleared by the veterinary services were leaving the port (no physical fencing and no permanent controls) the IC does not comply with the requirements for all HC and the current procedure is only acceptable for frozen fish in bulk.

5.1.9.3 IC Caramiñal: HC

The audit team noted:

- The IC receives a low number of large consignments of frozen fish tuna subspecies in bulk for further processing in the nearby processing plant. The unloading takes a few days and consists of many trucks transporting the product from the vessel to the factory in non-refrigerated trucks covered by a plastic sheet. The unloading process from the vessel to the trucks is not performed under shelter.
- Facilities had all rooms and areas for the approval. Minor problems such as wooden doors, non-washable ceiling or dirty drains were observed in IC Caramiñal.
- Large bulk consignments of fish for further processing were received, and there were no suitable storing facilities available for storage in the port. The procedure described for Huelva BIP was implemented in the IC.
- The need for restriction in the approval category for frozen fishery products only was observed during the audit.

5.1.10 BIP A Coruña–Laxe (port)

5.1.10.1 IC A Coruña: HC, NHC

The IC received 110 consignments in 2011 and 8 during 2012.

The audit team noted:

- There were new facilities in full compliance with all requirements. They have been ready for use for several months. However, official controls are still carried out in the old facilities, which have severe non-conformities, hampering the effectiveness and completeness of the official controls and increasing the risk for food safety.
- The old BIP is located in the area of the port where bulk products are handled (soja, coal).

During the audit there was no activity with those products, but staff met indicated that this was unusual and that the area is heavily soiled during the opening hours of the BIP.

- The internal design of the old BIP does not allow for a proper separation between flows of staff and of products. Access to changing rooms is only possible through the unloading area.
- The motors of the cold stores in an old BIP are non-functioning and, based on the information from the BIP's staff, this had been ongoing for a long time. The Port Authority's representative indicated that they were not easily repairable, and the new facilities were ready to use.
- The doors of the docks in the new BIP do not close in a manner to prevent access of dirt and small animals.
- The old BIP has two docks. The design of one of them does not allow the unloading of pallets from containers. In the other dock, the actions required for this unloading are dangerous for the staff and officials acknowledge that physical inspections were done in the container.
- The BIP had been audited by the Central Competent Authorities and all the deficiencies had been noted. However, the delay in using the new facilities was not addressed.

5.1.10.2 IC Laxe: HC

No consignments were received in the IC during the two previous years.

The audit team noted:

- The facilities did not comply structurally with the approval requirements. The Competent Authority stated that the IC would be suspended after the audit.

5.1.11 BIP Santiago de Compostela (airport): HC(2), NHC(2)

The audit team noted:

- The layout of the BIP facilities does not comply in full with requirements laid down in EU legislation, namely because the access of personal and goods is done through the same entry. However, the risk for public health is limited by (i) the high standard kept in maintenance and hygiene and (ii) the low number of consignments and the limitation for packed products.

Conclusion

There is a variety in the levels of compliance of the facilities of the BIPs and ICs visited during the audit:

- Most of the facilities comply with the minimum structural and operational requirements of Decision 2001/812/EC and Directive 91/496/EEC for their respective approval categories: Almería BIP (port), Sevilla BIP (port), Vilagarcía–Ribeira–Caramiñal (IC Vilagarcía), Vigo (IC Pescanova), Marín BIP (port), Almería BIP (airport) and Santiago de Compostela BIP (airport).
- The following facilities did not comply with all the structural and operational requirements of Decision 2001/812/EC and Directive 91/496/EEC relevant for their approval categories: Málaga

BIP (port), Huelva BIP (port), Marín port (IC Protea Productos del Mar), Vilagarcía–Ribeira–Caramiñal port (IC Ribeira and IC Caramiñal) and Vigo port (IC Puerto Vieira and IC Frig. Morrazo).

- Two facilities Sevilla BIP (airport) and A Coruna-Laxe port (IC Laxe) have severe deficiencies that indicate the need for an immediate suspension of the activity.

- The situation in A Coruna-Laxe BIP, where new facilities in full compliance are available for use but the controls are carried out in a facility where the adequate hygiene and temperature controls cannot be ensured, requires immediate action by the Competent Authorities.

5.2 SYSTEM TO MAINTAIN COMPLIANCE WITH APPROVAL REQUIREMENTS

Legal Requirements

For POAO, Article 2 of Commission Decision 2001/812/EC indicates that BIPs, in order to maintain their approval, should be provided with facilities, equipment and procedures as specified in this Decision. Article 4 of the same Decision indicates that facilities in approved BIPs must be equipped, maintained and operated in line with the requirements set down in the Annex to this Decision and in relevant EU legislation.

For live animals, the requirements for BIP facilities, their equipment and hygiene are laid down in Directive 91/496/EEC.

Findings

As indicated in the report DG(SANCO) 2011-8926, the competences regarding BIPs are divided as follows:

- The two functional Ministries (MAGRAMA and MSSSI) have competence to authorise BIPs, supervise import controls, provide instructions and procedures for BIP staff and to liaise with the EU Commission on import control matters. The MAGRAMA has the responsibility for products of animal origin not used for human consumption (NHC) and live animals. The MSSSI has responsibility for all products of animal origin for human consumption.
- The MINHAP is the Competent Authority responsible for providing necessary equipment and staff in the BIPs. Requests for equipment and staff are passed from the functional Ministries to the representative of the MINHAP in the Autonomous Community, who then forwards it to the central level.
- For BIPs located in airports, the structure and maintenance of the facilities is the competence of AENA (for BIPs situated at airports) with one exception, the BIP at Ciudad Real airport) which is privately owned. This BIP was not visited during the current audit.
- For BIPs located in airports, the building and maintenance of the facilities is the responsibility of the Public Body for State's Ports, with some exceptions (in what refers to the current audit, A Coruna-Laxe, Caramiñal and Ribeira ICs are responsibility of *Portos de Galicia*, a public entity under the Autonomous Government -*Xunta de Galicia*-).

- Regarding ICs, those with bigger import activity are privately managed.

The MSSSI carry out visits for verification on BIP facilities, according to the established multi-annual plan. When relevant, a report requesting an action plan is issued and sent to the BIP, to the Public Body for State's Ports or to AENA and to the representatives of the MSSSI in the Autonomous Community where the BIP is situated. When the action plan is received at central level, it is evaluated¹.

The multi-annual plan 2011-2015 of the MSSSI foresees to evaluate the facilities of all the BIPs. The representatives of MSSSI indicated that a procedure to supervise facilities by local representatives of the MSSSI was under development.

The MAGRAMA performed audits during 2010 (including facilities) through AENOR. In 2011, performance of internal audits were assigned to the Services' General Inspection Unit (*Inspección General de Servicios*) of the MAGRAMA, independent from the technical Units and attached to the Sub-Secretary. The staff of this Unit attended audit training provided by the EU Commission. After the audit, a report is in place similar to the one explained for the MSSSI.

Report DG(SANCO) 2011-8926 referred to an IT programme (QUESTOR) as an adequate tool for harmonising and co-coordinating the verification systems of the two functional Ministries. However, the Competent Authorities indicated during the opening meeting that the programme was no longer used by MSSSI. MAGRAMA still use this programme to draw up reports and to follow-up on audits and supervisory visits of BIPs.

The audit team noted:

- Representatives of the MINHAP indicated that its budget was decreased by 40% in the last year.
- Representatives of MSSSI indicated that due to the budgetary restrictions, during 2011 only three supervisory visits scheduled in BIPs took place out of ten. For 2012, eight visits were programmed and five had been performed at the time of the FVO audit.
- A draft of the procedure to carry out supervision at local level was presented to the audit team by the MSSSI.
- In 2011, AENOR carried out two external audits in two BIPs on behalf of the MAGRAMA. During 2012, four internal audits had been performed by the Services' General Inspection Unit of the MAGRAMA.
- Audits/supervisory activities on BIP facilities are performed independently by the functional Ministries, even in cases where facilities are shared (e.g. Sevilla port BIP)².
- Action plans were not always requested or presented after the respective audit/supervisions, and those developed did not always include actions to address all deficiencies detected. In

¹ In their response to the draft report, the Competent Authorities noted that the report from the verification visits to facilities not only states that an action plan must be provided but also that a timetable for the implementation of corrective and/or preventive measures addressing the weaknesses or shortcomings identified be included. These measures include system-wide measures such as communication and coordination with other bodies concerned and the concrete changes and action concerning the relevant procedures.

² In their response to the draft report, the Competent Authorities noted that audits and supervisory activities on shared facilities are now being performed together by the functional Ministries.

most cases, deadlines were not indicated (e.g in Huelva port BIP, the facilities for NHC were inspected by the MAGRAMA in 2009. A new project was indicated in the action plan with the date 2010. The new facilities had not been built and the deficiencies found in 2009 still persisted at the time of the current FVO audit).

- Although the follow-up process was incompletely documented, deficiencies indicated in the audit reports from the functional Ministries had been in several cases corrected in the BIPs visited during the FVO audit.
- Requests for equipment from the functional Ministries to the MINHAP were documented. However, big delays were observed in obtaining the equipment requested (e.g a BIP requested a freezer to store samples and the equipment had not been received after two years). Problems in getting basic office consumables (e.g paper for printers) were detected.
- One BIP co-ordinator indicated that, due to shortage of funds for petrol, supervisory visits in one BIP under his responsibility did not take place.
- In relation to the BIPs visited in the Autonomous Community of Galicia (Vigo, Marín, Vilagarcía–Ribeira–Caramiñal, A Coruña–Laxe and Santiago de Compostela), the audit team noted that staff is organised as a pool of veterinary inspectors, veterinary technicians and administrative staff, covering three BIPs (for MSSSI) or four BIPs (for the MAGRAMA), with their respective ICs. The veterinarians are present on demand, as consignments are routinely pre-notified. Distances between BIPs and ICs are considerable.
- As described under heading 5.1.9, the facilities in the BIP in A Coruna-Laxe (port) have severe deficiencies which hamper the guarantees on public and animal health. New facilities have been built at the highest standards by *Portos de Galicia*, and have been available for use for sometime. However, the move to the new facilities did not take place because the final arrangements (gathering furniture and transfer of available equipment) was not agreed. The functional Ministries claimed that an Agreement needed to be signed between *Portos de Galicia* and the MINHAP for this purpose, but representatives of MINHAP denied this factor as the cause of the delay³.

Conclusion

While the current system of supervision and audits is effective at detecting structural and hygienic deficiencies at BIPs, in certain cases, the absence of documented actions plans⁴ and deadlines allied with a failure to enforce corrective actions timely compromise the ability of the Competent Authority to ensure that all operating BIPs maintain compliance with approval requirements.

Overall the availability of resources appears sufficient to support the import controls system. However, the poor management of those resources and the inefficient co-ordination between the functional Ministries, the MINHAP and the Public Bodies involved in the import controls and facilities management undermines the effectiveness of the controls (reduction of the verification activities, inadequate facilities) which increases the risk for a failure of the system.

³In their response to the draft report, the Competent Authorities noted that every time a new facility is handed over and made available by a port authority to the health inspection services, an agreement must be drawn up between the said authority and the MINHAP. However, the administrative processing of such agreements do not lead in any way to a delay concerning the actual use of the facilities.

⁴ In their response to the draft report, the Competent Authorities noted that since 2010 the MAGRAMA and 2011 the MSSSI, have systems based on documented supervision and audits in which reports are produced and Competent Authorities are requested to produce action plans which must include the corrective measures to be taken to remedy shortcomings.

6 OVERALL CONCLUSIONS

There is a variation in the level of compliance of the facilities visited during the audit. Meanwhile most of them comply with the minimum structural and operational requirements of Decision 2001/812/EC and Directive 91/496/EEC, others do not do so for all their approval categories (Málaga BIP (port), Huelva BIP (port), Marín port (IC Protea Productos del Mar), Vilagarcía-Ribeira-Caramiñal port (IC Ribeira and IC Caramiñal) and Vigo port (IC Puerto Vieira and IC Frig. Morrazo). The severe deficiencies in Sevilla BIP (airport) and A Coruna-Laxe port (IC Laxe) indicate the need for an immediate suspension of the activity. The situation in A Coruna-Laxe BIP, where new facilities in full compliance are available for use but the controls are carried out in a facility where the adequate hygiene and temperature controls cannot be ensured, requires immediate action by the Competent Authorities.

While the current system of supervision and audits is effective at detecting structural and hygienic deficiencies at BIPs, in certain cases, the absence of documented actions plans and deadlines allied with a failure to enforce timely corrective actions, compromises the ability of the Competent Authorities to ensure that all operating BIPs maintain compliance with approval requirements. This situation was already noted in the previous 2011 FVO audit.

The availability of resources appears sufficient to support the import controls system. However, the inefficient co-ordination between the functional Ministries, the MINHAP and the Public Bodies involved in the import controls and facilities management undermines the effectiveness of the controls (reduction of the verification activities, inadequate facilities) which increases the risk for a failure of the system.

7 CLOSING MEETING

A closing meeting was held on 15 June 2012 with representatives of the Central Competent Authorities, where main findings and the preliminary conclusions of the audit were presented by the audit team. The Central Competent Authority commented upon some issues and agreed with the preliminary conclusions.

8 RECOMMENDATIONS

The Spanish Competent Authorities are requested to provide, within one month of receipt of the report, a response including an action plan setting out the actions planned/undertaken to satisfactorily address the following recommendations:

Nº.	Recommendation
1.	To align the system of supervision/audit of the facilities with the requirements laid down in Article 4.6 of Regulation (EC) No 882/2004, ensuring that appropriate measures are taken in the light of their results, in order to ensure that all BIPs and ICs have facilities compliant with the requirements laid down in Decision 2001/812/EC and Directive 91/496/EEC.
2.	To ensure that BIPs and ICs comply with all structural and equipment requirements in Commission Decision 2001/812/EC and Council Directive 91/496/EEC for the

N°.	Recommendation
	categories they are approved.
3.	To ensure that import controls (e.g at the BIP in A Coruna-Laxe) for products of animal origin are only performed in appropriate BIP facilities (compliant with structural requirements in Commission Decision 2001/812/EC), in line with the requirements laid down in Article 4.2(d) of Regulation (EC) No 882/2004.

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=2012-6500

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2009/821/EC	OJ L 296, 12.11.2009, p.1	2009/821/EC: Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces
Dir. 91/496/EEC	OJ L 268, 24.9.1991, p. 56-68	Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC
Dir. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
Dec. 2001/812/EC	OJ L 306, 23.11.2001, p. 28-33	2001/812/EC: Commission Decision of 21 November 2001 laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries