FINAL REPORT
OF A MISSION
CARRIED OUT IN SPAIN
FROM 22 MAY TO 1 JUNE 2007
IN ORDER TO EVALUATE THE
IMPLEMENTATION OF HEALTH RULES ON
ANIMAL BY-PRODUCTS AND
OFFICIAL CONTROLS FOR GELATINE

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

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Spain, from 22 May to 1 June 2007.

The objective of the mission was to evaluate the measures put in place to give effect to EC rules firstly on animal by-products not intended for human consumption (ABP) including gelatine not intended for non-human consumption as laid down in Regulation (EC) No 1774/2002 and other EU legislation derived from this Regulation and secondly on gelatine intended for human consumption as laid down in Regulation (EC) No 853/2004 respectively.

In terms of scope, the mission covered the control systems in place for ABP including gelatine intended not for human consumption and Gelatine for human consumption and reviewed and verified their operation. The evaluation included measures taken in response to the recommendations made in a previous FVO mission regarding ABP.

Overall the mission concludes that:

- With regards to ABP: Steps have been taken to ensure better compliance with Regulation (EC) No 1774/2002 in the future through the production of a national control plan for ABP and guidelines for official controls and approvals; all this will help to harmonize the system throughout Spain. However, the current control system for ABP was not yet fully effective, as most of the afore-mentioned measures have not entered into force and there were a number of shortcomings, notably: a) gaps in the responsibilities for official controls; b) ineffective communication and co-ordination between CAs responsible for ABP; and c) deficiencies in official controls at various levels. In particular, systemic deficiencies in commercial documents together with the absence of official controls in some ABP plants receiving ABP from food operators could affect the flow of ABP in their permitted chains only. As a consequence, the majority of the recommendations of the previous FVO mission cannot be considered as having been fully or satisfactorily addressed.

- With regards to gelatine: There was a largely satisfactory control system in place for the chain of gelatine, although the correct channelling of raw materials for the production of both gelatine intended and not intended for human consumption could be affected by some weaknesses in approvals and official controls, respectively.

The report makes a number of recommendations addressed to the Spanish competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place.
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1. INTRODUCTION

The mission took place in Spain from 22 May to 1 June 2007.

The inspection team, which comprised three inspectors from the Food and Veterinary Office (FVO), was accompanied throughout the mission by representatives from the two Central Competent Authorities (CCAs), the Ministry of Agriculture, Fisheries and Food (Ministerio de Agricultura, Pesca y Alimentación, MAPA) and the Food Safety Agency (Agencia Española de Seguridad Alimentaria, AESAN), and representatives from the Autonomous Communities (ACs).

An opening meeting was held on 22 May 2007 with the CCA, during which the mission objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the mission was requested.

2. OBJECTIVES AND SCOPE OF THE MISSION

The overall objective of the mission was to evaluate the measures put in place to give effect to EU rules concerning:

a. Animal by-products (ABP – subproductos animales no destinados a consumo humano, SANDACH), as laid down in Regulation (EC) No 1774/2002 \(^{(1,2)}\) of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning ABP not intended for human consumption. This includes gelatine not intended for human consumption (i.e. gelatine for animal nutrition and technical use), as set out in this Regulation.


In terms of scope, the mission focused on:

a. The general elements of the control systems in place for ABP and reviewed and verified their operation, i.e. the capability of the competent authorities to ensure the correct flow and destination of ABP. Within this context and where relevant, the evaluation followed up on the outcome of a previous mission concerning ABP (mission DG(SANCO)/8088/2006), and the recommendations made in this respect.

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\(^{(1)}\) Legal acts quoted in this document refer, where applicable, to the last amended version.


\(^{(4)}\) OJ L 147, 31.05.2001, p. 1.
b. The sourcing and traceability of gelatine and the raw materials from which it is produced (5); particular attention was paid to rules on specified risk material (SRM) (6) and official controls following rapid testing for bovine spongiform encephalopathy (7).

The evaluation included measures taken in response to recommendations made in a previous FVO mission which addressed the above issues.

The mission itinerary included the following:

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3. LEGAL BASIS FOR THE MISSION

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

– Art. 27 of Regulation (EC) No 1774/2002;
– Art. 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the

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verification of compliance with feed and food law, animal health and animal welfare rules (8).

- Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States (9).

4. BACKGROUND

Two missions concerning ABP have been carried in Spain. The first one was carried out from 22 November to 3 December 2004, the results of which are described in report DG(SANCO)/7248/2004 – MR Final (hereafter: report 7248/2004). The second one was carried out from 23 January to 3 February 2006, the results of which are described in report DG(SANCO)/8088/2006 – MR Final (hereafter: report 8088/2006). These reports are accessible at:

http://europa.eu.int/comm/food/fvo/ir_search_en.cfm

Following report 8088/2006 a number of recommendations were made to the CCA, which subsequently informed the Commission of actions that would be taken aimed at addressing the recommendations (hereafter: action plan). Where appropriate, both the relevant recommendations and the action plan are outlined under Section 5.

5. MAIN FINDINGS

5.1. ABP

5.1.1. STRUCTURE IN PLACE FOR THE HANDLING OF ABP

The structure in place for the handling of ABP is described in report 7248/2004. The relevant recommendation of report 8088/2006 concerned the need for handling all ABP as required in the Regulation (EC) No 1774/2002, in particular regarding the milk and retail sectors.

In response to the above recommendation, the CCA noted that the Comisión Nacional SANDACH (National Commission for ABP - see report 8088/2006) had produced guidelines for operators when disposing of ABP in the milk sector and was planning to do this also for the retail sector to ensure the compliance with Regulation (EC) No 1774/2002.

Since 2002, 14 out of the 17 ACs have in place an insurance scheme to cover the collection and process of fallen ruminants; the percentages of animals under the scheme show a steady increase, and now around 90% of the bovines are covered. The implementation of this insurance scheme is voluntarily decided by the ACs. An insurance scheme for the collection of fallen non-ruminants has been introduced at a later stage and steadily increases its coverage of the population. A study on alternative methods for on-the-spot disposal of dead animals of other species farmed under intensive condition (pigs, poultry and rabbits), carried out by the CCA, has

been finalized and the results were reported to the European Food Safety Authority. The CCA stated that the concerned establishments ended their participation in the study and now dispose of their ABP according to Regulation (EC) No 1774/2002.

Observations:
- In general, infrastructures and arrangements are in place for the collection, transport, handling, processing, disposal of and use of most Category 1 materials.
- Guidelines for the correct disposal of ABP from the milk sector have been prepared by the National Commission for ABP and sent to all ACs (10).
- The system for collection of former foodstuffs (FFS) in the retail sector makes use of the transitional measures allowing processed FFS to be landfilled as domestic waste.
- With regards to disposal of raw material of animal origin in the retail sector:
  - The CA of two ACs visited stated that raw material of animal origin from wholesalers are disposed of correctly in ABP plants but that raw material of animal origin from the majority of big and small supermarkets is disposed as domestic waste, which is landfilled in some cases.
  - The CA of one other AC visited stated that the biggest wholesalers dispose of their raw material of animal origin correctly but not the other wholesalers or the big or small supermarkets which also dispose this raw material as domestic waste, which is landfilled in some cases.
- The CCA declared that guidelines for the correct disposal of ABP from the retail sector are in preparation and should be published in 2007.

5.1.2. COMPETENT AUTHORITIES

The CAs in the ABP sector have been described in report 8088/2006. The relevant recommendations of report 8088/2006 concerned the responsibilities of each CA in the AC and their coordination, in particular in relation with the approval of ABP plants and the controls of the different categories of ABP.

In response to the above recommendations, the CCA noted that a list has been created outlining for each AC which CA is responsible for both approval and controls of the different types of ABP plants.

Observations:
- A national list has been created in which most ACs list all the different CAs involved in official controls of the ABP chain (including the approval of ABP plants). In a few ACs, the responsibility for some areas (in particular transport, technical plants and final users of ABP) was not yet attributed and for two ACs there was no information with regards to responsibility for ABP controls, despite the fact that the CCA had requested this information several times; in both these ACs there are many slaughterhouses, cutting and milk processing plants plus food wholesalers and retailers. The mission team was later provided with a letter from those two ACs outlining which CAs are responsible for ABP

(10) In their response to the draft report the Spanish authorities noted that the above mentioned guidelines have been sent to the CAs and operators and also posted in the web; moreover, they have been also included in an Annex to the white book for ABP (see section 5.1.5.1).
plants of each category; however, for one AC, this did not include information concerning responsibilities for technical plants or ABP generating food establishments.

- In one AC visited the responsibilities outlined in the national list were only legally binding as of October 2007 pending the approval of a respective decree. This resulted in a delay in approval of technical plants and premises falling under Art. 23 of Regulation (EC) No 1774/2002. In another AC visited the CA responsible for ABP (including raw materials of animal origin from the retail sector) did not visit food wholesalers or supermarkets and the CA responsible for food establishments stated that they had no power to issue a warning or fine with regards to non-compliances concerning ABP. The mission team was informed during the final meeting by the CAs concerned that the respective responsibilities will be clarified and that the FVO will be informed subsequently.

- In one AC (which was not visited), the CAs dealing with food establishments have declared that their responsibility for official controls on ABP is restricted exclusively to Category 1 and seized materials, and that this responsibility ceased once ABP leave the food establishments; the mission team requested information from the CCA about which CA in that AC had responsibility for Category 2 and 3 ABP in food establishments and whether controls on those in food establishments including means of transport and the destination of ABP were carried out, however, this could not be clarified.

- In the specific sectors where the competencies for ABP controls had been defined, there was a lack of communication and co-ordination between the CA, both within and between ACs (see section 5.1.5.2). The CCA informed the mission team that the National Commission for ABP is the responsible body co-ordinating the different CA and administrations involved in the ABP sector.

- Information about non-compliances in commercial documents was, according to the CAs met, rarely exchanged between the CAs (either within the ACs or of other ACs).

- According to the different CAs met in the ACs visited, information about controls conducted and non-compliance was rarely exchanged between the CAs (either within the ACs or of other ACs) unless there was an immediate threat to humans, animals or the environment.

- According to the CCA no training on ABP has been provided to new staff at border inspection post (BIPs) since 2005 and none is planned for 2007, despite the fact that since 2006, 30% of the staff employed in the BIPs were mostly new to such specific controls. The CCA stated that this situation existed due to insufficient staff resources in the CCA and that training would be beneficial for the new staff to allow them to execute their tasks competently.

### 5.1.3. LEGAL PROVISIONS

The relevant legal provisions have been described in report 7248/2004. The relevant recommendation of report 8088/2006 concerned the notification to the Commission of the use of the derogations set out in Artt. 23 and 24 of Regulation (EC) No 1774/2002.
In response to the above recommendations, the CCA noted that:

- Information on derogations applied by the ACs would be collected during the next meeting of the national commission on ABP in September 2006.
- No remote areas have yet been declared and criteria are currently being determined on which the ACs can define remote areas, which after approval through the National Commissions for ABP will be sent to the European Commission.

Observations:

- According to information received from the CCA, three of the 17 ACs apply derogations set out in Art. 23 of Regulation (EC) No 1774/2002. The CCA stated further that they have not yet notified the Commission about the use of these derogations where required by Art. 23 (2) of Regulation (EC) No 1774/2002.
- Some ACs not included in the three ACs mentioned by the CCA had establishments falling under Art. 23 which were sometimes not known to the responsible CA of the AC. Many taxidermists exist in various ACs, according to information obtained from the Spanish taxidermist association, and the CAs of two ACs visited stated that not all taxidermists were known and none were approved as technical plants.
- In one AC visited, a farm with 1,500 crocodiles for skin production existed, which was not included in a list of users as required by Art. 23 of Regulation (EC) No 1774/2002. The CA stated that they have to start the process of establishing this list of users and to authorise and register premises like zoos currently using ABP allowed for feeding in line with Art. 23 of Regulation (EC) No 1774/2002.
- The CCA declared that the derogations set out in Art. 24 of Regulation (EC) No 1774/2002 were nationally not applied and that they are currently in the process of establishing common criteria to facilitate the definition of remote areas by the ACs; they will inform the Commission once remote areas have been defined. One AC provided information to the mission team concerning their use of the derogation regarding disposal of fallen stock in remote areas because of the geographic characteristics and the type of husbandry in the area; the CA of the AC has officially asked the CCA to provide guidelines to define remote areas. The CA of three other ACs visited stated that they do not make use of this derogation.

5.1.4. APPROVAL OF ABP PLANTS AND OTHER PREMISES

The relevant recommendations of report 8088/2006 concerned the inspection of all plants under the approval process, and the validation of processing plans. In response to these recommendations, the CCA noted that:

- A national database for ABP plants requiring approval, accessible for all ACs and where approval information could be continuously updated, would be created. The list will be open to the general public.
- Instructions would be developed defining which types of plants and operators need to be approved and what approval requirements need to be fulfilled.
- Instructions on approval including validation requirements would be prepared as guidance for all ACs.
According to the CCA, the national database covering all plants requiring approval under Regulation (EC) No 1774/2002 is fully operational and accessible to all CA concerned as of January 2007. They noted that it is the responsibility of the ACs to upload the information on approval and to keep it up to date, and that detailed guidelines have been established describing which plants/users need approval, authorisation or registration under Regulation (EC) No 1774/2002 and what the requirements for approval are. The CCA also declared that these guidelines on the approval of ABP plants had been sent to the ACs and included in the white book for ABP (see 5.1.5.1).

Observations:

- Guideline documents have been developed by the National Commission for ABP and distributed to all ACs, defining which types of plants and operators need to be approved and what approval requirements need to be fulfilled and including a checklist facilitating verification of the approval requirements and validation of processing plants. The guidelines were available in all ACs visited which have started to implement them. Official controls in the two ABP plants visited included the validation procedure as referred to in Annex V (Chapter V) to Regulation (EC) No 1774/2002.

- The database for ABP plants includes many but not all plants under the scope of Regulation (EC) No 1774/2002. Some ACs include in their list all types of plants and premises (including technical plants and final users) while in other ACs certain plants were not included (intermediate, composting, storage, and technical plants).

- In one AC visited most but not all plants requiring approval under Regulation (EC) No 1774/2002 have been approved (these omitted plants included a few Category 2 and 3 processing and intermediate plants plus several composting and technical plants). A representative of the CA (in this AC) in charge of the approval of Category 1 and 2 ABP plants plus composting and technical plants producing fertilizers informed the mission team that these plants are in the process of approval. Information about the outstanding approval of Category 3 processing plants and all technical plants was requested, but it was not provided to the mission team.

- In two other ACs visited, several tanneries, taxidermists and composting plants exist which were not approved under Regulation (EC) No 1774/2002. In one of these ACs two Category 3 intermediate plants dealing with fresh or salted hides destined for technical use were neither approved nor known to the CA responsible for the approval of ABP plants.

- Two ACs had, according to the database for ABP plants, no plants requiring approval under Regulation (EC) No 1774/2002 (these ACs had, according to the national food establishment database, more than 20 slaughterhouses for various species including ruminants plus several meat cutting plants, milk processing plants and food retailers). The CCA stated that they had asked these ACs to provide this information, but that they have not received any and that they therefore did not know about the situation with regards to ABP plants in those two ACs. During the mission, one of these two ACs submitted information stating that all Category 1 ABP are sent directly from slaughterhouses to ABP plants in other ACs, however, information on how Category 2 and 3 materials were disposed of was not provided; the other AC submitted information stating that all ABP are sent directly from
slaughterhouses to ABP plants in other ACs; no information was provided regarding the existence of intermediate plants for ABP which could support the collection of ABP from slaughterhouses and also of raw materials of animal origin from the retail sector.

- The information concerning the destination of ABP included in commercial documents was often not used by the CAs met in order to have an overview of the plants operating without approval at AC level and national level.

- The plants visited have implemented their own-check systems, which is one of the requirements for the initial approval, and the validation procedure set out in Annex V (Chapter V) to Regulation (EC) No 1774/2002 was correctly carried out in the two processing plants visited.

5.1.5. OFFICIAL CONTROLS

5.1.5.1. Organisation of official controls and administrative provisions

The relevant recommendation of report 8088/2006 concerned documented procedures in order to ensure the uniformity and consistency of official controls. In response to this recommendation, the CCA noted that a national ABP plan was being prepared which would cover the whole ABP chain and details concerning inspections of the control system; this plan would become part of the Multi-Annual National Control Plan developed under Regulation (EC) No 882/2004.

According to representatives from the National Commission for ABP, a white book for ABP covering the whole ABP sector in Spain was produced (11). This document has been the basis for the elaboration, by the National Commission for ABP, of the national ABP control plan (Plan General de Control de los SANDACH), which was approved on 26 April 2007 and aims at serving as a framework document for all ACs. In their view the national ABP plan: a) is binding for all ACs; b) covers the whole ABP chain, providing for each ABP plant a risk assessment score to define the inspection frequency; c) outlines the type of controls to be conducted; d) covers national, intra-community traded and imported ABP; and e) foresees that all ACs report once a year to the CCA the controls conducted and non-compliances found using a uniform template which allows to see in detail whether the requirements of the plan have been met and what kind of non-compliances have been found and the action taken.

The CCA informed the mission team that detailed guidelines have been developed by the working groups of the National Commission for ABP covering the following topics: i) plants requiring approval under Regulation (EC) No 1774/2002, ii) authorisation and controls of Category 1 and 2 ABP plants including detailed checklists, iii) requirements for storage of ABP at storage and intermediate plants, iv) authorisation of composting plants using ABP, v) ABP requirements in the milk sector, and vi) requirements for fallen stock at farm level.

The mission team noted that:

- The CCA and all ACs visited stated that it is their common understanding that the national ABP control plan should be fully implemented during 2008.

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(11) In their response to the draft report the Spanish authorities noted that the white book for ABP is accessible at:

According representatives from the National Commission for ABP, one of the reasons for creation of a nationally binding control plan was to ensure that official controls are conducted consistently. According to the CAs in the ACs visited, the new national ABP control plan will help to effectively implement official controls in a harmonised way in all sectors and categories.

Controls on ABP were generally included in the check lists for food hygiene, but one OV in charge of food hygiene met in one AC visited declared that ABP controls were often neglected.

5.1.5.2. Implementation of official controls along the chain

The relevant recommendation of report 8088/2006 concerned the use and correctness of commercial documents. In response to this recommendation, the CCA noted that a commercial document template which reflects the requirements of Regulation (EC) No 1774/2002 and legally binding in all ACs was under preparation. According to representatives from the MAPA, the National Commission for ABP agreed in April 2007 the template for this national commercial document which will become legally binding at the end of 2007 (12).

Observations:

- Many commercial documents issued in slaughterhouses and records for ABP examined did not always contain the information specified in Annex II to Regulation (EC) No 1774/2002 (quantity of materials, warning sentences, animal species, destination and approval number of the plant of destination). The OVs had not always noted the afore-mentioned shortcomings and consequently not informed the operators in order to take corrective actions.
- Commercial documents issued or received in processing, intermediate and technical plants visited were not always in accordance with Annex II to Regulation (EC) No 1774/2002; examples were found where the category of the material, the required warning sentence, and/or the approval number of the plant of origin/destination were not mentioned. The CAs responsible for official controls in the ABP plants had not noted the above shortcomings, nor (where relevant) brought them to the attention of the CAs responsible for the slaughterhouses and cutting plants where the material came from.
- In one AC visited the CA responsible for food hygiene did check the premises to which hides were dispatched (for human consumption or for technical purposes) but did not share this information with the CAs responsible for ABP, despite the fact that some of the plants of destination had not been approved under Regulation (EC) No 1774/2002.
- In one slaughterhouse visited, Category 3 material intended for animal feed was stored in a non-chilled dump exposed to full sunshine and birds for up to two days prior to delivery to a Category 3 processing plant (which was delivering part of the processed products for petfood production) However, the CAs responsible for the slaughterhouse had not noted this deficiency.

(12) In their response to the draft report the Spanish authorities noted that the template is already available for CAs and operators; it is included in an Annex to the white book for ABP.
A channelling procedure for ABP was in place in the BIP visited, although the CCA confirmed that the channelling procedure was not always implemented in other BIPs. The BIP visited also notified the place of destination of the channelled consignments, however, a confirmation of arrival was rarely received; the CAs stated that no follow-up was done to verify whether the consignments had actually reached their intended destination.

The operator of a Category 3 processing plant did not inform the CA about a non-compliance discovered in the plant own-checks, as required by Art. 25 of Regulation (EC) No 1774/2002 (the concerned batch of MBM was contaminated with Salmonella; it was reprocessed and then confirmed free from Salmonella). The official in charge of official controls at this plant was not aware about this non-compliance and stated that he did not always have a detailed look at the documentation of the plant's own checks.

A big food retailer has been disposing of raw material of animal origin (fish) as domestic waste since Regulation (EC) No 1774/2002 came into force. However, the CAs responsible for official controls had not noted this.

The frequency of visits to ABP plants varies between different ACs (in some ACs Category 1 processing plants are visited twice a year, in some quarterly and in others monthly). The CA of one AC visited stated that official control plans were not yet based on a risk assessment but that this will be done once the new national ABP control plan is be implemented.

A plan to take samples on a regular base in ABP plants existed in one of the ACs visited but not in another where the sampling was rarely carried out since it was not considered to be important.

A Category 3 processing plant visited dispatched 350 consignments of processed animal protein (PAP) to other Member States in 2006. The commercial documents accompanying the consignments of PAP were not in line with the model set out in Annex II of Regulation (EC) No 1774/2002. Moreover, no evidence could be provided (either by the CAs responsible for this plant, the CAs at the AC, or the CCA) that the Member States concerned had authorised the receipt of PAP from Spain. Furthermore, aside from two notifications, the Member States of destination have not been informed of these dispatches.

In one AC visited, the CA declared that raw milk and whey from milk processing plants was used for feeding purposes in farms, but that the respective milk plants were not registered and the farms not authorised for this purpose and that no animal health risk assessment had been carried out in accordance with Annexes I and II to Regulation (EC) No 79/2005 (13). The CA declared that they still have to start the respective registration, authorisation and risk assessment.

5.1.5.3. Supervision

According to the CCA, the intention of creating the new ABP control plan and detailed guidance documents prepared by the national Commission for ABP is to

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enable consistent controls on ABP in all ACs. They also declared that audits in line with the requirements of Art. 4(6) of Regulation (EC) No 882/2004 are planned to be introduce by each AC.

Observations:

- In one ACs visited no plan existed on how to verify the effectiveness of official controls. According to the CAs in two other ACs visited, the "central" level supervised the work of the provinces (although this did not include participation in on-the spot checks); there were no procedures regarding the verification of the effectiveness of official controls. Many of the non-compliances found by the mission team had not been detected by these supervisory systems (none as far as commercial documents were concerned).

- According to the CCAs, the verification of effectiveness and consistency of the veterinary checks on ABP carried out in BIPs (for which the CCAs are responsible) has not yet taken place, due to shortages in human resources. A regional coordinator for BIPs met declared that this task was not part of his responsibilities, and that he had to support BIP staff when specific questions concerning official controls arise. The CCA confirmed that there were no procedures regarding the harmonisation of the task of the BIP coordinators.

5.2. GELATINE

5.2.1. INFORMATION ON THE GELATINE SECTOR

Three plants are producing gelatine for human consumption according to the requirements of Regulation (EC) No 853/2004 in Spain, of which none use raw material from bovines; the raw material used is mainly porcine skins and poultry bones. Bovine material is dispatched to other Member States for the production of gelatine. In Spain, all gelatine is produced under standards for human consumption, but a part is later intended for technical uses (including pharmaceutical ones). The total production is about 10,000 tons of gelatine per year (each plant is producing between 2,000 and 4,000 tons per year). In addition, two plants are approved for producing technical gelatine (mainly glue), of which they produce smaller amounts, according to the requirements of Regulation (EC) No 1774/2002. There are no plants approved for the production of gelatine for the purpose of animal nutrition.

There are 26 plants approved under food legislation for collecting and/or processing raw material for production of gelatine for human consumption from approved slaughterhouses or cutting plants in Spain. These are either tanneries or collection centres for bovine hides (19 plants) or collection centres for pig skins (seven plants). According to the CCA, these plants are all handling only hides or skins derived from animals fit for human consumption. Raw material for gelatine (mainly pig skins and bovine hides) from approved slaughterhouses and cutting plants are sent either directly or via collection centres or tanneries to the gelatine plants in Spain or in other Member States.

In 2006 the raw material used for the production of gelatine for human consumption were mainly obtained within Spain and a smaller amount was traded from other Member States.
Spain has not made use of the derogation provided for in Commission Regulation (EC) No 878/2004 (14) to permit the use of Category 1 and 2 materials in the production of technical gelatine.

Apart from gelatine for human consumption there have been no imports of raw material for the production of gelatine for human consumption in 2006. There have been some imports of technical gelatine.

5.2.2. COMPETENT AUTHORITIES

5.2.2.1. Organisation and responsibilities

Although the responsibilities for the organisation and operation of controls systems are shared between the Ministry of Health and Consumer Affairs (Ministerio de Sanidad y Consumo, MISACO) and MAPA, the overall responsibilities for the work and the preparation of national legislation regarding official controls of gelatine for human consumption as required by Regulation (EC) No 853/2004 lie in the AESAN within the MISACO (15). In addition, the AESAN is overall responsible for the co-ordination of official controls in slaughterhouses, cutting plants and other food plants of matters relating to the categorisation and dispatch of ABP and controls on SRM.

Overall responsibilities for the work and the preparation of national legislation in relation to ABP and gelatine not intended for human consumption (i.e. gelatine for animal nutrition and technical use) lie within MAPA.

The ACs have the responsibility for the implementation and operation of control systems for gelatine (for human consumption as well as for animal nutrition and technical use). The ACs are also responsible for drawing up guidelines on how to perform these controls. Local veterinary services in the ACs are responsible for official controls at local level for matters relating to safeguarding public health and animal health, and they have to implement and control veterinary legislation in respect on certain premises (gelatine plants, slaughterhouses, cutting plants, collection centres, tanneries, and intermediate plants).

Observations:

- Local inspectors met at food plants did not seem to have a clear understanding of their responsibilities and tasks as regards ABP (bovine hides) produced and dispatched from the establishments under their responsibility food plants. According to the discussions held, the reason was that since ABP are not food they do not seem to fall under their remit.

5.2.2.2. Resources, training and information

In general the AESAN keeps the ACs informed about issues relating to Regulation (EC) No 853/2004 and ABP via, among others, an intranet. According to representatives from the AESAN met, in order to ensure communication and coordination between the different levels of administration and to ensure controls between and within ACs, technical meetings are regularly held with the ACs, where issues of current interest are dealt with.


(15) In their response to the draft report the Spanish authorities noted that the system for official controls of gelatine for human consumption is independent from the system for official controls of ABP.
Observations:

- According to information received from the CCA there have been some national seminars/meetings covering, among others, aspects of Regulation (EC) No 853/2004, where representatives from all ACs participated. However, none of the seminars/meetings dealt specifically with sourcing or tracing of raw material for gelatine or other official controls relating to gelatine.

5.2.2.3. Internal supervision

Observations:

- In most plants visited there was no internal supervision of official controls specifically in relation to sourcing and tracing of raw material for gelatine and other controls of gelatine.
- In a gelatine plant visited there was a system in place where the local inspector made a report after each inspection and send a copy to the local inspection unit in that AC. In a hide plant approved for human consumption and the gelatine plant visited there were no verifications of the official controls from a higher level.

5.2.3. LEGAL AND ADMINISTRATIVE PROVISIONS

Observations:

- In all the ACs visited, guidelines had been produced on official controls on gelatine for human consumption. In addition, all ACs visited have produced guidelines on controls of ABP including SRM controls.

5.2.4. IMPLEMENTATION OF OFFICIAL CONTROLS OF GELATINE

5.2.4.1. Official on-the-spot inspections

a.) Establishments delivering raw materials

Observations:

- In one AC visited 13 collection centres for bovine hides were registered and approved for dispatching raw material intended for food grade gelatine. According to the CAs, they were only dealing with food grade hides, so there were no problems concerning separation of food grade and ABP grade hides. However, the 13 hide plants were, according to information received from the CA, also operating as tanneries, but they were not registered as technical plants as required by Art. 18 of Regulation (EC) No 1774/2002.
- In two out of three ACs visited, intermediate plants and tanneries dealing with ABP grade hides from bovines and small ruminants were not approved in accordance with Artt. 10 or 18 of Regulation (EC) No 1774/2002 and, in addition, according to the CAs there were no official controls of these plants.
- One AC (which was not visited) provided lists of suppliers for two collection centres (for clippings of bovine hides) approved for delivering raw materials for gelatine for human consumption as required by Section XIV of Annex III to Regulation (EC) No 853/2004; however, several of the suppliers (tanneries) for these two collection centres were not authorised for delivering raw material for the production of gelatine for human consumption.
- In one slaughterhouse and in one collection centre for porcine skins visited, documents accompanying consignments of raw material for the production of food grade gelatine were largely in compliance with Community requirements.
despite some minor discrepancies. This was also confirmed at the visit to the bovine hide plant, where consignments of bovine hides arriving and consignments of raw material for the production of gelatine for human consumption dispatched to other Member States were accompanied by the correct documents.

b.) Establishments producing gelatine

Observations:

- In the gelatine plant visited a hazard analysis and critical control point (HACCP) programme was in place. Samples were taken from the finished products to check for residues and microbiological limits, and the examined parameters went beyond requirements in Regulation (EC) No 853/2004 and Regulation (EC) No 2073/2005 (16). Since the CA operated with five-year approvals, the gelatine plant was not approved in accordance with Regulation (EC) No 853/2004 for producing food grade gelatine, but according to information received from the AC there was an approval process taking place. Wrapping and packaging materials containing gelatine were marked "gelatine fit for human consumption", and the date of preparation was indicated as required in Section XIV, Chapter V of Annex III to Regulation (EC) No 853/2004. Documents that accompanied incoming consignments of raw material from Spain and from other Member States were in compliance with Section XIV, Chapter II of Annex III to Regulation (EC) No 853/2004.

- Concerning official controls, there were regular inspections in 2005, 2006 and the last inspection was carried out in January 2007. ON each occasion a report was produced, which included information on official controls of documents for incoming raw materials to the plant.

5.2.4.2. Controls on imports

Observations:

- Import certificates that accompanied consignments of gelatine for human consumption from third countries were seen to be in compliance with Regulation (EC) No 2074/2005 (17).

- Import certificates that accompanied consignments of technical gelatine from third countries were seen to be in compliance with Regulation (EC) No 1774/2002.

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6. CONCLUSIONS

6.1. ABP

6.1.1. STRUCTURE IN PLACE FOR THE HANDLING OF ABP

1. Arrangements and infrastructures are largely in place as regards the organisation of separation, collection, transport, storage, processing, disposal of and use of ABP and derived products. However, arrangements for the handling of raw material of animal origin from the retail sector were still lacking in some cases, as it is disposed of in ways permitted only for FFS, which contravenes Art. 1 of Regulation (EC) No 197/2006 (18). Therefore, the relevant recommendation in the previous report has not been fully addressed.

6.1.2. COMPETENT AUTHORITIES

1. Progress has been made since the previous mission in defining most of the responsibilities for official controls and arranging mechanisms for communication and co-ordination between different CAs responsible for ABP. However, the relevant recommendation in the previous report cannot be considered satisfactorily addressed yet because: a) some gaps still remain regarding responsibilities for official controls of technical plants and final users of ABP which is not in line with Art 4 (1) of Regulation No 882/2004; b) in one AC in particular, the CAs have declared that official veterinarians responsible for food business operators do not carry out official tasks over ABP at these premises, which is contrary to the requirements set out in Section I (Chapter I) of Annex I to Regulation (EC) No 854/2004 (19); and c) communication and co-ordination between different CAs responsible for ABP required by Art. 4 (3 and 5) of Regulation (EC) No 882/2004 have proved to be still ineffective.

2. There was a lack of training on import requirements of ABP for new staff at BIPs which, given the high turnover of officials at this level, could affect the competent and consistent execution of the relevant official controls required by Art. 6 of Regulation (EC) No 882/2004.

6.1.3. LEGAL PROVISIONS

1. The CCA was still lacking a complete picture regarding the implementation by the ACs of derogations on the use and disposal of ABP defined in Artt. 23 and 24 of Regulation (EC) No 1774/2002; moreover, the Commission has not been yet notified of the use of some of these derogations, where required by the aforementioned Articles. Therefore, the relevant recommendation in the previous report has not been addressed.

6.1.4. APPROVAL OF ABP PLANTS AND OTHER PREMISES

1. Progress has been made since the previous mission with the creation of a national database for plants requiring approval under Regulation (EC) No 1774/2002 and in publishing guidelines for approval requirements. However, the list of plants


required by Art. 26 is not yet complete, given that some plants have not yet been approved in accordance with Regulation (EC) No 1774/2002; in particular, the latter concerned some processing and intermediate plants and many technical plants. Therefore, the relevant recommendation in the previous report has not been satisfactorily addressed.

2. Validation of processing plants has been done as required in Annex V (Chapter V) to Regulation (EC) No 1774/2002. Therefore, the relevant recommendation in the previous report has been satisfactorily addressed.

6.1.5. OFFICIAL CONTROLS

1. Progress has been made since the previous mission through the approval of a national ABP control plan and several guideline documents have been issued supporting that official controls are organised on the basis of risks and along the entire ABP chain, and carried out in a consistent and documented manner. This will facilitate that official controls to ensure compliance with the requirements of Regulation (EC) No 1774/2002 will be carried out in accordance with the principles set out in Artt. 3(1), 4(4) and 8(1) of Regulation (EC) No 882/2004. Nevertheless, most of the afore-mentioned measures have not yet been implemented given that they have been only recently created and approved.

2. Although a national template for commercial documents has been recently created, commercial documents accompanying ABP and processed products often did not include the information required in Annex II to Regulation (EC) No 1774/2002, and, furthermore, official controls paid very little attention to compliance with this requirement. Therefore, the relevant recommendation in the previous report has not been satisfactorily addressed yet, and the correct flow of ABP is still compromised.

3. The absence of knowledge of some ABP plants (of destination of ABP generated at food operators) and the fact that official controls therein, as required in Art. 26 (1) of Regulation (EC) No 1774/2002, have not been carried out raise further doubts as to whether ABP flow only in their permitted chains or not.

4. A channelling procedure for imported ABP in accordance with Directive 97/78/EC (20) was not always in place, although it is required for products under Chapter X and XI of Annex VIII to Regulation (EC) No 1774/2002.

5. The dispatch of processed animal proteins to other Member States did not respect the requirements set out in Art. 8 of Regulation (EC) No 1774/2002, since in many cases it could not be ensured that the CAs of the place of destination had authorised the receipt of the material.

6. Farms receiving raw milk and whey were not always registered and authorised as required in Annexes I and II to Regulation (EC) No 79/2005, for which a risk assessment for epizootic diseases is necessary.

7. Procedures in place to verify the effectiveness of official controls over ABP, as required by Art. 8 (3) of Regulation (EC) No 882/2004, are either absent or inefficient given that they were not able to detect most of the shortcomings found

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by the mission team. Therefore, the relevant recommendation in the previous report has not been satisfactorily addressed.

6.2. **GELATINE**

6.2.1. **COMPETENT AUTHORITIES**

1. The responsibilities of the CA involved in the official controls of food grade gelatine were clearly defined in accordance with Art. 4 (1) of Regulation (EC) No 882/2004. However, arrangements to verify the effectiveness of official controls on gelatine, as required by Art. 8 (3a) of Regulation (EC) No 882/2004, were not in place.

6.2.2. **LEGAL AND ADMINISTRATIVE PROVISIONS**

1. National provisions have been implemented regarding gelatine for human consumption in accordance with requirements of Regulation (EC) No 853/2004.

6.2.3. **IMPLEMENTATION OF OFFICIAL CONTROLS ON GELATINE**

1. Overall there was a system in place which meets the requirements of Section XIV of Annex III to Regulation (EC) No 853/2004 in respect of the production of gelatine for human consumption, and trade documents for consignments of raw material intended for food grade gelatine were largely in compliance with the said regulation. However, the correct channelling of raw material could be affected because tanneries were not specifically authorised by the CAs for supplying raw material for the production of gelatine intended for human consumption, although this is a requirement set out in Section XIV (Chapter I, p. 5) of Annex III to Regulation (EC) No 853/2004.

2. Concerning ABP grade hides, official controls required by Art. 26 (1) of Regulation (EC) No 1774/2002 were not always carried out in intermediate and technical plants handling this material. This could affect the correct channelling of raw material for the production of gelatine not intended for human consumption in other Member States receiving these hides and derived products.

3. Import certificates for consignments of gelatine for human consumption and of technical gelatine were seen to be in compliance with Regulation (EC) No 853/2004 and Regulation (EC) No 1774/2002, respectively.

6.3. **OVERALL CONCLUSION**

With regards to ABP:

Steps have been taken to ensure better compliance with Regulation (EC) No 1774/2002 in the future through the production of a national control plan for ABP and guidelines for official controls and approvals; all this will help to harmonize the system throughout Spain. However, the current control system for ABP was not yet fully effective, as most of the afore-mentioned measures have not entered into force and there were a number of shortcomings, notably: a) gaps in the responsibilities for official controls; b) ineffective communication and co-ordination between CAs responsible for ABP; and c) deficiencies in official controls at various levels. In particular, systemic deficiencies in commercial documents together with the absence of official controls in some ABP plants receiving ABP from food operators could affect the flow of ABP in their permitted chains only. As a consequence, the majority of the recommendations of the previous FVO mission cannot be considered as having been fully or satisfactorily addressed.
With regards to gelatine:
There was a largely satisfactory control system in place for the chain of gelatine, although the correct channelling of raw materials for the production of both gelatine intended and not intended for human consumption could be affected by some weaknesses in approvals and official controls, respectively.

7. CLOSING MEETING

A closing meeting was held on 1 June 2007 with the representatives of the CCA and the ACs. At this meeting, main findings and preliminary conclusions of the mission were presented by the inspection team. The CCA did not indicate any disagreement with the findings and conclusions.

8. RECOMMENDATIONS

The CCA is invited to provide details of the actions taken and planned, including deadline for their completion within 20 working days following the receipt of the translated final report.

With regard to ABP:

1. To ensure that transitional measures for the disposal of former foodstuffs, as set out in Regulation (EC) No 197/2006, are no longer applied to raw material of animal origin, and that this material is disposed of as required by Art. 6 (2) of Regulation (EC) No 1774/2002.

2. To finalize the clarification of responsibilities of the CAs in the ACs in relation to official controls of technical plants and final users of ABP, as required by Art. 4(1) of Regulation (EC) No 882/2004.

3. To ensure that official veterinarians responsible for food business operators verify compliance with the procedures of the operators concerning collection, transport, storage, handling, processing and use of disposal of ABP (of all categories), as required by Section I (Chapter I) of Annex I to Regulation (EC) No 854/2004.

4. To pursue the efforts to establish efficient and effective coordination and cooperation between the different CAs responsible for official controls of ABP, as required by Art. 4(3 and 5) of Regulation (EC) No 882/2004.

5. To ensure that new staff in BIPs receive appropriate training enabling them to undertake their ABP duties competently and to carry out official controls of ABP in a consistent manner, as required by Art. 6 of Regulation (EC) No 882/2004.

6. To notify to the Commission, where necessary, the use of the derogations set out in Artt. 23 and 24 of Regulation (EC) No 1774/2002.

7. To approve ABP plants as required in Chapters III and IV of Regulation (EC) No 1774/2002, and to update the list of plants accordingly.

8. To take urgent actions to ensure that commercial documents used during transportation of ABP and processed products contain the information requested in Annex II to Regulation (EC) No 1774/2002.
9. To ensure official controls in all ABP plants, as required in Art. 26 (1) of Regulation (EC) No 1774/2002.


11. To ensure that any dispatch of processed animal proteins to other Member States is carried out after they have authorised the receipt of the material, as required by Art. 8 (2) of Regulation (EC) No 1774/2002.

12. To ensure that farms receiving raw milk and whey are subject to a risk assessment for epizootic diseases and are registered and authorized, as required by Annexes I and II to Regulation (EC) No 79/2005.

13. To ensure that the effectiveness of the official controls on ABP is verified, as required by Art. 8 (3) of Regulation (EC) No 1774/2002.

14. To ensure that the effectiveness of the official controls on gelatine is verified, as required by Art. 8 (3) of Regulation (EC) No 1774/2002.

15. To ensure that tanneries supplying raw material for the production of gelatine intended for human consumption are specifically authorised for this purpose, as required by Section XIV (Chapter I, p. 5) of Annex III to Regulation (EC) No 853/2004.

16. To ensure official controls on ABP plants handling hides not intended for human consumption, as required by Art. 26 (1) of Regulation (EC) No 1774/2002.

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COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

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