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FINAL REPORT OF A MISSION
CARRIED OUT IN
ITALY
FROM 18 FEBRUARY TO 22 FEBRUARY 2008
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF HEALTH RULES ON CERTAIN
ANIMAL BY-PRODUCTS

*Please note that factual errors in the draft report have been corrected in response to comments by the
Competent Authority.*

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Italy from 18 to 22 February, 2007.

The overall objective of the mission was to evaluate a) the effectiveness of measures put in place to give effect to Regulation (EC) No 1774/2002, including some legal measures derived therefrom concerning certain animal by-products (Regulations (EC) No 878/2004, No 92/2005 and No 181/2006) and b) specific provisions for the export of processed animal proteins as laid down in Regulation (EC) No 999/2001.

Overall, of the methods provided for in the above Regulations, Italy avails only of the possibilities to use Category 1 fat in thermal boilers according to Regulation (EC) No 92/2005 and to use processed animal proteins (PAP) in organic fertilisers (OF/SI) according to Regulation (EC) No 181/2006. Competent Authorities (CAs) with responsibility for the topics covered by this mission have been designated and their organisation is broadly in line with the requirements of Regulation (EC) No 882/2004. All relevant plants are subject to regular official controls but certain deficiencies in the organisation and implementation of these controls prevents them from ensuring that all relevant requirements are fulfilled.

Nevertheless, there is a minimal risk that Category 1 fat intended for use in thermal boilers might be diverted to improper uses as all operators maintained detailed records that could demonstrate that the fat is only used as intended. In the case of OF/SI, there is an increased potential for these materials to be misused as official controls currently pay little attention to the flow of PAP sent directly to farms and, OF/SI dispatched by producers often did not carry the appropriate labels and warning sentences regarding application to pastureland as required by Regulation (EC) No 181/2006. Official controls to check that farms comply with Regulation (EC) No 181/2006 are at an early stage. In practice, most OF/SI sent to farms have been formulated in ways which makes them unsuitable for application to pastureland and too costly and unpalatable to be diverted into animal feed.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ABP	Animal by-products
Action plan	Actions announced/undertaken as submitted to the Commission services by the CCA in response to the recommendations made in mission report(s)
AUSL	Local Health Unit (<i>Azienda Sanitaria Locale</i>)
CA	Competent authority/ies
Category 1, 2, 3 material	Different categories of ABP as defined in Artt. 4, 5 and 6 of Regulation (EC) No 1774/2002, respectively
CCA	Central competent authority/ies
DVPHNFS	Directorate General for Veterinary Public Health, Nutrition and Food Safety (<i>Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti</i>)
FVO	Food and Veterinary Office
HACCP	Hazard analysis and critical control points
ICQ	Central Inspectorate for Quality Control of Foodstuff and Agricultural Products
MBM	Meat and bone meal
MIPAAF	Ministry of Agricultural and Fisheries Policies (<i>Ministero per le Politiche Agricole e Forestali</i>)
MoH	Ministry of Health (<i>Ministero della Salute</i>)
MS	Member States
OF/SI	Organic fertilizers and soil improvers
PAO	Products of animal origin
PAP	Processed animal proteins
Report 7120/2004	Report of a mission carried out in Italy from 18 to 29 October 2004 concerning animal by products
RPHS	Regional Public Health Service
TC	Third countries

1 INTRODUCTION

The mission took place in Italy from 18 to 22 February 2008.

The inspection team, which comprised two from the Food and Veterinary Office (FVO), was throughout the mission by from the Central Competent Authorities (CCAs), the Directorate General for Veterinary Public Health, Nutrition and Food Safety (*Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti- DVPHNFS*) of the Ministry of Health (*Ministero della Salute - MoH*) and, representatives of the of the Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQ) of the Ministry of Agricultural and Fisheries Policies (*Ministero per le Politiche Agricole e Forestali – MIPAAF*) accompanied the inspection team for part of the mission.

An opening meeting was held on 18 February 2008 with the CCAs, 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 OF THE MISSION

The overall objective of the mission was to evaluate the measures put in place to give effect to

a) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (ABP), including some legal measures derived therefrom:

– Commission Regulation (EC) No 878/2004 of 29 April 2004 laying down transitional measures for certain animal by-products defined as Category 1 and 2 materials, in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council.

– Commission Regulation (EC) No 92/2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards means of disposal or uses of animal by products and amending its Annex VI as regards biogas transformation and processing of rendered fats.

– Commission Regulation (EC) No 181/2006 of 1 February 2006 implementing Regulation (EC) No 1774/2002 as regards organic fertilisers and soil improvers (OF/SI) other than manure and amending that Regulation.

b) The requirements and specific rules applicable to the export of processed animal proteins (PAP) as laid down in Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

In terms of scope, the mission focused on the control measures in place and their operation, i.e. the capability of the competent authorities (CAs) to ensure the correct placing on the market, flow, destination, including import and export, and use of the

following ABP:

- Rendered fats derived from Category 1 material intended exclusively for technical uses;
- Bone and bone products containing vertebral columns and skull (considered specified risk material –SRM) exclusively for technical uses;
- Category 1 material treated and disposed of by the processes of alkaline hydrolysis, high pressure hydrolysis biogas, biodiesel production, or combustion in a thermal boiler (only for animal fat);
- OF/SI;
- PAP;
- Certain processed products derived from Category 2 materials (meat and bone meal (MBM) and greaves).

Within this context and where relevant, the evaluation followed up on the outcome of previous missions concerning the above mentioned topics.

The mission itinerary included the following visits:

Competent authorities visits			Comments
Competent authority	Central	√	Opening and closing (de-briefing) meeting
	Regional	√	Meetings in the 3 regions visited
	Local	√	Discussions held in one AUSL visited and in the plants visited
Sites			
Processing plants		4	Two Category 1 plants using fat in thermal boilers and two category 3 plants dispatching PAP for use in OF/SI.
Producers of OF/SI		3	Three producers of OF/SI using PAP – two approved in part according to Regulation (EC) No 1774/2002 and one authorised according to Ministerial Decree 217/2006.

3 LEGAL BASIS FOR THE MISSION

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

- 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 verification of compliance with feed and food law, animal health and animal welfare rules.
- Art. 27 of Regulation (EC) No 1774/2002.

4 BACKGROUND

The previous mission concerning ABP in Italy was carried out from 18 to 29 October 2004, the results of which are described in report DG(SANCO)/7120/2004 – MR Final (hereafter: report 7120/2004). This report is accessible at:

http://ec.europa.eu/comm/food/index_en.htm

A number of recommendations were subsequently made to the CCA, which in turn informed the Commission of actions that had been/would be taken aimed at addressing the recommendations made (hereafter: action plan). Where appropriate, both the relevant recommendations and the action plan are outlined under Section 5.

5 MAIN FINDINGS

5.1 INFORMATION ON THE ABP SECTOR

According to representatives of the DVPHNFS, the system in place for the collection, transport, use and disposal of ABP remains largely as described in report 7120/2004. In particular, most Category 2 ABP, except manure, are collected and processed with Category 1 materials and transformed in processing plants using methods 1 to 5 and the resulting meat and bone meal (MBM) and fats disposed of by incineration or, in the case of fats, used as fuel. According to data provided by the MoH, approximately 40,000 Tonnes of Category 1 fat produced in 2007 was used as fuel in thermal boilers according to Regulation (EC) No 92/2005. Approximately 66% of this was used directly by seven processing plants in their own boilers and most of the remainder was used for energy production in cement factories and electricity generating plants.

According to data provided by the MoH, in 2007, approximately 300,000 Tonnes of Category 3 PAP were brought in to Italy from other MS. Approximately 70% of this material was used for the production of OF/SI, according to Regulation (EC) No 181/2006, 10% was used in pet food and the remainder was incinerated. During the same period, no PAP, other than fishmeal, was sent from Italy to other Member States (MS) or exported to third countries (TC)

5.2 COMPETENT AUTHORITIES

5.2.1 Organisation and responsibilities

The organisation of the CAs with responsibilities for topics falling within the scope of this mission are described in the country profile for Italy and in report 7120/2004. The relevant documents are accessible at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

The DVPHNFS is the CCA for ABP, including those falling within the scope of this mission. At central level different offices are of particular relevance for the harmonisation and supervision of controls on ABP (border inspection posts, food processing industry, ABP premises and the pet food industry).

The competencies for implementing Regulation (EC) No 1774/2002 have been delegated to the authorities in Italy's 19 Regions and two autonomous provinces. Within the Regions, the Regional Public Health Services (RPHS) are responsible for co-ordination while Local Health Units (AUSL) are responsible for the practical implementation of official controls in establishments and plants involved in the ABP chain and also for certain on-farm checks concerning animal feed.

The Directorate General for Quality of Agricultural and Food Products (DGQPA) of MIPAAF is responsible for, amongst others, the production, distribution and placing on the market and the use of fertilisers which also include OF/SI, based on a national legal provision, Ministerial Decree 217/2006; in particular, Office VIII is responsible for regulating fertilisers. The control activity of MIPAAF is undertaken by the Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQ) which is an inspection body of MIPAAF responsible for fraud prevention. ICQ carries out controls on labelling and quality of a range of products, including OF/SI and also performs certain on farm checks relating to fertilisers. The organisation consists of two departments with responsibility for planning, coordination and administration while the control activities are implemented by 12 decentralised offices and 15 local units.

The Ministry of Environment has certain responsibilities, amongst others, for the control of incineration and co-incineration plants and burial sites.

Observations:

- While MIPAAF is responsible for all plants which produce OF/SI, the MoH is responsible for parts of such plants which trade PAP from other MS and are approved according to Regulation (EC) No 1774/2002 (see Section 5.7.1.).
- The roles of the CAs were clearly understood by officials met in the establishments visited.

5.2.2 Coordination

Observations:

- In one Region visited, coordination between the RPHS and the AUSL took place on a formal basis through monthly meetings of a technical committee made up of representatives of the Region and each AUSL.
- No information concerning farms using PAP directly as OF/SI had been provided to the relevant unit of the AUSL or the ICQ responsible for checking compliance with the relevant requirements of Regulation (EC) No 181/2006 (see Section 5.7.1.4.).

5.2.3 Resources and training

Observations:

- According to officials of the RPHS and AUSL met in one region visited, a working group has been established with a role in training officials. Training is provided on an on-going basis but nothing had been specifically provided concerning the methods for use and disposal of ABP within the scope of this mission.
- Representatives of the ICQ met in one plant visited had a limited awareness of certain requirements of Regulation (EC) No 181/2006. According to the officials met, this was because the official controls are currently based on Ministerial Decree 217/2006 which does not take into account all relevant requirements of the afore-mentioned Regulation and Regulation (EC) No 1774/2002.

5.2.4 Internal Supervision

According to the MoH, a system to assess the effectiveness of official controls has been established at a central level and a number of audits have been carried out mainly in food establishments, including slaughterhouses, but none of these specifically focussed on ABP. It is planned to audit of official controls of the ABP chain in 2008.

Since 2006, the RPHS have been required to collate data concerning the implementation of controls by the AUSL within the Region and to pass this to the MoH.

Observations:

- Each AUSL is responsible for supervising the effectiveness of official controls it has implemented, including those concerning the methods for use and disposal of ABP within the scope of this mission. According to representatives of all AUSL met in the Regions visited, supervisory activities are carried out regularly and include checks of control reports and on-the-spot inspections in ABP plants.
- Representatives of the RPHS met in one Region visited, stated that a database to be used for monitoring the implementation of official controls is currently being set up which will provide a basis for future supervisory activities.
- According to representatives of MIPAAF, there is currently no formalised system in place to ensure the effectiveness of the official controls, but it is intended to set up an audit office which will supervise the work of the decentralised offices.

5.3 ORGANISATION OF OFFICIAL CONTROLS ON ABP

According to representatives of the DVPHNFS, guidance for implementing controls on ABP was issued in June 2005. This included checklists for the inspection of each type of ABP plant and an indication of the minimum frequency of such checks. The AUSL are responsible for deciding the actual frequency of inspections to be carried on the basis of a risk assessment taking account of local conditions.

Observations:

- All plants visited which were approved according to Regulation (EC) No 1774/2002 and were availing of the specific methods of use and disposal of ABP within the scope of this mission were inspected regularly by the AUSL. In most cases, it was stated that such

ABP plants are inspected a minimum of 12 times per year.

- The guidance provided to the AUSL by the MoH concerning official controls in the ABP sector provides limited information relating to the checks to be performed regarding the specific requirements for the methods of use and disposal of ABP within the scope of this mission.
- According to representatives of the ICQ met, the main focus of official controls in plants producing OF/SI is sampling to check a range of quality parameters against those stated on the labels. Inspections are generally carried out in the case of suspicion or when the results of the sample analyses indicate non-compliance. These do not take into account all relevant requirements of Regulation (EC) No 181/2006 (see section 5.7.1.).
- According to representatives of the DVPHNFS, checks that farmers using OF/SI respect the relevant requirements of Regulation (EC) No 181/2006 are included in the official controls to check compliance with Regulation (EC) No 183/2005 which began in January 2008.

5.4 IMPLEMENTATION OF ABP REQUIREMENTS ALONG THE CHAIN

The procedures to be followed by each level of the CA concerning authorisations and control of consignments of processed ABP to be imported or exported to TC or traded with other MS are set down in a circular letter of the MoH of 6 July 2007. These include a requirement for the TRACES system to be used in order to notify the dispatch and receipt of consignments of ABP in accordance with the requirements of Art 8(4) and (5) of Regulation (EC) No 1774/2002.

Office VIII of DVPHNFS is responsible for issuing authorisations for intra community trade in ABP based on an application submitted by the operator with the support of the local AUSL, and checks carried out by Office III of DVPHNFS concerning the plant of origin and destination. The authorisations are valid for one year and specify the amount of ABP which may be received during this time.

According to data provided by the CCA, in 2007 a total of 40 authorisations were issued for the introduction of approximately 300,000 Tonnes of PAP from other MS.

Observations:

- The CAs provided copies of the bilateral agreements in place for the receipt of ABP from other MS in certain of the plants visited, as required by Art. 8 of Regulation (EC) No 1774/2002.
- According to representatives of the DVPHNFS, no consignments of ABP for which an authorisation would be required according to Art. 8 of Regulation (EC) No 1774/2002, other than fishmeal have been sent to other MS.

5.5 CERTAIN CATEGORY 1 AND 2 ABP INTENDED FOR TECHNICAL PURPOSES

According to the MoH, no authorisations have been granted to permit the use of the

derogations for the placing on the market or export and import or transit, respectively, of the Category 1 and 2 ABP listed in Art. 1 of Regulation (EC) No 878/2004.

5.6 ALTERNATIVE MEANS OF DISPOSAL AND USE OF ABP

5.6.1 Use of Category 1 fats in thermal boilers

5.6.1.1 Approval

According to representatives of the DVPHNFS, the RPHS are responsible for approving plants wishing to use rendered fats in a thermal boiler, based on a dossier of relevant technical information and the results of an inspection.

Observations:

- In the Regions visited, the plants using Category 1 fat in thermal boilers had been approved by the RPHS on the basis of information provided by the operator. However, in some cases, an approval had been granted even though the information provided was not in line with the relevant requirements of Annex VI to Regulation (EC) No 92/2005:
 - In one Category 1 processing plant visited, the RPHS had approved the use of Category 1 fat in a steam raising thermal boiler but, the operator confirmed that the equipment concerned was actually a low capacity incinerator which reached a maximum temperature of 850oC rather than 1100oC as required by Annex VI to Regulation (EC) No 92/2005.
 - The operator of a Category 1 processing plant visited had declared that the level of impurities in the fat to be used in the thermal boiler was below 0.15% as required by Annex VI to Regulation (EC) No 92/2005, but this could not be verified as the certificate of analyses on which this claim was made stated only that the level was below 0.5%. According to the officials responsible, this was due to the requirements of previous national legislation which was already repealed.
 - In another Region visited, an approval had been granted for Category 1 fat originating in another processing plant to be used in a thermal boiler. However, the fat concerned had been produced using Method 5 as defined in Chapter III of Annex V to Regulation (EC) No 1774/2002 and therefore should not be sent to other plants for use in thermal boilers according to Annex VI to Regulation (EC) No 92/2005. According to the RPHS, this fat was no longer being dispatched for use in other thermal boilers.
- According to officials met at all levels, these shortcomings were due in part to a lack of clarity regarding the distinctions between incinerators and thermal boilers.

5.6.1.2 Lists of approved plants

Observations:

- According to a representative of the DVPNHFS, seven processing plants and certain other plants have been approved to use Category 1 fat in a thermal boiler, in accordance with Regulation (EC) No 92/2005. However, no national list of such plants has been

established as required by Art. 26 of Regulation (EC) No 1774/2002.

5.6.1.3 Requirements

According to representatives of the DVPNHFS, research is being carried out with the aim of establishing a national standard method for measuring the level of impurities in fat but, in the meantime all operators of plants using or supplying fat where a maximum level of impurities applies are expected to carry out own checks using an existing method.

Observations:

- All plants visited which were using Category 1 fat in thermal boilers maintained up to date records relating to the production, use and dispatch of the fat as required by Chapter IV of Annex II to Regulation (EC) No 1774/2002. In addition, standard commercial documents, based on a national model, were used to accompany consignments of Category 1 fat sent to other plants for use in thermal boilers, in accordance with Annex II to Regulation (EC) No 1774/2002. A receipt confirming the arrival of the consignment at its destination was faxed back to the processing plant from which it had been dispatched.
- The operators of plants visited which were using Category 1 fat in thermal boilers were carrying out own checks to verify if the level of impurities was below 0.15% as required by Annex VI to Regulation (EC) No 92/2005. In one case, the certificate of analysis provided by the laboratory performing this task indicated that the level of impurities was below 0.5% and not 0.15% as required.
- The operators of plants visited which were using Category 1 fat in thermal boilers were able to demonstrate that the temperature achieved during combustion of the fat was 1100°C for 0.2 seconds, as set down in Annex VI to Regulation (EC) No 92/2005, except in one case, where the fat was actually being burned in a low capacity incinerator at 850°C.
- According to documents provided in the Regions visited, plants using Category 1 fat in thermal boilers were inspected regularly and the results recorded. However;
 - The shortcomings described above and in section 5.6.1.1. had not been identified by the officials responsible for controlling the plants.
 - In plants which did not have closed systems, no specific checks had been carried out to verify that fat had been used or dispatched as declared by the operator and had not been diverted.
 - In one processing plant visited which was using Category 1 fat in a thermal boiler, the inspection report for the processing and use of fat consisted of one tick box and the official responsible was unable to explain the nature of the checks performed to ensure compliance with the requirements of Annex VI to Regulation (EC) No 92/2005.

5.6.2 Others means of use or disposal of ABP

According to representatives of the DVPNHFS, the following means of use or disposal of

Category 1 ABP provided for in Art. 1 of Regulation (EC) No 92/2005 have not been authorised:

- Alkaline hydrolysis
- High temperature, high pressure hydrolysis
- High pressure hydrolysis biogas
- Biodiesel production
- Brookes gasification process.

5.7 ORGANIC FERTILISERS AND SOIL IMPROVERS

5.7.1 Producers

5.7.1.1 Approval

According to the national implementing provisions set down in the Circular Letter of the MoH of 13 September 2006, plants producing OF/SI using PAP do not need to be approved by the RPHS according to Regulation (EC) No 1774/2002 unless they trade in PAP from other MS. All other plants which produce OF/SI using PAP originating in Italy are required to obtain only an authorisation from MIPAAF based on Ministerial Decree 217/2006, which sets down conditions relating to the production, placing on the market and use of fertilisers, including OF/SI.

Observations:

- The Category 3 processing plants visited which supplied PAP for use in OF/SI were approved in accordance with Art. 17 of Regulation (EC) No 1774/2002 and in so far as it was checked they fulfilled the relevant requirements set down in Annexes V and VII to that Regulation.
- According to representatives of the DVPNHFS, it is only considered necessary to approve those plants transforming PAP traded from other MS into OF/SI to fulfil the requirements of Art. 8 of Regulation (EC) No 1774/2002.
- In one Region visited, plants transforming PAP traded from other MS into OF/SI were required to be approved as technical plants, in accordance with Art. 18 of Regulation (EC) No 1774/2002 but, in another, only the area for storing incoming PAP was approved as a Category 3 storage plant in accordance with Art. 11 of Regulation (EC) No 1774/2002. All other activities of this plant were considered to fall outside the scope of that Regulation.
- Ministerial Decree 217/2006 contains references to certain requirements of Regulation (EC) No 1774/2002, in particular concerning traceability. However, there is no requirement for operators to put in place own control systems to monitor critical control points, as would be required if the plant was approved according to Art. 18 of Regulation (EC) No 1774/2002. According to representatives of the ICQ met in a plant producing OF/SI, the authorisations granted in accordance with Ministerial Decree 217/2006 are product based with few specific requirements for the establishment as a

whole.

5.7.1.2 Lists of establishments

Observations:

- The plants producing OF/SI granted an approval according to Regulation (EC) No 1774/2002 have been assigned an individual alpha numeric code which identifies the activity for which they were approved and are included on the national list of ABP plants, in accordance with Art. 26 of Regulation (EC) No 1774/2002.
- A total of 763 plants authorised in accordance with Ministerial Decree 217/2006 which produce and/or place on the market fertilisers, including OF/SI, are listed in a national register.

5.7.1.3 Requirements

The circular letter of the MoH of 13 September 2006 clarifies the obligations of producers of OF/SI approved in accordance with Regulation (EC) No 1774/2002 in relation to pathogen control, documentation and the labelling of packaging as set down in the Annex to Regulation (EC) No 181/2006.

A circular letter of the MIPAAF of January 2008 includes a requirement that the packaging for OF/SI should bear the sentence concerning the period of time for which farmed animals should not have access to land to which OF/SI have been applied, as set down in point II(2) of the Annex to Regulation (EC) No 181/2006.

Observations:

- The Category 3 processing plants visited which were dispatching PAP for use in OF/SI and those activities of plants producing OF/SI approved according to Regulation (EC) No 1774/2002 were controlled regularly by the AUSL and the results recorded. Where appropriate, corrective measures had been required to remedy deficiencies identified and follow up checks had been carried out to ensure these had been implemented.
- In this regard, the mission team noted that:
 - All Category 3 processing plants visited which dispatched PAP for use as OF/SI kept detailed records and used commercial documents as required by Annex II to Regulation (EC) No 1774/2002. Where appropriate, the commercial documents bore the statement regarding application to land as required by point III(2) of the Annex to Regulation (EC) No 181/2006.
 - All operators of Category 3 processing plants visited which dispatched PAP for use in OF/SI had put in place systems to ensure the traceability of batches and carried out regular own checks to ensure that they were free from microbial contamination.
 - All consignments of PAP received by OF/SI producers were accompanied by commercial documents as required by Annex II to Regulation (EC) No 1774/2002.
- According to representatives of the ICQ met in one OF/SI producer visited which was only authorised according to Ministerial Decree 217/2006, regular samples had been

taken to check quality parameters against the label and a number of additional checks had been made relating to traceability and documentation. However, the results of these additional checks were not recorded and the officials responsible confirmed that they did not take full account of the relevant requirements of Regulations (EC) No 1774/2002 and (EC) No 181/2006 as these are not included in Ministerial Decree 217/2006.

- In this respect, in those parts of the OF/SI producers visited which were controlled only by ICQ, the mission team noted that:
 - Packaged OF/SI did not carry the statement concerning the period in which land should not be grazed following application, as required in Point II(2) of the Annex to Regulation (EC) No 181/2006 and the presence of PAP was not indicated on the list of ingredients in one plant visited. According to the operators met, it was not considered necessary to provide this information as the products were not all suitable for application to pasture and they had been formulated with minerals making them unpalatable to animals. In addition, their cost would make it unlikely that the products would be fed to animals.
 - Consignments of OF/SI dispatched by the producers visited were usually accompanied by documents but these did not always contain the information required in Annex II to Regulation (EC) No 1774/2002. According to representatives of the DVPHNFS, this was not necessary as the content of the commercial documents to be used is not specified in Regulation (EC) No 181/2006.
 - One OF/SI producer had a limited ability to trace consignments of OF/SI sent to farms. It was stated that an enhanced system of documentation and traceability was currently being developed.
 - One producer of OF/SI visited did not perform any checks to ensure products were free from microbial contamination. However, according to the officials, there was little likelihood that such contamination would occur as all products were heated to at least 80oC as part of the pelleting process.

5.7.2 Use

According to representatives of the DVPHNFS, a number of national legal requirements have been put in place to reduce the likelihood that OF/SI may be misused on farms with animals:

- Only Category 3 PAP is used for the production of OF/SI
- PAP may not be dispatched to farms with animals unless it is mixed with other fertilisers. Bulk consignments of PAP may only be dispatched to such farms if it is applied to land immediately.
- PAP may not be applied directly to pasture

Observations:

- According to the representatives of the RPHS and producers of OF/SI met only a very limited amount of PAP is used on OF/SI on farms which mainly produce flowers. However, the operator of a processing plant visited in one Region confirmed that at least

six farms were receiving PAP in bulk for use as an OF/SI. The official from the AUSL responsible for controlling the plant was unaware of this and did not know if the farms concerned kept animals.

- According to representatives of the DVPHNFS, checks that farmers using OF/SI comply with the relevant requirements of Regulation (EC) No 181/2006 have started recently as part of the controls to verify compliance with the requirements for feed hygiene set down in Regulation (EC) No 183/2005.
- According to data provided by MIPAAF, checks were carried out on farms to ensure compliance with the relevant requirements relating to use of fertilisers but these did not include all relevant requirements of Regulation (EC) No 181/2006.

5.8 ACTIONS TAKEN IN CASE OF NON-COMPLIANCE

Observations:

- In the regions visited, both representatives of the AUSL and ICQ met described administrative procedures in place for the imposition of penalties in case of non-compliance.
- The AUSL may impose a fine through the local Mayor. Neither the RPHS visited nor the MoH were able to provide an overview of the sanctions imposed locally as this information is maintained by the AUSL.

6 CONCLUSIONS

6.1 COMPETENT AUTHORITIES

1. The roles of CAs for the control of ABP falling within the scope of this mission have been defined and their organisation largely satisfies the requirements of Art. 4 of Regulation (EC) No 882/2004. However, there is limited coordination between and within the CAs, especially as regards the flow of information concerning the channeling and use of OF/SI, which hampers the ability to effectively target controls on farms to ensure compliance with Regulation (EC) No 181/2006.
2. There is a certain lack of awareness among officials responsible for ensuring that plants availing of the methods of use and disposal of ABP within the scope of this mission comply with the relevant requirements, which undermines the effectiveness of the official controls in this area. This is not in line with Art. 6 of Regulation (EC) No 882/2004.
3. There is a system in place to monitor the effectiveness of official controls by the various levels of the MoH, as required by Art. 8 of Regulation (EC) No 882/2004

however, checks on the effectiveness of controls in the ABP sector have so far only been carried out by the AUSLs. MIPAAF is at an early stage of establishing a system to monitor the effectiveness of the controls performed by the ICQ, in accordance with Art. 8 of Regulation (EC) No 882/2004.

6.2 ORGANISATION OF OFFICIAL CONTROLS

1. The MoH has put in place a system of official controls which ensures that all plants approved according to Regulation (EC) No 1774/2002 which avail of the methods of use and disposal of ABP within the scope of this mission are inspected regularly on the basis of risk, in accordance with Art. 3 of Regulations (EC) No 882/2004 and Art. 26 of Regulation (EC) No 1774/2002.
2. The MIPAAF aims to ensure that all producers of OF/SI will be sampled on a systematic basis but, the ability to ensure that the relevant requirements of Regulation (EC) No 181/2006 are fulfilled is limited as they are not all taken into account during official controls. This is not in line with Art. 9 of the afore-mentioned Regulation.

6.3 IMPORTS AND INTRA COMMUNITY TRADE

1. The procedures in place for imports and intra community trade in ABP satisfy the requirements of Art. 8 of Regulation (EC) No 1774/2002.

6.4 CERTAIN CATEGORY 1 AND 2 ABP INTENDED FOR TECHNICAL PURPOSES

1. The transitional measures for certain Category 1 and 2 ABP intended for technical purposes, as laid down in Regulation (EC) No 878/2004, are not being used in Italy.

6.5 ALTERNATIVE MEANS OF DISPOSAL AND USE OF ABP

1. The only alternative means of disposal and use of ABP, as laid down in Regulation (EC) No 92/2005, which has been authorised by the MoH is the use of Category 1 fat in thermal boilers.
2. There is a system in place to approve those plants using Category 1 fat in thermal boilers as required by Art. 3 of Regulation (EC) No 92/2005 and to carry out regular official controls to check compliance with the requirements of Annex VI to that

Regulation. However, the ability of these systems to ensure that the relevant requirements are always fulfilled is compromised owing to a lack of awareness of these requirements among officials.

3. The results of official inspections in plants using Category 1 fat in thermal boilers are generally recorded in accordance with Art. 9 of Regulation (EC) No 882/2004 but, this was not always done in sufficient detail to enable the effectiveness of the official controls to be verified, as required by Art. 8 of Regulation (EC) No 882/2004.
4. The CCA has not published a national list of plants approved to use Category 1 fat in thermal boilers as required by Art. 26 of Regulation (EC) No 1774/2002.
5. The operators of plants using Category 1 fat in thermal boilers maintained detailed records and used commercial documents containing the information required by Annex II to Regulation (EC) No 1774/2002 which enabled them to demonstrate that the fat had been used or transported as stated.

6.6 ORGANIC FERTILISERS AND SOIL IMPROVERS

1. The national interpretation of Regulation (EC) No 1774/2002 has excluded from its scope all producers of OF/SI using PAP other than those which introduce PAP from other MS and instead made them subject to national legal provisions which do not include all relevant requirements of Regulation (EC) No 1774/2002. This is not in line with Annex I to Regulation (EC) No 1774/2002 which foresees that the production of technical products including OF/SI should take place in technical plants approved in accordance with Art. 18 of that Regulation.
2. While the official controls of those plants approved according to Regulation (EC) No 1774/2002 which supply or produce OF/SI are generally satisfactory, those carried out by the ICQ in plants only authorised according to national legal provisions are not sufficient to ensure that all relevant requirements of Regulations (EC) No 1774/2002 and (EC) No 181/2006 are fulfilled. This is not in line with Art. 9 of Regulation (EC) No 181/2006. In addition, the results of the ICQ inspections are not recorded, as required by Art. 9 of Regulation (EC) No 882/2004.
3. A number of national measures have been put in place with the intention of reducing the likelihood that OF/SI could be used in feed but their effectiveness is not known as there is a limited awareness among officials of the flow of PAP to farms and official controls which could check compliance with the requirements of Regulation (EC) No 181/2006 have recently started. In practice, the risk that such products could be misused or come into contact with animals is reduced as many OF/SI are formulated with other minerals which makes them unsuitable for application to pasture and also reduces their palatability to animals.

6.7 ACTIONS TAKEN IN CASE OF NON-COMPLIANCE

1. Procedures are in place to enable the CAs to take appropriate action in the case of non-compliance, including the imposition of sanctions which fulfil the requirements of Art. 55 of Regulation (EC) No 882/2004.

6.8 OVERALL CONCLUSION

Overall, of the methods provided for in the above Regulations, Italy avails only of the possibilities to use Category 1 fat in thermal boilers according to Regulation (EC) No 92/2005 and to use PAP as OF/SI according to Regulation (EC) No 181/2006. CAs with responsibility for the topics covered by this mission have been designated and their organisation is broadly in line with the requirements of Regulation (EC) No 882/2004. All relevant plants are subject to regular official controls but certain deficiencies in the organisation and implementation of these controls prevents them from ensuring that all relevant requirements are fulfilled.

Nevertheless, there is a minimal risk that Category 1 fat intended for use in thermal boilers might be diverted to improper uses as all operators maintained detailed records that could demonstrate that the fat is only used as intended. In the case of OF/SI, there is an increased potential for these materials to be misused as officials currently pay little attention to the flow of PAP sent directly to farms and, OF/SI dispatched by producers often did not carry the appropriate labels and warning sentences regarding application to pastureland as required by Regulation (EC) No 181/2006. Official controls to check that farms comply with Regulation (EC) No 181/2006 are at an early stage. In practice, most OF/SI sent to farms have been formulated in ways which makes them unsuitable for application to pastureland and too costly and unpalatable to be diverted into animal feed.

7 CLOSING MEETING

A closing meeting was held on 22 February 2008 with the representatives of the CCA. At this meeting, main findings and preliminary conclusions of the mission were presented by the inspection team. The CCA did not indicate any major disagreement with these. During the meeting, additional information as requested by the mission team was provided by the CCA.

The representatives of the CCA provided details of actions which may be taken in response to the preliminary findings and conclusions:

- Steps will be taken to promote a more harmonised approach to the documentation of official controls, especially with a view to future supervisory activities.
- It is intended to draft a document to remind officials and operators of the

requirements for using Category 1 fat in thermal boilers as laid down in Annex VI of Regulation (EC) No 92/2005.

- Discussions will be held between the CCA in order to develop a procedure to improve the flow of information concerning farms receiving PAP for use as OF/SI.
- An explanatory circular to add to the Ministerial Decree will be developed setting down the documents to be kept.

8 RECOMMENDATIONS

The CCA of Italy are invited to provide details of the actions taken and planned, including deadline for their completion within 25 working days after receipt of the report.

No.	Recommendation
1	To take steps to put in place an effective system of coordination between and within the CAs responsible for controlling the flow of PAP as OF/SI, as required by Art. 4 of Regulation (EC) No 882/2004, in order that the official controls can effectively verify that OF/SI are channelled and used in accordance with Regulation (EC) No 181/2006, particularly at farm level.
2	To ensure that all staff responsible for performing official controls to check compliance with the requirements of Regulations (EC) No 92/2005 and (EC) No 181/2006 receive adequate training and guidance to enable them to undertake their tasks competently and consistently as required by Art. 6 of Regulation (EC) No 882/2004.
3	To ensure that the results of official controls to check compliance with the legal requirements falling within the scope of this mission are recorded, as required by Art. 9 of Regulation (EC) No 882/2004, and in sufficient detail to enable the effectiveness of the official controls to be verified in accordance with Art. 8 of the said Regulation.
4	To ensure that all plants approved to use Category 1 fat in thermal boilers satisfy the requirements set down in Annex VI to Regulation (EC) No 92/2005.
5	To publish a national list of those plants approved in accordance with Regulation (EC) No 92/2005 to use Category 1 fat in thermal boilers, as required by Art. 26 of Regulation (EC) No 1774/2002.
6	To ensure that plants which produce OF/SI using PAP are approved as technical plants in accordance with Art. 18 of Regulation (EC) No 1774/2002 and to ensure that the relevant requirements of the said Regulation and of Regulation (EC) No 181/2006 are fulfilled.
7	To ensure that farms receiving OF/SI satisfy the relevant requirements of Regulation (EC) No 181/2006.

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

http://ec.europa.eu/food/fvo/ap/ap_italy_7743_2008.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Decision 98/139/EC	OJ L 38, 12.2.1998, p. 10–13	98/139/EC: Commission Decision 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
Regulation (EC) No 1774/2002	OJ L 273, 10.10.2002, p. 1–95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
Regulation (EC) No 999/2001	OJ L 147, 31.5.2001, p. 1–40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules