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FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
ITALY  
FROM 03 TO 11 SEPTEMBER 2012  
IN ORDER TO EVALUATE THE CONTROL SYSTEM IN PLACE GOVERNING THE  
PRODUCTION OF MECHANICALLY SEPARATED MEAT

*In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.*

### ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) audit in Italy, which took place from 3 to 11 September 2012, in order to evaluate the control system in place governing the production and placing on the market of mechanically separated meat (MSM).*

*The report concludes that there is an official control system implemented in Italy to control the production of MSM. The system implemented does not show major deficiencies and is in general able to demonstrate that European Union (EU) requirements are complied with. Nevertheless some deficiencies identified by the audit team had not been detected during official controls, and in particular concerning approval of establishments, general hygiene requirements (maintenance, structure, condensation, cleanliness and hygiene practices) and specific temperature requirements for MSM.*

*The report includes a number of recommendations addressed to the Italian Competent Authorities, aimed at rectifying the identified shortcomings and enhancing the implementation of the official control system in place.*

# Table of Contents

<b>1</b>	<b><u>INTRODUCTION</u></b> .....	<b>1</b>
<b>2</b>	<b><u>OBJECTIVES</u></b> .....	<b>1</b>
<b>3</b>	<b><u>LEGAL BASIS</u></b> .....	<b>2</b>
<b>4</b>	<b><u>BACKGROUND</u></b> .....	<b>2</b>
4.1	<u>PREVIOUS FVO MISSIONS</u> .....	2
4.2	<u>PRODUCTION AND TRADE INFORMATION</u> .....	2
<b>5</b>	<b><u>FINDINGS AND CONCLUSIONS</u></b> .....	<b>3</b>
5.1	<u>COMPETENT AUTHORITY</u> .....	3
5.2	<u>LEGISLATION, IMPLEMENTING MEASURES AND GUIDELINES</u> .....	4
5.3	<u>OFFICIAL CONTROLS OVER THE PRODUCTION AND PLACING ON THE MARKET</u> .....	5
5.3.1	<u>APPROVAL PROCEDURES</u> .....	5
5.3.2	<u>OFFICIAL CONTROLS AT MSM PRODUCTION ESTABLISHMENT LEVEL</u> .....	6
5.3.3	<u>OFFICIAL CONTROLS AT LEVEL OF ESTABLISHMENTS PRODUCING RAW MATERIAL</u> .....	8
5.3.4	<u>OFFICIAL CONTROLS AT LEVEL OF ESTABLISHMENTS USING MSM</u> .....	9
5.3.5	<u>OFFICIAL CONTROLS ON FBO'S COMPLIANCE WITH MICROBIOLOGICAL CRITERIA FOR FOODSTUFFS</u> .....	10
5.3.6	<u>TRACEABILITY – LABELLING – IDENTIFICATION MARKING</u> .....	11
5.3.7	<u>RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF)</u> .....	12
<b>6</b>	<b><u>OVERALL CONCLUSIONS</u></b> .....	<b>13</b>
<b>7</b>	<b><u>CLOSING MEETING</u></b> .....	<b>13</b>
<b>8</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>13</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>15</b>

## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
ASL	<i>Azienda Sanitaria Locale</i> , Local Health Unit
CA/CCA	Competent Authority / Central Competent Authority
EC	European Community
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis – Critical Control Points
HP	Hygiene Package, i.e. Regulations (EC) No 852/2004, 853/2004 and 854/2004.
MSM	Mechanically Separated Meat
OJ	Official Journal
OV	Official Veterinarian
RASFF	Rapid Alert for Food and Feed (Regulation (EC) No 178/2002)
RVS	Regional Veterinary Services
SANCO	Health and Consumers Directorate General of the European Commission

## 1 INTRODUCTION

This audit took place in Italy from 3 to 11 September 2012 and was undertaken as part of the FVO's audit programme.

The audit team comprised two auditors from the FVO. Representatives from the Central and Regional competent authorities (the Ministry of Health, *Ministero della Salute*, and the Regional Veterinary Services, *Servizi Veterinari Regionali* - hereafter: CCA and RVS, respectively) accompanied the team during the whole audit.

An opening meeting was held on 3 September 2012 in Bologna with representatives from the CCA and from the RVS of two Italian Regions. At this meeting the audit team confirmed the objectives of, and itinerary for the audit, requested clarification of certain points of information provided by the CCA before the audit as well as additional information regarding specific elements of the control system in place.

## 2 OBJECTIVES

The objectives of this audit were to assess, in the sector of production of MSM whether:

- the general rules for performance of official controls laid down in 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, are complied with, and
- the official controls system in place for the production chain and placing on the market of MSM is in compliance with EU requirements<sup>1</sup>.

The table below lists the sites visited and the meetings held in order to achieve the above objectives:

Competent authority		Comments
Central and Regional	3	Opening and closing meeting and one clarification meeting
Food processing facilities		
Cutting plants	1	One independent cutting plant, in addition to the seven indicated below.
MSM production establishments	7	Seven establishments in total producing MSM, of which four produced chicken and / or turkey MSM and three produced pork MSM. All the establishments visited had a co-located cutting plant. Three establishments were also MSM users, i.e. meat product establishments.

<sup>1</sup> MSM is defined in point 1.14 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, and specific requirements for its production are described in Annex III, Section V of the same Regulation.

Meat product / Meat preparation establishments using MSM as an ingredient	5	One independent meat product establishment and four with other activities.
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### 3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004.

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

### 4 BACKGROUND

#### 4.1 PREVIOUS FVO MISSIONS

This was the first audit to Italy specifically on MSM.

#### 4.2 PRODUCTION AND TRADE INFORMATION

The information in the table below was provided by the CCA and indicates the quantity of MSM (in metric tonnes) produced in Italy in 2010 and in 2011 broken down by species:

Species	2010	2011
Chicken	46 679	47 414
Turkey	20 548	23 614
Pork	4 351	4 186
<b>Total</b>	<b>71 578</b>	<b>75 214</b>

Concerning trade with other Member States and / or export to Third Countries of MSM, the CCA informed the audit team that it is not possible obtain this information through the relevant database and information exchange systems (e.g. TRACES (Trade Control and Expert System), because there is no specific CN (Combined nomenclature to classify goods when declared to customs in the Community) for this commodity. Such information can only be obtained by individual establishments.

The table below details only the trade and import / export of MSM from / to establishments producing MSM, and provided by the CCA. It does not include MSM directly traded and / or imported by meat preparation and meat product establishments.

	2010	2011
MSM sent to Italy (metric tonnes)		
From other Member States	1 288	1 048
From Third Countries	-	-
MSM sent from Italy (metric tonnes)		
To other Member States	1 088	2 185
To Third Countries	-	-

## 5 FINDINGS AND CONCLUSIONS

### 5.1 COMPETENT AUTHORITY

#### Legal requirements

Articles 4, 8, 54 and 55 of Regulation (EC) No 882/2004.

#### Findings

The CCA responsible for the MSM sector is the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection of the Ministry of Health.

The 19 Regions and 2 autonomous Provinces have responsibility, within their territories, for planning, co-ordination, guidance, authorisation and verification of controls (for the purpose of this report, references to 'Regions' should be read as including the two autonomous Provinces).

Official Veterinarians (OVs) from the Local Health Units (*Aziende Sanitarie Locali - ASL*) are responsible for the implementation of official controls in the establishments. Official controls are organised by each ASL on the basis of regional guidelines.

A more detailed description of the CAs can be found in the Country Profile for Italy on the following website: [http://ec.europa.eu/food/fvo/country\\_profiles\\_en.cfm](http://ec.europa.eu/food/fvo/country_profiles_en.cfm)

The system of official controls over the production chain of MSM is the same as for all other food of animal origin. The audit team made no observations concerning the CAs' legal powers or on the measures implemented to ensure co-ordination and co-operation between and within the CAs. Audits in this specific sector have not yet been performed, although an internal audit performed in 2012 on the official controls in one Region included the sector of MSM together with others, such as eggs and egg products and poultry meat.

All establishments visited were under official control by the Veterinary Services of the ASL. The frequency of official controls was based on the risk categorisation, made according to Regional guidances. This risk categorisation of establishments is re-assessed every year.

Evidence of official controls was available in all the establishments visited. When findings were

made, these were clearly reported to the food business operator (FBO) by the OV, in a written document with an indication of a deadline for remedial action. Evidence of follow-up visits was also available.

The Ministry for Agriculture, Foodstuffs and Forestry Policies (*Ministero delle Politiche Agricole, Alimentari e Forestali*) and the Ministry for Economic Development (*Ministero dello Sviluppo Economico*) are the CCAs responsible for issuing legislation and guidance on food labelling. The competence for official controls on labelling at establishment level remains with the OV.

## **Conclusions**

The Italian CAs are clearly designated and have adequate legal powers to perform official controls within the scope of this audit, in line with Article 4 of Regulation (EC) No 882/2004.

### **5.2 LEGISLATION, IMPLEMENTING MEASURES AND GUIDELINES**

#### **Legal requirements**

Article 29(1) of the Treaty on the functioning of the EU requires that the Member States adopt all measures of national law necessary to implement legally binding Union acts.

Article 7 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004, on the hygiene of foodstuff, stipulates that Member States shall encourage the development of national guides to good practise for hygiene and for the application of Hazard Analysis – Critical Control Points (HACCP) in accordance with Article 8 of the Regulation. Article 8(1) of the same Regulation stipulates that national guides to good practice shall be developed and disseminated by food business sectors in consultation with the stakeholders.

#### **Findings**

National Decree No 193 of 6 November 2007 lays down the administrative sanctions for infringements to the Hygiene Package (hereafter: HP) legislation.

Technical working groups are organised at national level with the participation of the CAs from all Regions and Autonomous Provinces, to draft and issue guidance. Several guidelines have been issued for the implementation of the HP.

Guidance on official controls is issued by the Regional CAs. These guidelines co-ordinate the activities of the ASL and include instructions on risk categorisation, minimum inspection frequency, sampling programmes, check-lists and templates for recording inspections, non-compliances and their follow-up.

In September 2011 the Region Emilia Romagna and the ASL of Modena organised a seminar on MSM which was open to producers, inspectors and consumers. The Regional CA indicated that this seminar helped to clarify the legal requirements to both stakeholders and inspectors.

On 31 July 2012, in preparation for this audit, the CCA issued a note to all the RVS reminding them of the specific requirements for MSM production and use.

The CCA stated that their definition of MSM is the same as provided for in EU legislation,

regardless of the type of technology used as long as flesh-bearing bones are used as raw material. The CCA also confirmed their understanding that in Italy the use of flesh-bearing bones from ruminants for the production of MSM is clearly forbidden by both Regulation (EC) No 999/2001 and national legislation.

## **Conclusions**

The Italian CAs have adequate implementing legal measures in place and documented procedures for the performance of official controls in the sector of MSM.

### **5.3 OFFICIAL CONTROLS OVER THE PRODUCTION AND PLACING ON THE MARKET**

#### *5.3.1 Approval procedures*

## **Legal requirements**

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004 and Article 31(2) of Regulation (EC) No 882/2004.

## **Findings**

The system for approval of establishments is described in the Country Profile for Italy. The CCA explained that the national database of approved establishments, called SINTESI National Veterinary Integrated Information System SINTESI (*Sistema INTEgrato per gli Scambi e le Importazioni*, Integrated system for intra-Union trade and Import), is kept up to date through the annual report of the establishments' activities sent by the RVS to the CCA.

In their letter of 31.7.2012 (mentioned in section 5.2) the CCA requested the RVS to review existing approvals of MSM establishments, to ensure that ruminant species were excluded in the MSM approval.

In reviewing the approval documentation of the MSM producing establishments visited, the audit team made the following observations:

- Before the entry into force of the HP in 2006, the production of MSM was authorised under a more generic approval for meat preparations.
- In the establishments visited, existing approval documents had been updated and replaced to take into account the HP provisions. In one establishment in Veneto the activity of MSM production was included under the activities of meat preparations until August 2012, when an updated document was issued. The approval documents seen in Emilia Romagna indicated for each activity the species concerned.

For all the establishments visited their activities including the MSM production were correctly identified in the list of approved establishments published on the Ministry of Health's web-site.

In the framework of a request for information by the audit team concerning a recent RASFF alert (see section 5.3.7), it was found that one establishment, approved as a slaughterhouse and cutting plant, was producing MSM although it was not appearing on the list of approved establishments published on the Ministry of Health's web-site.

## Conclusions

The system for approval of establishments is overall in line with EU requirements.

The national database of establishments was not fully updated, contrary to the provisions of Article 31(2)(f) of Regulation (EC) No 882/2004.

### *5.3.2 Official controls at MSM production establishment level*

## Legal requirements

Article 4 of Regulation (EC) No 854/2004.

Article 9 of Regulation (EC) No 999/2001.

## Findings concerning general hygiene requirements

The audit team visited seven establishments producing MSM, of which four produced chicken and / or turkey MSM and three produced pork MSM.

In all establishments visited reports of official controls were available. Where deficiencies had been identified by the CA, these had been reported to the FBO. A deadline had been agreed and follow-up performed.

In the establishments visited the general hygiene requirements were overall adequate. However, the audit team identified deficiencies which were not detected and / or reported by the CA, such as:

- in one establishment the presence of condensation had not been reported by the OV. In addition, several crates used for the MSM were broken and / or insufficiently cleaned, despite the OV requesting in August 2012 to stop immediately using the most damaged ones and to replace them by the end of 2012. These deficiencies are not in compliance with the provisions of paragraph 2(b), Chapter I and paragraph 1 of Chapter V of Annex II to Regulation (EC) No 852/2004.
- In another establishment the MSM machine and the skip containing MSM were not protected against contamination: cables and other dirty fixtures were above the machine; trays with MSM were placed under the line transporting chicken and turkey legs; liners for the MSM trays were incorrectly used leading to potential cross-contamination. This is not in compliance with the provisions of Chapter II(1)(b), Chapter I(2)(c) and Chapter X(3) of Annex II to Regulation (EC) No 852/2004.
- In a third establishment the MSM machine was insufficiently cleaned although the FBO's pre operative check-list indicated that the machine had been checked and found compliant with the cleanliness criteria. This is not in compliance with the provisions of Chapter V(1) (a) of Annex II to Regulation (EC) No 852/2004<sup>2</sup>.

All establishments visited had HACCP based procedures in place and the relevant records were kept, in line with the requirements of Article 5 of Regulation (EC) No 852/2004.

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<sup>2</sup> In their response to the draft report, the CA noted that the establishment ceased the activity of MSM production in December 2012.

## Findings specifically concerning MSM production requirements

All establishments visited were producing MSM as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. Although not required under the mentioned point of legislation, analysis of the calcium content of the MSM produced were carried out in three establishments and showed that the calcium content was lower than 1000 ppm (Annex IV to Regulation (EC) No 2074/2005).

In the establishments visited the FBOs could demonstrate that the maximum delay from the date of slaughter as laid down in point 4(a), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004 was taken into account when the raw material was used for producing MSM. When the delay was exceeded, the raw material was to be considered and disposed of as category 3 animal by-product. However, in one establishment a traceability exercise showed that at least two batches of pork legs coming from external slaughterhouses had been processed to obtain flesh-bearing bones used for the production of MSM, although more than five days had elapsed since slaughter<sup>3</sup>.

In addition, in the establishments visited the following shortcomings had not been identified by the CA:

- In all establishments the MSM which was not used within one hour of production, was not chilled immediately at a temperature of no more than +2°C. This is not in compliance with paragraph 4(d) of Chapter III, Section V, Annex III to Regulation (EC) No 853/2004.
- In three establishments the FBOs could not provide evidence that the temperature of -18°C was reached within six hours when the MSM was frozen<sup>4</sup>. Only one FBO could demonstrate the use of a temperature recording device once a week, showing that the temperature of -18°C was reached in 5.5 hours, i.e. less than 6 hours, as required by paragraph 4(e), Chapter III, Section V of Annex III to Regulation (EC) No 853/2004.
- In one establishment the chilled MSM was not always used within 24 hours of production (i.e. the production of Saturday afternoon was used on Monday morning) (paragraph 4(e), Chapter III, Section V of Annex III to Regulation (EC) No 853/2004). In addition, the frozen MSM was stored in a cold room where the temperature recorded was -14°C for several hours and the room was in direct communication with the cold room for chilled products (paragraph 4(f), Chapter III, Section V of Annex III to Regulation (EC) No 853/2004).

The shelf-life, as indicated on the labels of the frozen MSM produced, was three months in all establishments visited, in line with the requirements of paragraph 4(f), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004.

In all establishments visited the MSM was used or sold for use in heat treated meat products, i.e. frankfurters and breaded poultry products, in line with the provisions of paragraph 4(g), Chapter III, Section V, Annex III of Regulation (EC) No 853/2004.

No establishment producing the type of MSM as referred to in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004 was visited by the audit team. According to the CA,

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3 In their response to the draft report, the CA noted that the establishment ceased the activity of MSM production in December 2012.

4 In their response to the draft report, the CA noted that one of these three establishments ceased the activity of MSM production in December 2012.

only a few establishments in Italy are producing this type of MSM which is used in meat preparations such as hamburgers and sausages. The establishments visited used a technique not supposed to alter the bone structure. However, they were in fact all producing a type of MSM as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004 as they did not comply with all other specific requirements laid down in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004.

## **Conclusions**

Official controls over the production of MSM were overall adequate, although the CA failed to identify some deficiencies related to general hygiene and to specific requirements laid down in Regulations (EC) No 852/2004 and (EC) No 853/2004.

### *5.3.3 Official controls at level of establishments producing raw material*

## **Findings**

The audit team visited eight establishments producing raw material for MSM production, i.e. flesh-bearing bones or carcasses, of which:

- one pig cutting plant supplying bones to other establishments in Italy for MSM production.
- Three pig and four poultry cutting plants processing the flesh-bearing bones / carcasses in the same establishment for MSM production. Two of these cutting plants were also selling flesh-bearing bones to other MSM producers.

In none of the establishments visited were flesh-bearing bones / carcasses sold abroad.

The conditions of storage and transport of the raw material were generally in compliance with the hygiene and temperature requirements of Chapter IV and Chapter IX, paragraph 2, of Annex II to Regulation (EC) No 852/2004 and of paragraph 4(b), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. Bones were protected against contamination and were processed either immediately after deboning or, when stored, kept in a cold store at a temperature of less than +2°C.

In a pig cutting plant producing cuts for hams and flesh-bearing bones, the procedure implemented for handling abscesses was leading to contamination of the whole cutting line. Moreover, other deficiencies were noticed by the audit team during the visit, e.g. the temperature of the cutting room was 14°C; the temperature in the cold room for the storage of the legs was up to 8°C; metallic trays not easy to clean were in contact with meat cuts. The above deficiencies are not in compliance with the requirements laid down in paragraph 3, Chapter IX of Annex II to Regulation (EC) No 852/2004, paragraph 2(b) of Chapter V and 2 of Chapter VII, Section I, Annex III to Regulation (EC) No 853/2004 and Chapter V of Annex II to Regulation (EC) No 852/2004.

The above deficiencies had not been detected and / or reported beforehand by the CA. Nevertheless, after the visit the CA took action imposing the destruction of the contaminated meat and requiring the FBO to implement other corrective measures (e.g. correction of the setting of the temperature in the cutting room and staff training). Copy of the inspection report with the corrective actions requested was then provided to the audit team.

## Conclusions

Official controls in the establishments producing raw material for MSM production were overall adequate, with the exception of one establishment.

### 5.3.4 Official controls at level of establishments using MSM

## Findings

The audit team visited five establishments using MSM for manufacturing heat-treated meat products, such as frankfurters, chicken nuggets, *cordon bleu* and other similar products.

In four out of the five establishments visited the audit team noticed certain deficiencies which had not always been identified, reported or followed-up by the CA. For example:

- In one establishment broken and / or unclean crates were used; the state of maintenance and cleanliness of the production room was insufficient (dirty air socks, presence of rust and flaking paint on walls and ceiling, dirty lamp covers; presence of condensation above the hoppers where the ingredients were mixed; build up of wet starch on all surrounding equipment and fixtures). The equipment for mixing the ingredients, working in continuous process, was cleaned only once a week. The location and layout of the room where crates were washed was inadequate (crossing of clean and dirty crates; storage of the clean crates in the corridor under dripping condensation).
- In a second establishment, although the structure and the state of maintenance were overall adequate, the processing area showed some deficiencies: a rusty element was above the cutter and a pipe ducting water from the evaporator to the drain, was broken and leaking on the floor just behind the cutter. In addition, there was an unprotected bulb in the lift used for exposed MSM.
- In a third establishment some deficiencies concerning maintenance and cleaning had already been noticed by the CA but were not yet corrected: presence of rust in some areas on the ceiling, a pipe leaking from the ceiling and close to the tray with frankfurters ready to be skinned before vacuum packing and pasteurising. The freezer where raw material (i.e. MSM) was stored was overloaded, some MSM packages were damaged and the MSM was exposed, there was frozen condensation and broken wooden pallets stacked above MSM blocks protected only by plastic wrapping.
- In a fourth establishment the layout was inadequate, several doors were not completely protecting the establishment against pest and external contamination and in some areas the paint was flaking from the ceiling. In the processing rooms the hygiene was inadequate (dirty floor, bad smell, semi-elaborated products left exposed during the lunch break, a bee flying around, the high room temperature, build up of technical lubricant just above semi-elaborated products, drinking water dispenser in the packaging room).

The above deficiencies are not in compliance with several provisions of Annex II to Regulation (EC) No 853/2004.

## Conclusions

In three out of five establishments visited using MSM, the official controls failed to identify the FBOs' lack of compliance with several requirements of Regulation (EC) No 852/2004 concerning in particular the state of maintenance and cleanliness of the premises, processing rooms and equipment and hygiene during production.

In one establishment visited, the CA did not take action to ensure that the FBO remedies the situation (Article 54 of Regulation (EC) No 852/2004).

#### *5.3.5 Official controls on FBO's compliance with microbiological criteria for foodstuffs*

### **Legal requirements**

Article 4 of Regulation (EC) No 854/2004, in particular paragraphs (2), (5) and (8).

Article 11 of Regulation (EC) No 882/2004.

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

### **Findings**

#### *FBOs sampling activities*

In all establishments visited a sampling plan for microbiological analysis was in place, and results of the analysis performed were available. All external laboratories used by the FBOs visited were accredited in compliance with the national legislation.

The MSM producing establishments visited were producing the type of MSM as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004, used only to manufacture heat treated meat products. For this type of MSM there are no microbiological criteria to be complied with. Nevertheless, testing for microbiological criteria was part of the HACCP based procedures also in these establishments.

The meat product establishments using MSM to produce heat treated meat products visited by the audit team had sampling programmes in place based on the requirements of Regulation (EC) No 2073/2005. When reviewing the FBO sampling plans and their implementation, the audit team made the following observations, which had not been detected or reported by the CA:

- The sampling frequency was in compliance with the requirements of Regulation (EC) No 2073/2005. However, in several cases the number of sample units was incorrect (i.e. only one sample tested instead of the required five).
- The methods used were in compliance with those defined in Regulation (EC) No 2073/2005. When an alternative method was used, sufficient evidence was provided demonstrating its validation against the EU reference methods. However, in one establishment the results of the test used for *E.coli* in minced meat could not be compared with the limits set in Regulation (EC) No 2073/2005.

## *Official sampling*

The guidance issued by the CCA on the implementation of Regulation (EC) No 2073/2005 gives indications regarding official controls on the microbiological tests made by the FBOs. Verification by the CA is performed both by official sampling, mainly for the food safety criteria, and by assessment of the actions taken by the FBO, e.g. the correct implementation of the sampling plan, the accreditation of the laboratory and the use of the appropriate methods, and the actions taken by the FBO following the results. Official samples are taken on the basis of a sampling plan drafted at regional level.

In the establishments visited the results of official samples were available. When results were unsatisfactory, corrective action was requested by the CA. As an example, in one establishment the total plate count at 30°C was considered too high for a batch of MSM and the CA requested the FBO to improve the hygiene.

Targeted samples can also be taken. For instance, the Veterinary Office for Compliance with EU Requirements (*Ufficio Veterinario per gli Adempimenti CE* – hereafter: UVAC) in Emilia Romagna requested the OV of one establishment to sample a consignment of frozen chicken MSM from another Member State for the research of *E.coli*. See also section 5.3.7 for further details.

## **Conclusions**

Verification of the FBO's compliance with microbiological criteria for foodstuffs is part of the official controls carried out by the Italian CAs, in compliance with the requirements of Regulations (EC) No 854/2004 and (EC) 2073/2005. Nevertheless, these official controls failed to identify some deficiencies concerning in particular the number of sampling units.

### *5.3.6 Traceability – Labelling – Identification marking*

## **Legal requirements**

Article 4(2) of Regulation (EC) No 854/2004 and Chapter IV, Section V, Annex III to Regulation (EC) No 854/2004 (Labelling).

Article 4(6) of Regulation (EC) No 854/2004 and Section I, Annex II to Regulation (EC) No 853/2004 (Identification marking).

Regulation (EC) No 178/2002 (Traceability and labelling).

## **Findings**

### *Traceability*

Traceability systems were in place in the establishments visited. Traceability checks are part of the official controls. The audit team performed a traceability exercise in one establishment with satisfactory results.

### *Labelling*

In the establishments visited producing MSM for other establishments, the label put on the pallets

of frozen MSM indicated “*carne separata meccanicamente*” (i.e. mechanically separated meat). The label always indicated that the MSM had to be used for the production of heat-treated products.

The denomination used on accompanying documents, such as CMR, invoices and any other commercial documents, as well as on documents accompanying official samples and laboratory test results, was not entirely satisfactory. Terms such as: ‘MDM’ (i.e. 'mechanically de-boned meat'), ‘MDM *pollo/tacchino congelato*’ (i.e. 'frozen MDM chicken/turkey'), ‘*purea di tacchino congelata* MDM’ (i.e. 'frozen mashed turkey MDM'), ‘*carnetta*’, etc were often used. Similar misleading denominations appeared also on the documents accompanying MSM consignments from other Member States.

In the establishments visited, the presence of MSM was clearly indicated on the labelling of meat products, including the species from which it had been obtained and the percentage.

Minced poultry skin or pork fat used as ingredients in chicken nuggets and in frankfurters produced in two establishments visited were indicated in the labelling as ‘*carne di pollo*’ (i.e. 'chicken meat') in the first case and counted towards the meat content in the second case. This is not in compliance with EU and Italian legislation (Directive of the European Parliament and of the Council No 2000/13/EC transposed into Italian Decree No 109/1992 as amended by Decree No 181/2003), as only skeletal muscle can be considered as meat on the label.

#### *Identification marking*

Identification marking was always present on the products/documents.

### **Conclusions**

Official controls on traceability, identification marking and labelling were overall adequate. However, despite the correct labelling, the use of denominations other than 'mechanically separated meat' on documentation is misleading.

Moreover, the CA failed to identify the incorrect use of the denomination 'meat' on the labelling for pork fat and chicken skin used as ingredients in meat products (Directive 2000/13/EC).

#### *5.3.7 Rapid Alert System for Food and Feed (RASFF)*

### **Legal requirements**

Article 50 of Regulation (EC) No 178/2002.

Regulation (EC) No 16/2011.

### **Findings**

The audit team assessed the actions taken by the CA concerning two RASFF notifications for MSM.

Notification No 2011.1578 concerned *E.coli* in frozen chicken MSM from another Member State. The UVAC required the OV to perform official checks including sample taking for laboratory tests. The test result was favourable and no further action was taken.

Notification No 2012.1197 of 21 August 2012 concerned the presence of chloramphenicol in frozen chicken MSM from Italy. The investigation performed by the Italian CA at the establishment where the MSM had been produced identified the recipients of the consignments affected. However, this establishment did not appear on the list of MSM establishments published on the Ministry of Health's web-site. At the time of this audit the investigation by the CCA was still ongoing.

## **Conclusions**

The actions taken by the Italian CAs in relation to the RASFF notifications assessed were adequate.

## **6 OVERALL CONCLUSIONS**

There is an official control system implemented in Italy to control the production of MSM. This system implemented does not show major deficiencies and is in general able to demonstrate that EU requirements are complied with. Nevertheless some deficiencies identified by the audit team had not been detected during official controls, and in particular concerning approval of establishments, general hygiene requirements (maintenance, structure, condensation, cleanliness and hygiene practices) and specific temperature requirements for MSM.

## **7 CLOSING MEETING**

During the closing meeting held in Rome on 11 September 2012, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting the CCA offered their initial comments and acknowledged the findings of the audit team in the establishments visited and undertook to address them.

## **8 RECOMMENDATIONS**

The Italian CCA should provide the Commission Services with guarantees and an action plan, including a timetable for its completion, within twenty five working days of receipt of the report, in order to address all the deficiencies identified in the report and in particular the following recommendations:

<b>N°.</b>	<b>Recommendation</b>
1.	The Competent Authority should ensure that the list of approved establishments in the sector of mechanically separated meat is kept up to date, as required by Article 31(f) of Regulation (EC) No 882/2004.
2.	The Competent Authority should ensure that effectiveness of official controls is improved, in order to identify and to report all deficiencies in the food business operators' premises, as required by Article 4(2)(a) of Regulation (EC) No 882/2004.

N°.	Recommendation
3.	In order to comply with EU requirements, the Competent Authority should ensure that deficiencies found by the audit team in the establishments visited are corrected and are not present in other approved establishments (Article 54 of Regulation (EC) No 882/2004).
4.	The Competent Authority should ensure that when food business operators' own sampling programmes are implemented, the sampling protocols and test methods used are in compliance with those of Regulation (EC) No 2073/2005.
5.	The Competent Authority should ensure that the presence of ingredients in meat products such as pork fat and chicken skin are correctly labelled as required by Directive 2000/13/EC.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2012-6359](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6359)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 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
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 16/2011	OJ L 6, 11.1.2011, p. 7-10	Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs