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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

GERMANY

FROM 15 TO 24 OCTOBER 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 Germany, which took place from 15 to 24 October 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 Germany to control the production and use of MSM. However, the results of the official control were documented to varying degrees which did not always allow for an assessment of what had been checked by the Competent Authorities (CAs). The official controls failed to identify several deficiencies and, in particular, concerning approval of establishments, specific requirements for MSM production and labelling.*

*The report includes a number of recommendations addressed to the German CAs aimed at rectifying the identified shortcomings and enhancing the implementation of the system of official controls in place.*

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
BfR	Federal Institute for Risk Assessment ( <i>Bundesinstitut für Risikobewertung</i> )
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection ( <i>Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz</i> )
BVL	Federal Office of Consumer Protection and Food Safety ( <i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i> )
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CMR	Convention on the Contract for the International Carriage of Goods by Road ( <i>Convention relative au contrat de transport international de marchandises par route</i> )
CN code	Combined nomenclature to classify goods when declared to customs in the Community
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
HP	Hygiene Package: Regulations (EC) No 852/2004, No 853/2004, No 854/2004 and No 882/2004
LANUV	State Agency for Nature, the Environment and Consumer Protection ( <i>Landesamt für Natur, Umwelt und Verbraucherschutz</i> )
LAVES	Lower Saxony Regional Office for Consumer protection and Food Safety ( <i>Niedersächsische Landesamt für Verbraucherschutz und Lebensmittelsicherheit</i> )
MANCP	Multi-Annual National Control Plan
MRI	Max Rubner Institute ( <i>Max Rubner-Institut</i> )
MSM	Mechanically separated meat
NI	Lower Saxony ( <i>Niedersachsen</i> )
NRW	North-Rhine Westphalia ( <i>Nordrhein-Westfalen</i> )
OV	Official Veterinarian

## 1 INTRODUCTION

This audit took place in Germany from 15 to 24 October 2012 and was undertaken as part of the Food and Veterinary Office (hereafter: FVO)'s audit programme.

The audit team comprised three auditors from the FVO. The audit team was accompanied throughout the audit by a representative from the Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* - BVL).

An opening meeting was held on 15 October 2012 with the central competent authority (CCA) the Federal Ministry of Food, Agriculture and Consumer Protection (*Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz* – BMELV). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

## 2 OBJECTIVES

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

- the general rules for the 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 system of official controls 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 AUTHORITIES			Comments
Competent authorities	Central	2	Opening and closing meeting.
	Regional	2	Opening meeting with the <i>Länder</i> of <i>Nordrhein-Westfalen</i> and <i>Niedersachsen</i> .
	Local	1	One district office was visited and the officials responsible for controls of the individual establishments were always present during the visits to these.
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Cutting plants		3	One independent poultry cutting plant, two poultry and pork cutting plants co-located in MSM establishments.
MSM production establishments		5	Two establishments producing MSM from poultry and three producing MSM from pork.
Meat product establishments		3	Using MSM.

<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.

### 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 1. EU legal acts quoted in this report refer, where applicable, to the latest amended version.*

### 4 BACKGROUND

#### 4.1 PREVIOUS FVO AUDITS

This was the first audit to Germany 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 Germany in 2010 and in 2011 and broken down by species. It does not include the MSM produced from wishbones.

Species	Year 2010	Year 2011
Chicken	62 230	44 361
Turkey	17 235	20 123
Pork	54 026	64 603
<b>Total</b>	<b>133 491</b>	<b>129 087</b>

Concerning trade with other Member States and / or export to Third Countries of MSM, the CCA informed the audit team that the official foreign trade statistics provide no data on MSM because there is no separate CN (Combined nomenclature to classify goods when declared to customs in the Community) code 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 (in metric tonnes), and provided by the CCA. It does not include MSM directly traded and / or imported by meat preparation and meat product establishments. It does not include data from Nordrhein-Westfalen (NRW).

	Year 2010	Year 2011
<b>MSM sent to Germany</b>		
From other Member States	0	144
From Third Countries	0	0
<b>MSM sent from Germany</b>		
To other Member States	23 373	28 422
To Third Countries	42 791	32 360

## 5 FINDINGS AND CONCLUSIONS

### 5.1 COMPETENT AUTHORITY

#### Legal requirements

Articles 4, 8, 9, 54 and 55 of Regulation (EC) No 882/2004.

#### Findings

The CAs are clearly designated for the areas covered by this audit but the organisation can vary between and within the individual *Länder*. The *Länder* level is responsible for implementing the official controls and enforcement whereas the CCA is responsible for federal legislation in these areas. The systems of official controls over the production chain of MSM is the same as for other food of animal origin. A description of the control systems can be found in the country profile for Germany which is accessible at:

[http://ec.europa.eu/food/fvo/country\\_profiles\\_en.cfm](http://ec.europa.eu/food/fvo/country_profiles_en.cfm)

In the *Länder* visited there was a quality management system in place which contained *inter alia* several documents used for the official controls. These documents, when seen had in many cases been further adapted at district level. There was also a system in place for reporting results of official controls based on a computer software programme (BALVI-IP). It was noted that the higher levels of the official services within the *Länder* only have limited access to the data of BALVI-IP.

In one of the *Länder* visited a more harmonised approach was seen on the use of the documents of the quality management system as well as of the BALVI-IP which can make co-operation and co-ordination easier to facilitate. However, in one district visited in this *Land* the BALVI-IP was not used for official controls of MSM establishments.

Systems for internal audit were in place in the *Länder* visited but no specific audits on the MSM sector have been performed. The CAs had sufficient legal powers to carry out their tasks.

The frequency of official controls was determined based on risk according to a system laid down in Federal legislation. In the establishments visited the set frequencies were generally followed but in one establishment visited, only two written reports were available for 2012 whereas the set inspection frequency was one inspection per month. The official veterinarian (OV) stated that the missing reports were oral only.

Evidence of official controls was available in all establishments visited. Where findings were made, these were clearly reported to the FBO by the OV, in a written document with an indication of a deadline for remedial action. However, documented evidence of follow-up by the OV was not always available.

In two districts visited the reports seen were not fully in compliance with the requirements of Article 9 of Regulation (EC) No 882/2004. These reports did not indicate the control methods applied, which made it difficult to assess what actually had been controlled (*i.e.* the CA could not demonstrate that the official controls covered audits of good hygiene practices and Hazard Analysis Critical Control Points (HACCP) based procedures as required by Article 4 of Regulation (EC) No 854/2004).

#### Conclusion

The German CAs are clearly designated and have adequate resources and legal powers. Reports were however, not always drawn up after official controls and some of the reports seen were not fully in line with Article 9 of Regulation (EC) No 882/2004.

## 5.2 LEGISLATION, IMPLEMENTING MEASURES AND GUIDELINES

### Legal requirements

Article 291 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 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

The provisions of Regulations (EC) No 852/2004 and No 853/2004, including the definitions and hygiene requirements for MSM set out in Point 1.14 of Annex I and in Chapter I, Chapter II, Chapter III and Chapter IV of Annex III Part V of Regulation (EC) No 853/2004, are directly applicable in Germany. Also directly applicable are the microbiological criteria laid down in Regulation (EC) No 2073/2005 and the maximum calcium content stated in Regulation (EC) No 2074/2005.

With regard to labelling of meat products / meat preparations containing MSM, the requirements of the above Regulation (EC) No 853/2004 are directly applicable. The relevant requirements of the Directive of the European Parliament and of the Council 2000/13/EC are transposed in the national regulation on the labelling of food (*Lebensmittel-Kennzeichnungsverordnung*, Annex 1 (paragraph 6 (4)(1))).

In the *Länder* visited there are no additional legal provisions on the production and use of MSM.

The *Länder* Working Group for Consumer Health Protection, responsible for co-ordinating the implementation of legal provisions, has not issued any specific opinion on the requirements for MSM production and use.

In 2006 the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung* – hereafter: BfR) issued a document concerning MSM production methods and the different degree of changes in the muscle fibres. In this document it is concluded that the term MSM applies to all types of products obtained by deboning by mechanical means.

In 2008 the Max Rubner Institute (*Max Rubner Institut* - hereafter: MRI) published research on the characterisation of mechanically deboned broiler meat, concluding that the product obtained from wishbone meat corresponds to fresh meat.

In 2010 the BfR issued a document on wishbone meat, referring to both the 2008 MRI research and to their own document from 2006. It states that "a legally relevant distinction between MSM with an altered structure of the muscle cells and meat produced in a similar way, but in which the structure of the muscle cells stayed intact, can hardly be made". However, it concludes that the muscle fibre structure remains intact. This document also points out that the muscle fibre structure is not the only issue to be taken into account for the classification of the product. The interpretation of this issue varied between officials within one *Land* visited.

### Conclusion

The German CAs have adequate implementing legal measures in place for the performance of official controls on the production and placing on the market of MSM. However, documented procedures for this specific sector were, when seen, rather limited and the available opinions on



MSM issued by two Federal scientific institutions did not provide clear guidance to the Food Business Operators (FBOs) or to the officials.

### 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 Germany and in previous FVO audit reports.

In NRW the State Agency for Nature, the Environment and Consumer Protection (*Landesamt für Natur, Umwelt und Verbraucherschutz* – hereafter: LANUV) is the authority responsible for the approval of establishments for which the average production is above a specified quantity. The districts CAs are responsible for the approval of the remaining establishments. The LANUV may carry out joint inspections with the local authorities in the approved establishment but there is no set frequency for this. Such joint inspections can be performed if there is a major change in the production, a new building or specific problems.

In NRW the approval document of one MSM establishment did not mention the MSM activity. The NRW CAs explained that establishments which received an approval before the applicability of the Hygiene Package (HP) (i.e., before 1.1.2006) maintained their old approval. Before this date the production of MSM was considered as a collateral activity of cutting plants and did not need a specific approval or a specific indication in the approval document. After the applicability of the HP, the NRW CA considered it unnecessary to provide such establishments with a specific formal approval for MSM production. However, Article 3(5)(b) of Regulation (EC) No 854/2004 requires the CA to approve also establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In addition, there was no evidence from the inspection reports seen for this establishment, that the specific requirements for MSM were checked during official controls.

In Lower Saxony (NI) the Lower Saxony Regional Office for Consumer protection and Food Safety (*Niedersächsische Landesamt für Verbraucherschutz und Lebensmittelsicherheit*, hereafter: LAVES) is the authority responsible for the approval of establishments. In addition to the official controls carried out by the local CAs, joint inspections with the latter are carried out by the LAVES to ensure that the conditions under which the approval was granted continue to be fulfilled, on the basis of a set risk-based frequency. The reports of the inspections carried out from the LAVES in NI were detailed and provided evidence that the approval conditions were kept under review.

In NI establishments with an old approval had received an amendment of the approval document to include the MSM activity, after an assessment from the responsible CA. This was the case for two establishments visited in NI.

In both *Länder* visited, establishments starting MSM production after the applicability of the HP received a specific approval letter for this activity.

As regards listing of establishments, the audit team noticed discrepancies when comparing the list published on the website of the BVL with the list provided by the CCA before this audit. In particular, a number of establishments which are producing MSM do not appear on the website list

and conversely, a number of MSM establishments on the website list are actually not in operation for this activity. The CCA pointed out that there are several establishments in Germany, not only in NRW, producing MSM under the old approval as a cutting plant and therefore not appearing in section V (minced meat, meat preparations and MSM) of the website list.

In addition, the audit team noticed that the CAs had different interpretation on whether establishments using wishbones as raw material to produce MSM should or should not be approved as MSM establishments. As a consequence, not all such establishments appear on the website list in the section of MSM establishments.

### **Conclusion**

Some establishments producing MSM which were operating before 01.01.2006 are still approved as cutting plants and the CA cannot ensure that all of them meet the specific requirements laid down in Annex III to Regulation (EC) No 853/2004. This is not in compliance with Article 4 of Regulation (EC) No 853/2004 and Article 3 of Regulation (EC) No 854/2004.

In addition, the listing of approved establishments was not fully up-to-date, 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 9 of Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

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

### **Findings**

The CCA confirmed that MSM from ruminants' bones is not produced in Germany.

The audit team visited five establishments producing MSM, of which two produced chicken and / or turkey MSM, two produced pork MSM and one pork and turkey MSM.

#### ***Findings concerning general hygiene requirements***

In three establishments visited the general hygiene requirements were overall adequate.

In the remaining two establishments the audit team noticed deficiencies that, although already detected and reported during official controls, had not yet been corrected. For example (not all deficiencies were present in both establishments):

- Surfaces and equipment were not maintained in sound conditions.
- Premises were not fully pest proof (external doors with gaps; broken seal around a pipe on the external wall of a processing room).
- Presence of condensation on the ceiling, in particular where exposed meat was processed.

In addition, the inadequate storage conditions for packaging and wrapping material had not been detected during official controls.

Moreover, during the visit, the audit team noticed in one of these two establishments that amongst the raw material (poultry carcasses) accepted by the FBO there were a piece of plastic, carcasses contaminated by technical lubricant and a piece of intestine. In the other establishment unhygienic practices were observed, i.e. staff sweeping the floor in the presence of unpacked meat.

The above deficiencies are not in compliance with several provisions of Annex II to Regulation

(EC) No 852/2004.

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. However, there was insufficient evidence in the inspection reports to demonstrate that official controls included audits of HACCP based procedures. In addition, in one establishment the official controls had failed to detect that the HACCP based procedures were inaccurate: the HACCP plan indicated that the MSM produced was frozen on-site and dispatched as frozen, but in reality the MSM was sent as chilled to another establishment (a cold store) for freezing and storing.

#### ***Findings concerning specific MSM production requirements***

Four of the establishments visited declared that they were producing MSM as referred to in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. However, in two of them not all the relevant requirements were complied with as the mechanical separation was not performed immediately after deboning (point 3(b) Chapter III, Section V, Annex III to Regulation (EC) No 853/2004) and the bone structure was altered by the mechanical separation. Therefore the MSM produced by these two establishments was the type as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. These non-compliances had not been identified during official controls.

Concerning the remaining two establishments, both were generally in compliance with the requirements laid down in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. Nevertheless the FBO of one of them, producing MSM from chicken wishbones, did not recognise this product as MSM, which was traded as "*Hänchen Baaderfleisch tiefgefroren*" (i.e. "frozen chicken *baader* meat"). The various levels of CAs had not reached an agreement on the classification of this product.

In the fifth establishment visited the MSM produced was the type as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. In this establishment the official controls failed to identify that the FBO could not demonstrate that the MSM frozen after production reached an internal temperature of -18°C within six hours (point 4(e), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004).

Analysis of the calcium content of the MSM produced was carried out in all five establishments visited, and showed that in all cases it was lower than 1 000 ppm (Annex IV to Regulation (EC) No 2074/2005).

As regards the raw material used to produce MSM (flesh-bearing bones and poultry carcasses), in two establishments the FBOs could demonstrate that the delay between slaughtering and deboning did not exceed the limits set in points 3(a) and 4(a), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. In two other establishments the OV's had detected a deficiency in this regard and corrective action had been taken. In the fifth establishment the FBO could not always demonstrate the delay between slaughtering and deboning and this deficiency had not been identified during official controls.

There is no shelf life limit imposed by EU legislation for the type of MSM as referred to in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004, whereas for the type as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004, the shelf life of frozen MSM is a maximum of three months.

The shelf life indicated for the MSM produced in the establishments visited was generally in line with the EU requirements, with the exception of one establishment. Here the shelf life indicated was one year instead of three months, on the basis that according to both the FBO and the CA the MSM produced was the type as referred to in point 3, Chapter III, Section V, Annex III to Regulation (EC)

No 853/2004 but, as already detailed in this section of the report, it did not fully comply with the relevant requirements.

The shelf life indicated by the producer of MSM that was used as an ingredient in one meat product establishment visited was six months. However, there was no evidence that this MSM was the type as referred to in point 3, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004. This deficiency had not been detected by official controls.

With the exception of two of the MSM producers visited, the denomination “mechanically separated meat” was not used in the documents (e.g., CMR waybills, invoices and any other commercial documents) accompanying MSM sold to traders or to other establishments for further processing. Denominations such as: 'MDM' or "*gebaadertes fleisch*" (i.e., "*baader* meat") were mostly used for MSM. The audit team noticed that the denomination "*gebaadertes fleisch*" (i.e., "*baader* meat") was commonly used also for products for which the raw material used were meat trimmings without bones.

In the establishments visited producing the type of MSM which could only be used to manufacture heat treated meat products (points 3(e) and 4(g), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004), the audit team noticed the following:

- In two establishments, correct reference was made on commercial documents and labels to the legal reference identifying the type of MSM produced and its use.
- In two other establishments the information on the type of MSM produced was not clearly communicated by the FBOs to their customers and the fifth establishment was selling the MSM under a different commercial name.

## **Conclusion**

Official controls over the production of MSM were overall adequate in relation to general hygiene requirements. However, the CA failed to enforce certain requirements and to identify some deficiencies within the provisions laid down in Regulation (EC) No 852/2004 in two out of five establishments. In addition, official controls in relation to HACCP based procedures were insufficiently documented.

Official controls failed to identify deficiencies related to specific EU requirements applicable to each category of MSM (i.e. MSM as referred to in point 3 and MSM as referred to in point 4, Chapter III, Section V, Annex III to Regulation (EC) No 853/2004).

The MSM sold to other establishments for trade or for further processing is not always correctly identified and / or accompanied by the necessary information which allows the FBOs to use it in meat preparations and meat products in accordance with the requirements of points 3(e) and 4(g), Section V, Annex III to Regulation (EC) No 853/2004.

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

## **Findings**

The audit team visited one independent cutting plant supplying turkey necks to one of the MSM establishments visited by the audit team, and two cutting plants integrated in MSM establishments.

In the independent cutting plant the audit team noticed the presence of an excess of grease on the rails, which had been previously reported by the OV, and which had contaminated some meat cuts. In addition, there was condensation on the ceiling of the chiller above exposed whole turkey carcasses (Paragraph 2(b), Chapter I, Annex II to Regulation (EC) No 852/2004), which had not been reported in previous official controls.

The official controls in the two cutting plants integrated with the MSM establishments visited were overall adequate.

## **Conclusion**

Official controls in establishments supplying raw material for MSM production were overall adequate, although these controls failed to enforce and to detect some hygiene requirements in one establishment.

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

## **Findings**

The audit team visited three establishments using MSM as an ingredient for manufacturing heat-treated meat products, such as heat treated sausages and reconstituted hams.

In two establishments the hygiene requirements were generally met. However, the presence of condensation, noticed by the audit team over exposed products in both establishments (Paragraph 2(b), Chapter I, Annex II to Regulation (EC) No 852/2004), had not been reported during previous official controls.

In the third establishment the official controls had not detected that action had not been taken by the FBO when the MSM received was above the required transport temperature of not more than +2°C (points 3(c) and 4(b) of Chapter III, Section V, Annex III to Regulation (EC) No 853/2004).

## **Conclusion**

Official controls in establishments using MSM as an ingredient in meat products were overall adequate. However, the official controls failed to detect some deficiencies in the three establishments visited.

### *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**

### *FBO's sampling activities*

In all establishments visited a sampling plan for microbiological analysis was in place, including those establishments (three out of five visited) producing the type of MSM as referred to in point 4 of Chapter III, Section V, Annex III to Regulation (EC) No 853/2004, for which there are no microbiological criteria to be complied with.

Results of the analyses performed were available. All external laboratories used by the FBOs of the establishments visited were accredited in compliance with the national legislation. The methods used were in compliance with those defined in Regulation (EC) No 2073/2005 and when an alternative method was used, sufficient evidence was provided to demonstrate its validation against EU reference methods.

However, there was no evidence that the FBOs' compliance with microbiological criteria was assessed during official controls as the reports were insufficiently detailed. Evidence of such

verification was only available in one establishment.

The official controls did not detect that in two establishments the sampling procedures were incorrect, i.e. one sample unit was tested instead of the required five.

### ***Official sampling***

Official sampling was performed in all establishments visited, based on a national plan. Samples were sent to accredited laboratories.

Following unsatisfactory results after official sampling for *E. coli* and total bacteria count in one of the establishments visited, the CA took action requesting the FBO to intensify the cleaning and disinfection in the establishment.

### **Conclusion**

Official controls on the FBOs' compliance with microbiological criteria were in several cases insufficiently supported by documentary evidence. In addition, the official controls failed to identify the incorrect implementation of the sampling protocols by two FBOs (Regulation (EC) No 2073/2005).

#### *5.3.6 Traceability, labelling and identification marking*

### **Legal requirements**

Article 4(2) of Regulation (EC) No 854/2004 and Chapter IV, Section V, Annex III to Regulation (EC) No 853/2004 (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 of the European Parliament and of the Council laying down the general principles and requirements of the food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (traceability and labelling).

### **Findings**

#### ***Traceability***

Traceability systems were in place in the establishments visited. However, as described in previous sections of this report, there was not always documented evidence that traceability was verified during official controls. Where the audit team performed traceability exercises in the establishments visited, the results were satisfactory.

#### ***Labelling***

In one out of the three meat product establishments visited, the CA had detected during official controls that the presence of MSM in meat products for the final consumers was not indicated on the labels. However, although this had been described in a report in February 2011, the FBO had only recently started to amend the labels. At the time of the visit by the audit team, most products containing MSM were correctly labelled. For other products the presence of MSM was indicated without specification of its percentage and the animal species from which it derived. In addition, the chicken skin used as an ingredient in meat products was counted towards the meat content. These deficiencies are not in compliance with the requirements of Directive 2000/13/EC.

In the remaining two establishments official controls failed to identify that certain meat products containing MSM, as declared to the audit team by the FBOs, and which were packaged and labelled for exclusive sale in other Member States, were incorrectly labelled:

- In one establishment the correct wording was used to indicate the presence of MSM,

whereas wording different from "mechanically separated meat" was used for English and for the language of the Member State of destination.

- In the second establishment the presence of MSM was not indicated on the labels of packed sliced pork ham and ham strips/cubes, made from muscle pieces and MSM. In addition, the description of one of the products indicated that it was made only from thigh muscle cuts. However, pork MSM can only be obtained from flesh-bearing bones other than, *inter alia*, femur and tibia (Paragraph 3(b)(ii), Chapter II, Section V, Annex III to Regulation (EC) No 853/2004).

### **Identification marking**

Identification marking was generally satisfactory with the exception of one establishment where pallets of MSM in the blast freezer were unidentified.

### **Conclusion**

Official controls on traceability and identification marking were overall adequate, although insufficiently documented.

Nevertheless, the CAs failed to ensure the implementation of the provisions of Directive 2000/13/EC concerning the indication of the presence of MSM and of other ingredients such as chicken skin in meat products. In addition, the information indicated on the labels was misleading for the final consumers which is contrary to Article 16 of Regulation (EC) No 178/2002.

#### *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 one RASFF notification for MSM and one RASFF notification for a meat preparation.

Notification No 2011.1914 concerned the presence of *Salmonella* in frozen chicken MSM from Germany, sold to a Third Country. This consignment was released by the CA of the Third Country with the requirement to use it in heat treated meat products. Nevertheless the German CA performed an ad-hoc official control in the establishment concerned and verified the FBO procedures in particular concerning cleaning and controls on incoming raw material. The CA verified also the results of the intensified sampling for *Salmonella* performed by the FBO.

Notification No 2011.0166 concerned the presence of *Salmonella* in turkey and turkey/chicken kebabs from Germany, sold to another Member State. The CA put in place a reinforced supervision on the establishment of origin, and eventually withdrew its approval. The CA confirmed that MSM was not involved in this case.

### **Conclusion**

The actions taken by the German CA in relation to the RASFF notification assessed were adequate.

## **6 OVERALL CONCLUSIONS**

There is an official control system implemented in Germany to control the production and use of MSM. However, the results of the official controls were documented to varying degrees which did

not always allow an assessment of what had been checked by the CAs. The official controls failed to identify several deficiencies and, in particular, concerning the approval of establishments, specific requirements for MSM production and labelling.

## 7 CLOSING MEETING

During the closing meeting held in Berlin on 24 October 2012, the audit team presented the main findings and preliminary conclusions of the audit the CAs.

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

## 8 RECOMMENDATIONS

The German 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:

Nº.	Recommendation
1.	The Competent Authorities should ensure that reports are drawn up after official controls and are in line with the requirements of Article 9 of Regulation (EC) No 882/2004.
2.	The Competent Authorities should ensure that establishments producing mechanically separated meat meet the relevant requirements established in Annex III to Regulation (EC) No 853/2004 and are approved for the activities concerned in order to comply with the provisions of Article 4 of Regulation (EC) No 853/2004 and Article 3 of Regulation (EC) No 853/2004.
3.	The Competent Authorities should ensure that the list of approved establishments is kept up to date, as required by Article 31(f) of Regulation (EC) No 882/2004.
4.	To ensure that procedures are in place to ensure the effectiveness of official controls that are carried out and to ensure that corrective action is taken when needed, as required by Article 8.3 of Regulation (EC) No 882/2004.
5.	In order to comply with European Union requirements, the Competent Authorities should ensure that deficiencies found are corrected in the establishments visited and are not present in other approved establishments (Article 54 of Regulation (EC) No 882/2004).
6.	The Competent Authorities should ensure that European Union requirements for the production and use of mechanically separated meat are respected (Chapter III (3) and



N°.	Recommendation
	(4) of Section V of Annex III to Regulation (EC) No 853/2004).
7.	The Competent Authorities should ensure that when food business operators' sampling programmes are implemented, the sampling protocols are in compliance with those of Regulation (EC) No 2073/2005.
8.	The Competent Authorities should ensure that products containing mechanically separated meat, as well as other ingredients such as chicken skin, are correctly labelled in accordance with the requirements of Directive 2000/13/EC and indications on labels do not mislead consumers (Directive 2000/13/EC and Article 16 of Regulation (EC) No 178/2002).
9.	The Competent Authorities should ensure that mechanically separated meat sold to other establishments is accompanied by the necessary information which allows food business operators to use it in meat preparations and meat products in accordance with the requirements of points 3(e) and 4(g), Chapter III, Section V, Annex III to Regulation (EC) No 853/2004, and to label the products destined to the final consumers in accordance with the requirements of Directive 2000/13/EC and of paragraph 2, section VI, Annex III to Regulation (EC) No 853/2004.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2012-6355](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6355)

## 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. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 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