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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SWITZERLAND

FROM 17 TO 27 APRIL 2012

IN ORDER TO EVALUATE THE CONTROL SYSTEMS PERTAINING TO FOOD SAFETY ASPECTS IN RELATION TO CERTAIN ANIMAL PRODUCTS (CASINGS, GELATINE AND RAW MATERIALS FOR GELATINE) UNDER THE AUSPICES OF THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON TRADE IN AGRICULTURAL PRODUCTS

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

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Switzerland from 17 to 27 April 2012. The main objective of the audit was to evaluate the control systems pertaining to food safety aspects in relation to certain animal products (casings, gelatine and raw materials for gelatine) under the auspices of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products.

The structure and responsibilities of the Competent Authorities (CAs) remain unchanged. The Federal Authorities are responsible for preparing and issuing the national level legislation and monitoring the performance of the authorities at cantonal level while the 26 cantonal authorities are responsible for the execution and enforcement of the legislation and the issuing of cantonal implementing procedures.

The information at Federal level on inspections and enforcement carried out by the cantons is limited. The audits carried out by the Federal Food Chain Unit (FFCU) were able to detect shortcomings but it was up to the individual cantons to decide if they would react and take corrective action or if they would accept an audit.

During the FVO audit a total of ten establishments were visited.

Major problems were noted as regards the approvals of casing establishments and two of the establishments visited were on the published lists of approved establishments without having a valid approval. In one case a new approval had been issued two days before the FVO visit, based on a two and a half year old inspection report.

The staff met were generally well motivated and knowledgeable. Reports were drawn up after official controls but the inspection frequencies varied considerably between individual cantons, in particular for casing establishments. In more than one case limited staff resources were mentioned as the reason why set inspection frequencies had not been met.

Official controls carried out by the CA generally include verification of food business operators' (FBO) compliance with good hygiene practice and Hazard Analysis Critical Control Points (HACCP)-based procedures as required. The performance of the individual CA officials was in most cases considered to be of an acceptable or good standard. The overall situation in relation to general and specific hygiene requirements was, in most cases, considered to be acceptable in the establishments visited.

Traceability systems were in place in all the establishments visited and were, in most cases, found to be reliable. Labelling and identification marking on products received or ready for shipment had, in most cases, been done in a satisfactory way. However, in three of the ten establishments visited serious problems were identified in relation to labelling and/or the application of identification marking on products. In one canton the CA was not aware of the approval numbers of some of the establishments under their own responsibility which makes official controls of labelling impossible.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
Agreement	Agreement between the European Community and the Swiss Confederation on trade in agricultural products, approved by Council and Commission Decision 2002/309/EC
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
CL	Canton Laboratory (<i>Kantonales Laboratorium, KL</i>)
COM	European Commission
CVS	Canton Veterinary Service (<i>Kantonales Veterinäramt, VET</i>)
DG(SANCO)	Health & Consumers Directorate General
EC	European Community
EU	European Union
FBO(s)	Food Business Operator(s)
FFCU	Federal Food Chain Unit (<i>Bundeseinheit für die Lebensmittelkette, BLK</i>)
FOPH	Federal Office of Public Health (<i>Bundesamt für Gesundheit, BAG</i>)
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
HyV	Hygiene Ordinance (<i>Hygieneverordnung</i>)
LGV	Ordinance on food and consumer products (<i>Lebensmittel und Gebrauchsgegenständeverordnung</i>)
LMG	Food Act (<i>Lebensmittelgesetz</i>)
LKV	Ordinance on identification and advertising of foodstuffs (<i>Verordnung über die Kennzeichnung und Anpreisung von Lebensmitteln</i>)
MANCP	Multi-Annual National Control Plan
OV(s)	Official Veterinarian(s)
SFVO	Swiss Federal Veterinary Office (<i>Bundesamt für Veterinärwesen, BVET</i>)
VHyS	Ordinance on hygiene at slaughter (<i>Verordnung über die Hygiene beim Schlachten</i>)
VSFK	Ordinance on slaughter and meat inspection (<i>Verordnung über das Schlachten und die Fleischkontrolle</i>)

1 INTRODUCTION

The mission took place in Switzerland from 17 to 27 April 2012 as part of the planned audit programme of the FVO. The FVO audit team comprised two auditors from the FVO.

The FVO audit team was accompanied throughout the audit by a representative from the Central Competent Authorities (CCAs), the Swiss Federal Veterinary Office (SFVO) and the Federal Office of Public Health (FOPH).

The opening meeting was held on 17 April 2012 with the CCAs in Bern. At this meeting the FVO 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 objective of the audit was to verify that the Swiss Confederation enforcement and control programmes pertaining to certain animal products are functioning in the manner specified by Title II of Annex 11 to the Agreement between the European Community and the Swiss Confederation on trade on agricultural products¹.

The scope of the audit was to review the structure and operation of control systems in the Swiss Confederation pertaining to certain animal health and zoo-technical measures applicable to trade in animal products.

Areas covered by this audit included issues specified in Title II of Annex 11 to the Agreement, in particular food safety aspects in relation to the:

- Production of casings for human consumption;
- Production of gelatine for human consumption;
- Production of raw materials for gelatine; and
- Imports and exports of gelatine and casings as well as raw materials for the production of gelatine and casings, if applicable.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

COMPETENT AUTHORITIES			Comments
Competent authorities	Central	1	SFVO (opening and closing meetings)
	Regional	6	Canton level / 3 offices visited
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses		4	3 harvesting intestines for casing production / 2 producing raw materials for gelatine production
Casing establishments		5	3 co-located in slaughterhouses
Gelatine establishments		1	

3 LEGAL BASIS

The audit was carried out under the auspices of the Agreement and, in particular its Article 16 of

¹ Hereafter referred to as: the Agreement

Annex 11 on animal health and zoo-technical measures applicable to trade in live animals and animal products adopted by Council and Commission Decision 2002/309/EC, Euratom of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation (O.J. L 114 of 30.04.2002).

Article 46 of Regulation (EC) No 882/2004 stipulates that Community Controls in third countries shall verify compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation.

Full EU legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

This was the first FVO audit in Switzerland in order to review the official controls over the production of casings, gelatine and raw materials for the production of gelatine.

4.1 INFORMATION ON THE CASING SECTOR

Prior to the audit the SFVO provided the following statistical information on the imports and exports of casings, bladders and stomachs (Customs Code 0504.0090) for the year 2010 and 2011.

Direction	Countries / Quantity in tonnes	2010	2011
IMPORT	EU Member States	4 721	5 102
	Third Countries	280	374
	Total quantity imported	5 001	5 476
EXPORT	EU Member States	479	582
	Third Countries	294	25
	Total quantity exported	773	607

The information relating to casings includes both casings for further processing and final products.

The Swiss official list of establishments under section XIII (treated stomachs, bladders and intestines) includes 25 establishments of which 4 are listed as processing establishments only while 21 are listed as processing establishments with associated activities. Some of the slaughterhouses listed are only processing bovine tripe while others are also harvesting intestines for casing production in co-located casing processing establishments.

4.2 INFORMATION ON THE GELATINE SECTOR

Prior to the audit the SFVO provided the following statistic information on the imports and exports of gelatine (Customs Code 3503.0000) for the years 2010 and 2011.

Direction	Countries / Quantity in tonnes	2010	2011
IMPORT	EU Member States	5 118	5 199
	Third Countries	1 301	1 981
	Total quantity imported	6 419	7 180
EXPORT	EU Member States	3 463	3 499
	Third Countries	157	130
	Total quantity exported	3 620	3 629

These figures cover gelatine for technical use as well as for human consumption. It is therefore not possible from the information provided to extract the detailed information relating to gelatine for human consumption separately.

The Swiss official list of establishments under Section XIV (gelatine) includes four establishments in total, of which all are listed also for the processing of collagen while three are listed as processing establishments with other associated activities. The official list included at the time of announcing the audit five establishments but one of these was later removed from the list because no activities relating to gelatine had taken place for some time.

The CCA informed the FVO audit team that although being listed for the processing of gelatine there are no establishments in Switzerland producing gelatine for human consumption. The four establishments included on the official list are only further processing gelatine imported from the EU or third countries.

Prior to the audit the CCA did not provide an overview of establishments producing raw materials for the production of gelatine. The information provided in relation to one of the slaughterhouses included in the itinerary showed that large quantities of raw materials for the production of gelatine (bovine and porcine bones as well as pig skin) had been supplied to a gelatine producer in one EU Member State. During other visits the FVO audit team also noted that several of the other establishments provided raw materials for the production of gelatine to the same establishment in the EU.

5 FINDINGS AND CONCLUSIONS

Article 16 of Annex 11, Title II to the Agreement establishes that to increase confidence in the effective implementation of the provisions of this Title, each party shall have the right to carry out audit and verification procedures in respect of the exporting Party, which may include (a) an assessment of all or part of the competent authorities' control programme, including where appropriate, a review of the inspection and audit programmes, and (b) on-the-spot checks.

5.1 LEGISLATION

In the Agreement and in particular Chapter 1 of Appendix 6 to Annex 11 regarding food safety aspects included in public health sanitary measures of the evaluated sector, the recognition of equivalence is mutual. The legal requirements applicable to trade with the EU are the Swiss standards and special conditions in the Agreement.

Swiss standards

The Federal Act of 9 October 1992 on foodstuffs and consumer products (Food Act, *Lebensmittelgesetz, LMG*) as amended (SR 817.0), is the main Swiss legislation regarding public health sanitary measures.

Special conditions

According to Annex 11 to the Agreement, Appendix 6, Chapter I, Special Conditions (1) it is agreed that “Animal products intended for human consumption which are traded between the Member States of the Community and Switzerland will move under the same conditions only as animal products intended for human consumption which are traded between the Member States of the Community”.

Audit findings

- The specific requirements in Swiss legislation for the sectors concerned by this audit can be found in the relevant Swiss legal acts and are equivalent to the specific EU requirements.
- The Agreement was last amended by Decision 2010/797/EU and changes in the special conditions in Chapter 1 of Appendix 6 to Annex 11 excluded from the special conditions the requirement that Switzerland for exports to the Community should monitor compliance with Regulation (EC) No 853/2004.
- The special conditions also prolong the derogation for Trichinae examination of carcasses and meat of domestic swine kept for fattening and slaughter in low-capacity establishments until 31 December 2014.

Conclusion

In general the Swiss legislation provides satisfactory assurances that the provisions of the Agreement can be met.

5.2 COMPETENT AUTHORITIES

The structure and responsibilities of the CAs remain unchanged and are as described in the FVO audit report DG(SANCO)/2009-8217. Further information can also be found in the Multi-Annual National Control Plan (MANCP) of Switzerland which can be found at:

<http://www.bvet.admin.ch/blk/02557/index.html?lang=en>

Attached to the MANCP are the cantonal profiles which provide further data on the organisation of the individual cantons.

The Federal authorities are responsible for preparing and issuing the national level legislation and monitoring the performance of the authorities at cantonal level. Import and export controls are under the direct competence and execution of the Federal authorities.

The SFVO, in addition to animal health legislation is also responsible for meat and dairy production and for the lists of approved establishments in the sectors concerned and their publication.

The FOPH is responsible for legislation on public health and consumer protection, including legislation relating to meat and dairy processing. Risk assessment and risk management is also under the FOPH.

The FFCU under the strategic lead of the Directors from the SFVO, the FOPH and the Federal Office of Agriculture prepares and co-ordinates the implementation and evaluation of the MANCP as well as contingency plans. The FFCU supervises the implementation of legislation by the 26 cantonal authorities in the field of food safety, animal health and animal welfare as well as the Federal authorities regarding feed control, import of animals and animal products from third countries.

The cantonal authorities are responsible for the execution and enforcement of the legislation and the issuing of cantonal implementation procedures. The specific allocation of competences within the individual cantons is outlined in the MANCP. If the Cantonal Veterinary Service (CVS) and the Cantonal Laboratory (CL) are not merged it can be noted that as a general rule slaughterhouses are under the supervision of the CVS and other meat processing establishments are under the CL. Cutting plants can be under either of these depending on whether they are part of a slaughterhouse or a meat processing establishment. It was noted by the FVO audit team that joint inspections were frequently carried out by the CVS and CL.

The FVO audit team was informed that there are plans in the future to move the SFVO, which is currently under the Federal Department of Economic Affairs to the Federal Department of Home Affairs. This proposed change would lead to a situation where the SFVO and the FOPH are under the same Ministry.

5.2.1 Designation of Competent Authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs. Article 8 of the Regulation states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Swiss standards

The LMG is the main Swiss legislation regarding the organisation of the official controls and public health sanitary measures.

Audit findings

- The CAs were clearly designated for the areas covered by this audit.
- The organisation of the CAs at cantonal level varied considerably between the cantons visited.
- In one canton visited it was clearly stated that the merger between the two inspection services (CVS and CL) had led to a better co-operation and a more efficient administration. However, the FVO audit team noted that in some other cantons the co-ordination and co-operation was problematic. The CCA admitted that in some cantons the co-operation between the CVS and the CL was difficult.
- In March 2010 the FFCU finalised an audit series which started in November 2008 on the cantonal authorities regarding inspection and approval of establishments in the meat and milk sectors. The audit series involved most of the relevant CAs. However, the CL of two cantons (Bern and Basel Stadt) did not want to be included in the audits. The CCA stated

that they have no legal powers over the cantons but generally there is good co-operation during the audits. From the individual reports it is clear that the auditors of the FFCU were well capable of identifying relevant deficiencies. However, the FVO audit team noted that in individual cantons some of these deficiencies still persisted.

- The project on an information system for the food chain which would provide the CCAs with information on the official controls carried out is on-going and it was explained by the FOPH that for this year information will be gathered in the form of excel tables but in the future the platform used by the SFVO will be used as a model. The system used by the SFVO can provide basic data regarding approved establishments as well as the dates for inspections of these (but not on the contents) and the dates of approval.
- Article 36 of the LMG provides the legal basis for gathering information from the cantons on the official controls carried out and enforcement action taken. However, at present the information available at Federal level in this regard is very limited, which can also explain why the 2010 annual report to the MANCP contains very limited information on these topics. The guideline on preparing the annual report for the MANCP (Commission Decision 2008/654/EC) foresees much more detail on official controls and enforcement.
- After the audit the FVO audit team received information regarding an amendment of the LMG planned to be in force by the end of 2014 which could strengthen this legal basis for gathering information.

Conclusion

The information at federal level on inspections and enforcement carried out by the cantons is limited. The audits by the FFCU are able to detect shortcomings but it is for the cantons to decide if they will react and take corrective action or even accept an audit.

5.2.2 Staff performing official controls

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest. Article 6 of the Regulation requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Swiss standards

The requirements concerning professional qualifications for officials involved in controls of the sectors concerned are laid down in specific Swiss legislation.

Audit findings

- Some staff met had diplomas as a food controller or as a food inspector as well as being an official veterinarian (OV) and were therefore in theory allowed to work across the sectors.
- Staff met were generally well prepared and motivated and in most cases knowledgeable. Several of the officials could provide an overview of all the training they had received over a period of several years.

- Staffing numbers at Federal level remain virtually unchanged but there is one new post in the SFVO which in parts is concerned with the follow-up work of the audits carried out by the FFCU.
- It was explained to the FVO audit team in the cantons where the inspection frequencies had not been met that this was mainly down to a lack of staff resources. In one of the cantons visited it was demonstrated that the situation had improved significantly after an increase in staff numbers.
- The FVO audit team did not come across any situation where a possible conflict of interest was identified.
- The SFVO have an annual training programme and evidence was also seen at cantonal level regarding participation in these and other training activities. The FOPH also provided the FVO audit team with information on training activities carried out and evidence on participation of the staff concerned.
- The OV responsible for the single gelatine plant visited had participated in a FBO audit of one of their suppliers.

Conclusion

Official staff met were generally well motivated and knowledgeable and training is provided as necessary. Limited staff resources at cantonal level was in most cases the explanation provided when the set inspection frequencies had not been met.

5.2.3 Organisation of official controls

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on FBOs to undergo inspection by the CAs. The same article requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 7 of the Regulation requires that CAs carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Article 8 of the Regulation requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Swiss standards

Articles 24 and 25 of the LMG provide the legal basis regarding the right of entry into food premises during official controls and requires that the FBOs shall assist the officials. It also has requirements regarding transparency as well as confidentiality in Articles 12, 42 and 43.

The frequency of inspection shall according to Article 56 of the Ordinance on food and consumer

products (*Lebensmittel und Gebrauchsgegenständeverordnung, LGV*) be based on risk taking all the relevant criteria listed into account. The minimum frequency of inspections in slaughterhouses are laid down in Article 54 of the Swiss Ordinance on slaughter and meat inspection (*Verordnung über das Schlachten und die Fleischkontrolle, VSFK*).

Article 62 of the LGV requires that the official inspection bodies shall be accredited under ISO 17020.

Audit findings

- The CCA explained that all CLs have been accredited in accordance with Article 62 of the LGV. However, around 10 of the CVSs have not been accredited yet.
- Reports were drawn up after official controls and copies provided to the FBOs. In many cases a short report was provided at the time of the visit and the more detailed (full) report was sent by mail later.
- The check-lists, report templates and working instructions used during inspections were prepared at the cantonal level and varied considerably.
- The implementation of the requirements regarding inspection frequencies in Article of the LGV has been adopted differently in individual cantons. An information brochure was issued in February 2011 and there is an on-going project with the aim of achieving harmonisation in this area.
- The actual frequency of inspection in the establishments visited varied considerably for the casing establishments with a span from annual up to 4, 5 and 7 years, despite a foreseen frequency of once every 2-3 years as a minimum. For the slaughterhouses the frequency was annual with an inspection occasionally missing but in one slaughterhouse there had not been an inspection for 5 years. The gelatine establishment visited was inspected annually.
- The FFCU have noted in their audits that the set frequencies of inspection were not met in individual cantons.

Conclusion

All CLs and around 50% of CVSs are accredited. Reports were drawn up after official controls but the frequencies of inspection varied considerably between individual cantons in particular for casing establishments. In several cases the risk-based inspection frequencies had not been respected.

5.2.4 Enforcement measures

Legal requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation. Article 55 of the Regulation states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all the measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Swiss standards

The LMG has in Chapter 7 clear provisions for penalties regarding infringements of food

legislation.

Audit findings

- In 3 cantons out of the 26 the official services can impose administrative fines and in 1 canton visited it was shown that this tool was used when needed.
- Overall, limited evidence was seen as regards enforcement in the cantons/establishments visited. Follow-up of deficiencies identified was in some cases not documented or done during the next inspection which could be years away.

Conclusion

Limited evidence was seen as regards enforcement and follow-up. Effective enforcement cannot be guaranteed in cases where intervals between inspections are up to three to seven years.

5.3 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals. The same article also requires that the CAs prepare the lists of registered and approved establishments and keep the approval of establishments under review when carrying out official controls.

Article 4 of Regulation (EC) No 853/2004 requires Member States to approve establishments handling products of animal origin in accordance with Article 3, and they must comply with the requirements of Annexes II and III to the Regulation. However, in Article 4 (2.d) of Regulation (EC) No 853/2004, there is a possibility of an exemption from these requirements for approval for establishments carrying out only retail operations.

The Agreement requires in Chapter 1 of Appendix 6 to Annex 11 special conditions (2) Switzerland to draw up a list of its establishments approved in accordance with Article 31 of Regulation (EC) No 882/2004.

Swiss standards

Article 13 of the LGV provide the legal requirements for registration and approval of food businesses. Further requirements for the approval of slaughterhouses are laid down in Article 8 of the VSFK.

Audit findings

- On 31 March 2011 the FOPH updated their instruction No 7 concerning the interpretation of the legal requirements regarding approval of establishments. There is also a guidance document updated on 31 March 2011 regarding the information needed before and how to carry out an inspection for approval. The SFVO have an instruction updated in June 2008 concerning the approval of slaughterhouses.
- Examples were seen by the FVO audit team where casing establishments had continued their operations after their approvals had expired. In one case for two years and nine months and in another case four months, these establishments operated without a valid approval

until a new approval had been issued. In the first case an approval had been issued on 18 April 2012 (just before the visit by the FVO audit team) based on an inspection carried out on 23 June 2009 and in the second case there was no date on the approval letter itself.

- Two casing establishments visited had historic approvals from 2002 and 2005 respectively which had expired in May 2003 and at the end of 2006 (based on previous legislation, they were approved as export establishments with a validity of one year). For these two establishments there were no current approvals. The CA stated to the FVO audit team that they considered the establishments to be approved because they were listed on the published lists of approved establishments.
- One approval for a slaughterhouse had not been updated to reflect the change of approval number when approved for export in 2006 and still referred to an old approval number, which was not the one being used.
- One recent approval for a slaughterhouse referred to Article 13 of the LGV rather than Article 8 of the VSFK and did not provide all the information foreseen (slaughter capacity missing). The FVO audit team noted however, that the wording of the LGV was more clear.
- Some shortcomings were noted in the published lists of approved establishments, (e.g. name and slaughter species).
- There are no specific requirements or guidelines laid down at Federal level on what an approval document should contain. The FVO audit team observed that in the individual establishments visited it could be anything from clear letters containing all the relevant information to, in some cases, just a reference in an inspection report that the approval number is maintained.

Conclusion

Major problems were noted as regards the approval of casing establishments and two establishments visited were on the published lists of approved establishments without having a valid approval.

5.4 FOOD BUSINESS OPERATORS' COMPLIANCE WITH HYGIENE RULES AT ESTABLISHMENT LEVEL

5.4.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the FBO carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, sitting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

Swiss standards

The LMG is the main Swiss legislation regarding public health sanitary measures. The detailed

rules in relation to the equivalent requirements are laid down in the LGV and the Hygiene Ordinance (*Hygieneverordnung, HyV*).

For slaughter establishments the detailed rules in relation to the equivalent requirements are laid down in the VSFK and the Ordinance on Hygiene at Slaughter (*Verordnung über die Hygiene beim Schlachten, VHyS*).

Audit findings

During the visits the CAs carried out a full inspection in the casing and gelatine establishments while the visits to slaughterhouses only focussed on areas relevant to the harvesting of casings and the collection and dispatch of raw materials for gelatine. The overall situation in relation to general and specific hygiene requirements was considered to be acceptable in most of the establishments visited.

However, the following observations were made in individual establishments visited:

- In two co-located casing establishments a number of plastic bags with industrial salt were used to press nets of salted casings in a perforated container. In one case all the coloured printing on the bags had disappeared during this use. The CA instructed the FBO to establish a different procedure for this activity.
- The salt used in all the casing establishments was labelled as “Industrial Salt – Not for Human Consumption” (*“Gewerbesalt – Diese Technische Salz-qualität ist nicht für die menschliche oder tierische Ernährung bestimmt”*). The CA accepted the use in the casing industry because the data sheet stated that the salt could be used for the preservation of casings, (*“Zum Konservieren von Därmen”*). However, the labelling could be considered as misleading.
- In one slaughterhouse producing raw materials for gelatine the cleaning of the equipment in the collection area was unsatisfactory with old dirt on the chute transferring bones to the large transport container. The cleaning of plastic containers for pig skin was unsatisfactory. Old labels, in some cases with the approval numbers of other establishments, had not been removed from the plastic container. The FBO explained that these containers had been received cleaned and protected from a gelatine establishment in an EU Member State and that no further cleaning was therefore required.
- In one of the casing establishments visited the FVO audit team found discolouration of walls and ceiling (possibly mould) and rust on the equipment. The FBO was aware of the poor maintenance standard of one centrifuge for pig stomachs and explained that the old centrifuge would be replaced by a new centrifuge in the near future. The production flow in this casing establishment was unsatisfactory with only a very low wall separating the area for cleaning and cooking bovine tripe and the area for cleaning and salting pig intestines.
- In the same casing establishment a large unidentified plastic tank with liquid content was found in the chilling room for cleaned casings. According to the FBO of the slaughterhouse the tank contained a kind of “perfume” used to spray onto waste products in order to avoid odour problems. Additional clarification was requested during the visit and again during the final meeting but so far no further information has been provided.
- In another casing establishment the storage room was insufficient to hold all barrels containing salted casings. Some of the barrels were stored in the clean area with chipboard sheets (*“Spanplatten”*) for separation. Exposed chipboard was also found under stainless steel tables as part of their construction. A large opening was observed in the ceiling of the clean area which lead into a 20 foot export container on the roof. The FBO explained that he

had never observed this construction himself, that it had been there when they occupied the building. No one could explain its purpose.

Conclusion

The general and specific hygiene requirements of the Swiss legislation were respected in most cases but with some individual shortcomings identified.

5.4.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Section II of Annex II to Regulation (EC) No 853/2004 lays down the specific requirements for HACCP-based procedures in slaughterhouses.

Swiss standards

The requirements regarding own checks, including HACCP-based procedures and official controls are laid down in Article 23 of the LMG and in Chapter 5, Sections 1 of the LGV.

Audit findings

The HACCP programmes were only checked during the FVO audit in the areas covered by the audit. The following observations were made by the FVO audit team:

- In one casing establishment receiving salted casings in bulk from approved establishments in EU Member States and in third countries for further processing, re-wrapping and wholesale, the HACCP programme did not include salting as a critical control point. The FBO, however, was aware of this requirement that had only very recently been introduced in the newest version of the “Community Guide to Good Practice for Hygiene and the application of the HACCP principles in the production of natural sausage casings”, Version II, February 2012.
- In one gelatine establishment metal detection was identified as a critical control point in the HACCP programme. However, the HACCP programme did not define what corrective action to take if the critical control point was out of control and there had been no checks performed during a three week period when the metal detector had been removed for repairs. This was detected by the CA during the inspection performed on the day of the visit. The corrective action proposed by the FBO was not to consider this to be a critical control point in the future, without carrying out a new Hazard Analysis.

Conclusion

HACCP-based own control systems in line with the requirements of Article 5 of Regulation (EC) No 852/2004 were in place in the establishments visited and only a few shortcomings were identified.

5.4.3 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer.

Swiss standards

The requirements regarding traceability are laid down in Article 23a of the LMG. The requirements regarding labelling and identification markings are laid down in *inter alia* Article 26 of the LGV and the Swiss Ordinance on Identification and Advertising of Foodstuffs (*Verordnung des EDI über die Kennzeichnung und Anpreisung von Lebensmitteln, LKV*).

Audit findings

Traceability systems were in place in the establishments visited and in most cases found to be reliable. However, in one case the traceability could not be fully guaranteed:

- In one casing establishment the barrels with salted casings from several production dates were only identified and labelled immediately prior to shipment. The FBO explained that the responsible person had a system for placing the barrels in the chilling room and that he therefore was able to guarantee the traceability. However, this system cannot be verified.

In most cases the labelling and identification marking on products received or ready for shipment had been done in a satisfactory way. However, the following shortcomings were identified:

- Barrels with salted pig casings were in some cases sent to an EU Member State without any identification marks being applied. In other cases the barrels were sealed with cello-tape bearing the identification marks.
- In one establishment where casings were re-packed into smaller plastic containers (containing one hundred yards each) the FVO audit team found that the information on the containers did not include the animal species or the identification mark of the establishment. The containers were packed into cartons that had a small sticker with the calibre that only in some cases had the identification number pre-printed.
- In one gelatine establishment visited products were found in the storage area without proper labelling and identification markings. The FBO explained that gelatine received from one supplier in an EU Member State often arrived without proper labelling but it was possible to trace it back to the trade document via the batch code and weight, which was the only information available on some of the big sacks.

Conclusion

Traceability systems were in place in the establishments visited and in most cases found to be reliable. Labelling and identification marking of products were in most cases done in a satisfactory way.

5.5 OFFICIAL CONTROLS OVER APPLICATION OF HYGIENE RULES

Legal requirements

According to Article 4 of Regulation (EC) No 854/2004 the CAs shall carry out official controls to verify the FBOs' compliance with good hygiene practice and HACCP-based procedures and shall take special care to verify the FBOs' relevant records and documentation as regards compliance with food law.

Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with the requirements concerning the application of identification marks takes place in all approved establishments, in addition to verification of compliance with other traceability requirements.

Swiss standards

The LMG is the main Swiss legislation regarding official controls in food businesses. In addition, more detailed rules can be found in *inter alia* the LGV, the VSFK and the Ordinance on the Enforcement of Food Legislation (*Verordnung über den Vollzug der Lebensmittelgesetzgebung*).

Audit findings

Official controls carried out by the cantonal CAs generally include verification of FBOs' compliance with good hygiene practice and HACCP-based procedures as required. In some of the inspections followed, the official started by verifying the data available to check that the approval was still correct (i.e. the approval was clearly under review). The performance of the individual CA officials was in most cases considered to be of an acceptable or good standard.

The following observations were made by the FVO audit team in the establishments visited:

- Although the officials met were able to carry out the official controls over general and specific hygiene requirements in a satisfactory way during the FVO visits they had in the past missed several of the shortcomings identified.
- In one canton visited the CA did not know the approval number of some of the establishments under their own responsibility. This makes it impossible to carry out effective official controls regarding labelling and identification marking. They explained that the controls over labelling was the responsibility of the CL and not the CVS but that they had recently started to carry out combined inspections.
- Post-mortem inspection of pig intestines in three slaughterhouses was performed in the correct way by auxiliary meat inspectors and the transfer to co-located casing establishments done in satisfactory way.
- The shortcomings regarding identification marking identified by the FVO audit team in individual establishments visited indicates that this area is not always a priority during official controls.
- When checking inspection reports from a cutting plant not visited but co-located in a slaughterhouse visited, it was discovered that there was no documentation available to verify that the CA had followed up the deadlines provided for corrective actions. The CA explained that the inspection had been a combined one between the CVS and the CL and that the follow-up in relation to labelling problems was the responsibility of the CL. No information was available at the CVS to show that a deadline of the end of February 2012 had been

followed-up by the CL.

- The split system with CVS responsible for official controls relating to meat inspection and CL responsible for official controls relating to labelling and identification marking makes it difficult to ensure that all the official controls are carried out and followed up in a satisfactory way. In one case where the official controls had been carried out by the CVS and CL together the reporting procedure was very complicated and slow:
 - The CVS was responsible for the report but had to wait for, and include, the findings from a separate report produced by the CL. The report was produced nearly two months after the inspection.
 - The FBO's action plan, that was received before the report was finalised, had to be sent from the CVS to the CL for comments before preparing the decision that was sent back to the FBO more than four months after the inspection.

Conclusions

The CA's performance was in general considered acceptable or good but with some individual weaknesses clearly identified. There is still room for improvement as regards the co-operation between the CL and the CVS, in particular in cantons where the services are not merged.

5.6 OFFICIAL CERTIFICATION

Legal requirements

Council Directive 96/93/EC lays down the general rules to be observed by third countries in issuing certificates required for exports to the EU according to the specific EU veterinary legislation.

The specific animal and public health and veterinary certification requirements for the introduction into the EU of animal casings from third countries are laid down in Decision 2003/779/EC. The specific veterinary certification requirements for the introduction into the EU of gelatine for human consumption and raw materials for the production of gelatine for human consumption are laid down in Regulation (EC) No 2074/2005.

The model document to accompany raw materials destined for the production of gelatine or collagen intended for human consumption is laid down in the Appendix to Annex III to Regulation (EC) No 853/2004.

Audit findings

The export certificates for bovine casings received in one casing establishment visited from Brazil and Argentina were checked by the FVO audit team. No shortcomings were identified in the certificates. All bovine casings received from an EU listed establishment in Brazil could be traced back to an EU listed establishment in Argentina (triangular trade).

In another casing establishment the FVO audit team found all the required documentation in relation to direct imports of ovine casings from Iran kept on file. Several imports had taken place during 2011 and 2012.

Consignments of salted casings received via traders or directly from casing establishments in EU Member States were accompanied by trade documents.

The export certificates for gelatine imported from several third countries were checked in one gelatine establishment visited. No shortcomings were identified in the export certificates kept on

file.

Raw materials for the production of gelatine in a gelatine processing establishment in an EU Member State were accompanied by trade documents in line with the model document in the Appendix to Annex III of Regulation (EC) No 853/2004. However, the weights indicated on the trade documents and the customs documents were in one establishment only estimates and the difference between this estimate and the actual weight of one consignment could vary more than five tonnes (e.g. 16 000 kg on trade document and customs document – actual weight only 10 960 kg) which raises questions on the reliability of this documentation.

Conclusion

No major shortcomings were identified in relation to the controls over imported products but inaccuracies were identified in relation to documentation accompanying raw materials for gelatine production in the EU.

6 OVERALL CONCLUSIONS

In general the legislation, and organisation and operation of the CAs provide satisfactory assurances that the provisions in the Agreement in the sectors evaluated can be met.

However, major shortcomings were identified in relation to the approval of some establishments and the effectiveness of the enforcement action taken due to very long time gaps between official controls (inspections), which in some cases could be up to three to seven years.

7 CLOSING MEETING

A closing meeting was held on 27 April 2012 with the CCAs, the SFVO and the FOPH. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCAs of the relevant time limits for production of the report and their response.

The representatives of the CCAs acknowledged the serious problems identified in relation to establishment approvals and inspection frequencies and ensured the FVO audit team that this would receive more attention in the future.

8 RECOMMENDATIONS

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

Nº.	Recommendation
1.	To ensure that information on official controls and enforcement actions are gathered by the Central Competent Authority from all the cantons in line with Article 36 of the Swiss Law on Foodstuffs (Lebensmittelgesetz, LMG) in order to verify the effectiveness of the official controls.

N°.	Recommendation
2.	To ensure that official controls are carried out with the frequencies established in accordance with Article 56 of the Swiss Ordinance on food and commodities (Lebensmittel und Gebrauchsgegenständeverordnung, LGV) and Article 54 of the Swiss Ordinance on slaughter and meat inspection (Verordnung über das Schlachten und die Fleischkontrolle, VSFK).
3.	To take appropriate action in cases where non-compliances are identified in order to ensure that the operator remedies the situation as required in Article 56 of the Swiss Ordinance on enforcement of food legislation (Verordnung des EDI über den Vollzug der Lebensmittelgesetzgebung). The follow-up action taken should be documented in order to allow the effectiveness of the enforcement to be verified.
4.	To ensure that all listed food businesses have a valid approval obtained in accordance with the requirements of Article 8 of the Swiss Ordinance on slaughter and meat inspection (VSFK) or Article 13 of the Swiss Ordinance on food and commodities (LGV) and relevant guidance documents.
5.	To ensure that identification markings on products are applied in accordance with the requirements in Article 30 of the Swiss Ordinance on Identification and Advertising of Foodstuffs (Verordnung des EDI über die Kennzeichnung und Anpreisung von Lebensmitteln, LKV).
6.	To ensure that the information included in trade documents in line with the model document in the Appendix to Annex III of Regulation (EC) No 853/2004 for raw materials for the production of gelatine within the European Union are correct and not misleading.

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=2012-6350

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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

Legal Reference	Official Journal	Title
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. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures 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
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
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
Dec. 2002/309/EC	OJ L 114, 30.4.2002, p. 1	Decision 2002/309/EC of the Council, and of the Commission as regards the Agreement on Scientific and Technological Cooperation, of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation - Agreement between the European Community and the Swiss Confederation on trade in agricultural products
Dec. 2003/779/EC	OJ L 285, 1.11.2003, p. 38-41	2003/779/EC: Commission Decision of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries

Legal Reference	Official Journal	Title
Dec. 2008/654/EC	OJ L 214, 9.8.2008, p. 56-65	2008/654/EC: Commission Decision of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council