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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SWITZERLAND

FROM 26 FEBRUARY TO 08 MARCH 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS PERTAINING TO FOOD SAFETY ASPECTS IN RELATION TO CERTAIN ANIMAL PRODUCTS (MEAT, MEAT PRODUCTS, MEAT PREPARATION AND MINCED MEAT - MAMMALIAN ORIGIN) 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 26 February to 8 March 2013. The objectives of the audit were to verify that the Swiss Confederation's 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 products (hereafter referred to as 'the Agreement') and in addition to evaluate the follow-up action taken by the Competent Authorities (CAs) in response to the recommendations made in report DG(SANCO)/2012-6350 and DG(SANCO)/2009-8217.

The structure and responsibilities of the CAs has changed slightly. Since 1 January 2013 the Swiss Federal Veterinary Office (SFVO), which was previously under the Federal Department of Economic Affairs, was moved to the Federal Department of Home Affairs. The SFVO and the Federal Office of Public Health (FOPH) are now under the same Ministry. It is foreseen that the Food Safety Division of the FOPH will merge with the SFVO on 1 January 2014. 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 actions as announced in response to the recommendations of the previous report (DG(SANCO)/2012-6350), are still in the process of implementation. Slow progress in harmonization-calibration-standardization of the implementation of the requirements was noted. The information at federal level on inspections and enforcement carried out by the cantons is still limited. The Federal Food Chain Unit (FFCU) audited the cantons with the exception of two which refused to be audited. The FFCU was able to detect shortcomings but it was up to the individual cantons to decide if they would react and take corrective action.

During the FVO audit a total of nine establishments were visited. The staff met was generally well motivated and knowledgeable. The actual procedure to calculate the frequency of controls is risk based and has been determined by the Swiss Cantonal Chemist Association in 2007. However, in the different cantons visited, the frequency, the scope and the duration of inspections in the establishments visited varied considerably. Despite a calculated frequency based on a risk evaluation of once every one or two years as a minimum for meat product establishments, it varied from annually up to five years. In one canton, not all the parameters (e.g. own-checks and Hazard Analysis Critical Control Points (HACCP)) to calculate the risk were evaluated during every inspection and a full inspection was only carried out during the five year approval inspection. Reports were drawn up after official controls and transmitted to the food business operators (FBOs), but varied considerably in structure, scope, level of details of findings and non-compliances.

Some problems were noted as regards the approvals. Official controls generally include verification of FBOs' compliance with good hygiene practice and 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. In general, a rather tolerant attitude was noted with FBOs and the CA in regard to the implementation of the labelling and identification requirements. Shortcomings were identified in four of the nine establishments visited. Traceability systems were in place in all the establishments visited and were, in most cases, found to be reliable.

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)
CL	Canton Food Safety Authority (<i>Kantonales Laboratorium, KL</i>)
CVS	Canton Veterinary Service (<i>Kantonales Veterinäramt, VET</i>)
DG(SANCO)	Health & Consumers Directorate General
EC	European Community(ies)
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 audit took place in Switzerland from 26 February to 8 March 2013 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 SFVO and the FOPH.

The opening meeting was held on 26 February 2013 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 objectives of the audit were to verify that the Swiss Confederation's 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 products ¹ and in addition to evaluate the follow-up action taken by the Competent Authorities in response to the recommendations made in report DG(SANCO)/2012-6350 and DG(SANCO)/2009-8217.

The scope of the audit was to review the structure and operation of control systems in the Swiss Confederation pertaining to the food safety aspect in relation to the production of animal products for human consumption in particular fresh meat, minced meat, meat preparations and meat products of mammal origin, in particular, bovine, ovine, porcine, equine.

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	4	Canton level / 2 offices visited
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Slaughterhouses		3	One large pig slaughterhouse, two very small (several species) of which one not in operation during visit
Meat processing establishments		6	Meat products, meat preparations
Cutting plant		2	Cutting Plants were integrated in meat processing plants

3 LEGAL BASIS

The audit was carried out under:

- The auspices of the Agreement and, in particular the Article 16 of Annex 11 on animal health and zoo-technical measures applicable to trade in live animals and animal products;
- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council

¹Hereafter referred to as: the Agreement

of 29 April of 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules."

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 a follow-up FVO audit in Switzerland 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, and in addition to evaluate the follow-up action taken by the CAs in response to the recommendations made in reports DG(SANCO)/2009-8217 and DG(SANCO)/2012-6350.

These reports are accessible at: http://ec.europa.eu/food/fvo/index_en.cfm

The action plan received from the Swiss authorities in response to both report's recommendations provided satisfactory guarantees in relation to all the recommendations.

Chapter 1 of Appendix 6 to Annex 11 to the Agreement establishes that EU and Swiss public health sanitary measures with respect to animal products intended for human consumption are equivalent subject to special conditions. Therefore, the scope of the audit is verified against the Swiss standards included in the Agreement, and the EU requirements included in the special conditions, relevant for each chapter. In addition, the corresponding EU requirements to Swiss standards are included as well for clarity and reference.

Recital 5 of Decision No 1/2008 of the Joint Veterinary Committee regarding the amendment of Appendices 2, 3, 4, 5, 6 and 10 to Annex 11 to the Agreement states that the Swiss Confederation has undertaken to incorporate into its national legislation the provisions of Regulation (EC) No 882/2004.

The specific requirements concerning beef labelling found in Regulations (EC) No 1760/2000 and No 1825/2000 are not part of the Agreement and not verified in particular during this audit.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION AND COMPETENT AUTHORITIES

Legal requirements

Chapter 1 of Appendix 6 to Annex 11 to the Agreement establishes that EU and Swiss public health sanitary measures with respect to animal products intended for human consumption are equivalent subject to special conditions. The legal requirements applicable to trade with the EU are the Swiss standards and special conditions specified in that Appendix.

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

- On the basis of the Agreement, Appendix 6, special conditions (6) of Annex 11, Switzerland may derogate from the *Trichinella* examination of carcasses and meat of domestic swine kept for fattening and slaughter in low-capacity establishments until 31 December 2009. The CCA confirmed that this derogation has been prolonged for an additional five years, until 31 December 2014. Furthermore, this meat and products thereof are not to be traded to Member States and must carry a special health stamp. As noted already in report DG(SANCO)/2008-7900, this health stamp is oval in shape and slightly smaller but easy to confuse with the one used in EU approved establishments (4.5 cm rather than 6.5 cm wide).
- The Agreement is in the process of being amended concerning the Regulation (EC) No 1099/2009 on the protection of animals at the time of killing. The requirements of this Regulation are already in force since the beginning of 2010 with some minor differences concerning the transitional periods.
- In response to recommendation no 1 of the previous report DG(SANCO)/2012-6350 (*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*) the CA informed the FVO that changes in the Food Law are under discussion in the Parliament concerning the frequencies of official controls in establishments and concerning the data management system of the Cantonal Food Safety Authorities to report on various topics to the FPOH. These changes in the Food Law are expected to enter into force in 2015. The actual Memorandum of Understanding will be replaced in this respect. (See also 5.2.3 Organisation of official controls).
- A draft to modify the "*Verordnung des EDI über Lebensmittel tierischer Herkunft*" concerning the labelling of frozen food is in preparation and its date of coming into force is foreseen for the end of 2013.

Conclusion

In general, in the areas covered by this audit, the Swiss legislation as referred to in the Agreement is implemented and legislation is in place to implement the special conditions set out in the Agreement. However, although the announced actions are in the process of implementation, the progress is slow.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 3 of Regulation (EC) No 882/2004 lays down general obligations with regard to the organisation of official controls.

Article 4 of the Regulation lays down operational criteria for the CAs.

Article 6 of the Regulation requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

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 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.

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.

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 is the main Swiss legislation regarding the organisation of the official controls and public health sanitary measures.
- The requirements concerning professional qualifications for officials involved in controls of the sectors concerned are laid down in specific Swiss legislation.
- 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 into account all the relevant criteria listed. 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.
- The LMG has in Chapter 7 clear provisions for penalties regarding infringements of food legislation.

5.2.1 *Designation of Competent Authorities and operational criteria*

Description based on information provided by the CA.

The structure and responsibilities of the CAs as described in the FVO audit report DG(SANCO)/2009-8217 and 2012-6350 has changed slightly. Since 1 January 2013 the SFVO, which was previously under the Federal Department of Economic Affairs was moved to the Federal Department of Home Affairs. The SFVO and the FOPH are now under the same Ministry. It is foreseen that the Food Safety Division of the FOPH will merge with the SFVO on 1 January 2014.

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, including retail. Risk assessment and risk management is also under the FOPH.

The Federal Food Chain Unit (FFCU) under the strategic lead of the Directors of 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. During 2008-2010 all cantons have been audited concerning the approval of dairy and meat establishments.

- However some cantons did not give full assistance to the FFCU for performing the audits. Reports including recommendations were drafted. The cantons demonstrate some reluctance with the concept of federal audits, in particular, in regard to the enforcement of the recommendations.
- A follow-up programme with only paper based verification, is foreseen to start in August 2013. In addition, audits concerning animal welfare, border inspection posts, feed and animal health have been carried out during 2008 and 2013.
- A general report was drafted in order to develop a Multi Annual Risk Based Audit plan (2015-2019). However, some of the information presented, based on data provided by the cantons, does not allow conclusive analysis to be made.

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. In cantons where 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 the CL.

In response to recommendation no 1 of the previous audit report DG(SANCO)2012-6350 (*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*) the CA informed the FVO that the FOPH is developing a data management system for the cantonal food safety authorities (CL) to report on various topics to the FOPH. The cantons are bound by the Memorandum of Understanding to provide the data concerning the topics. It is expected that cantons will be able to provide complete data on the 18 topics from 2013. The Memorandum of Understanding will be replaced by a specific Article in the new Food Act, which is before Parliament and is expected to enter into force in 2015.

Audit findings

- The CAs were clearly designated for the areas covered by this audit as foreseen in the Agreement.
- The organisation of the CAs at cantonal level varied considerably between the cantons visited. Generally, slaughter and primary production is under the control of the CVS. In the four cantons visited the two inspection services were operating as different Units acting under the Cantonal Office responsible for Food Control. A clear separation still existed between the responsibilities of both Departments and the implementation of the official controls. As a result, two officials from the two different Departments visit the same plants (eg. a meat product plant with integrated cutting plant). In another canton, the approval conditions and obligations of the FBOs (the structural and own checks) were checked by an official of the “*Lebensmittelsicherheit*” and, in addition, in the small slaughterhouses the veterinary controls were checked by an official veterinarian (OV) from “*Veterinärdienst*”. Considering the difficulties of accessibility of the establishments in the different valleys and travel time spent, resources are not optimised. (Also relevant for 5.2.3.)
- The power of the federal authorities to co-ordinate and to direct the implementation of the requirements by the cantons is very limited. In order to overcome this lacuna, to improve the harmonization and to co-ordinate the controls in the cantons, the Association of the Swiss Cantonal Chemists “*Verband der Kantonschemiker der Schweiz*” has created two working groups with representatives of the cantons and, for the first time, also with the Food Safety Division of the FOPH. The outcome of these working groups, however, has no legal binding value until such time as the Food Act is amended.
- The first working group on “inspection” is trying to find a common position ensuring consistent performance, and is developing a document that can be used by the CA to draft a New Ordinance on Official Controls. It was the continuation of the previous work by this Association that had led to the elaboration of a document “Concept to determine the risk of a food plant” and that is, for the time, being used as a basis to determine the frequencies of supervision in food establishments, including establishments covered by the scope of this audit in the cantons. There is not yet an agreement on the new text.
- The second working group “products control” has been created to suggest and determine national campaigns to be carried out by the cantons (in and on borders) and to manage the data.
- 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. Changes in the Food Act (LMG) to strengthen the legal basis concerning the frequencies of official controls in establishments and for gathering information on the data management system of the Cantonal Food Safety Authorities to report on various topics to the FOPH are under discussion in the Parliament.

- The project concerning data gathering and harmonization, as already described in the previous report is on-going but progress is slow and the system is not yet fully operational. At present the information available at federal level in this regard is very limited, which can also explain why the MANCP 2011 contains very limited or not very specific information on these topics, as indicated previously.

Conclusion

The CAs were clearly designated for the official controls covered by this audit. The actions to implement the CA response to the recommendations of the previous report concerning procedures to ensure corrective action and the updating of documentation have not yet been completed. The food law has not yet been amended with the effect that there is insufficient feed back to federal level on inspections and enforcement activities performed by the cantons. While a functioning audit system has been put in place, there is no means of guaranteeing that the individual cantons react and take appropriate corrective actions.

5.2.2 Staff performing official controls

Audit findings

- It is foreseen in Article 5 of the *Bildungsverordnung* SR916.402. that a private veterinarian can be appointed to carry out specific veterinary controls without having succeeded the complete education as OV.
- The appointment of veterinarians in the cantons with the exception of two is now done by the cantonal administrations and no longer by the municipalities, to avoid a conflict of interest. The FVO audit team did not come across any situation where a possible conflict of interest was identified.
- Some staff met had diplomas as a food controller or as a food inspector as well as being an OV and were therefore in theory allowed to work across the sectors.
- Staffing numbers at federal level remain virtually unchanged. It was explained to the FVO audit team in the cantons where the inspection frequencies had not been met that this was mainly due to a lack of staff resources or that the priorities in the canton were requesting the deployment of the staff differently.
- 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.

Training:

- 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 of the participation of the staff concerned.

- The Swiss Cantonal Chemist Association organise a two day training course per year for all four regions. In 2012 it covered “meat and meat preparations”, for 2013 “Internet Trade” is scheduled.
- In 2010 the federal level BVET and the FOPH organised training on controls in cutting plants.

Conclusion

Official staff met were generally well motivated and knowledgeable, free of any conflict of interest 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

Audit findings

In response to recommendation no 2 of the previous audit report DG(SANCO)/2012-6350 (*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)*) the CA informed the FVO that the federal authorities and cantonal food safety authorities (CL) have jointly established minimum frequencies for the different categories of establishments which were expected to be published as a recommendation by the end of 2012. The CCA explained that all CLs have been accredited in accordance with Article 62 of the LGV. However, approximately 10 of the CVSs have not yet been accredited.

- The check-lists, report templates and working instructions used during inspections were prepared at the cantonal level and varied considerably.
- Reports were drawn up after official controls and copies were provided to the FBOs but also varied considerably: very structured, covering the correct scope, detailed description of findings and non-compliances, versus one line: nothing to mention.
- The actual procedure to calculate the frequency of controls in meat processing plants is risk based and has been determined by the Swiss Cantonal Chemist Association “*Verband der Kantonschemiker der Schweiz*” in 2007. Changes in the Food Act (LMG) to strengthen the legal basis concerning the frequencies of official controls in establishments are under discussion in the Parliament. (See also Findings 5.2.1).
- However, in the different cantons visited, the frequency, the scope and the duration of inspections in the establishments visited varied considerably. Despite a calculated frequency based on a risk evaluation of once every one or two years as a minimum for meat product establishments, it was not followed and varied from annual up to five years. For the slaughterhouses the frequency was annual with an inspection occasionally missing. In one canton, not all the parameters (e.g. own-checks and HACCP) to calculate the risk were evaluated during every inspection and a full inspection was only carried out during the five year approval inspection.
 - Re-evaluation of the risks is carried out based on the findings in different categories, however, in one canton visited only some of these categories were evaluated during every inspection, and only a full inspection was carried out during the five year approval inspection. Therefore the procedure for risk evaluation was not followed.
 - In one canton the calculated frequencies were not followed because other priorities in

the canton prevailed .

- Considering the fact that the official of the “*Lebensmittelsicherheit*” was inspecting the slaughterhouse when not in operation, it limited the possibilities to evaluate correctly the operational conditions.
- See also point 5.2.1 Findings second bullet point concerning the organisation of the CAs
- The FFCU have noted in their audits that the set frequencies of inspection were not met in individual cantons. The FVO audit team was not informed that this triggered any changes by the cantons in this respect.

Conclusion

Official controls performed by the cantons were effective, particularly in relation to ensuring impartiality, consistency and quality. However, the frequencies, the scope of the inspections and reporting varied considerably between individual cantons and, in several cases, the risk-based inspection frequencies had not been respected, weakening the efficiency of the official controls.

5.2.4 Enforcement measures

Audit findings

In response to recommendation no 3 of the previous audit report DG(SANCO/2012-6350 (*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) the CA informed the FVO that the federal authorities would request the cantonal authorities in writing to carry out and report on the follow-up checks in cases where considerable shortcomings were noted. In order to have a clear and systematic overview of the outstanding follow-up checks of cantonal veterinary offices and to improve supervision, plans are being made for follow-up checks to be included in the veterinary service’s existing data management system. The cantons have received the above-mentioned request.

- Overall, limited evidence was seen as regards the enforcement in the cantons/establishments visited. Follow-up of deficiencies identified was in some cases not documented or was done during the next inspection which could be years later. One of the cantons visited could demonstrate a system that keeps track of outstanding follow-up checks and results of inspections carried out. No such system was in place in the other cantons visited.
- All cantons can impose administrative fees if shortcomings are noted. They are also able to impose fines or even to launch criminal proceedings. In 2 cantons visited it was shown that this tool was used when needed. During one of the audits an administrative fine was given.

Conclusion

While action has been taken to improve enforcement and follow-up activities, this has not been uniformly effective and, as a consequence, recommendation 3 of the previous report has not been fully addressed.

5.3 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS LEGAL REQUIREMENTS

Legal requirements

Special conditions

Chapter 1 of Appendix 6 to the Agreement requires Switzerland, as special condition (2), 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 provides 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

In response to recommendation no 4 of the previous audit report (DG(SANCO)/2012-6350 (*To ensure that all listed food business have a valid approval obtained with the requirements of Article 8 of the Swiss Ordinance on slaughter and meat inspection (VSFK) or Article 13 of the of the Swiss Ordinance on food and commodities (LGV) and relevant documents*) the CCA informed the FVO that the cantons would be reminded in writing about the obligations concerning approval and to renew the approvals issued before January 2006 by the end of 2012 and to provide them with the data to up-date the BVET website before the end of 2012 and that the guidelines would be brought into line before the end of 2012. The guidelines concerning Article 13 for approval were updated on 2 December 2012 and lay down at federal level what an approval document should contain.

- The cantons were informed about the obligations concerning approval and invited to provide the data to update the database on the BVET website before the end of 2012. In one canton visited, the CA did not react to the request of the CCA in September 2012 to verify and to update the activities covered by the approvals.
- Some deficiencies in regard to the approval were noted:
 - In one case, a cold store adjacent to a meat product establishment, but storing also for third parties, operated without specific approval. The hygienic conditions were verified during the inspection of the meat product establishment.
 - An establishment used only for intermediate ripening of fermented sausages produced in another establishment, located in a cellar of a medieval castle open to the public, was approved without fulfilling the requirements. The operator had started these activities without informing the CA. A similar case occurred with a cottage in the Alps where dried hams were ripened.
 - In one establishment the re-approval did not cover the production of cooked ham.
- A FBO, registered as a “butcher” supplied the greater part of his production of “*Bundenfleisch*” and sausages to 30 different retailers throughout Switzerland. The FVO audit team was informed that Articles 12 and 13 of the LGV allows it to have this kind of business without an approval and is as a consequence more tolerant than the derogation included in Article 1 of Regulation (EC) No 853/2004 where no approval is required if the supply is, in accordance with national law, a marginal, localised and restricted activity of a retail establishment that mainly supplies the final consumer. In that event, only Regulation (EC) No 852/2004 applies. These conditions are however not fulfilled.

Conclusion

Despite the corrective actions taken by the CCA, deficiencies remain in the implementation of approval procedures and, as a consequence, recommendation 4 of the previous report has not been fully addressed.

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 establishes 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 Food Chain Information 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

Note: *Due to time constraints during this FVO audit, the CAs were not always able to carry out a full inspection in the meat establishments and slaughterhouses.*

Structures, cleaning and maintenance were in general of a high standard.

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

- Although the infrastructure was good, unhygienic slaughter with extensive contamination of the bovine carcass took place in a very small slaughterhouse.
- Sterilizers were not operating above 82°C. In one slaughterhouse, the slaughter took place without any functioning equipment to allow sterilization.
- Presence of dirty crates, kept in reception area for several days.
- In a big slaughterhouse for pigs:
 - meat from the bleeding point not removed from pig carcasses and declared fit for human consumption;
 - insufficient de-hairing;
 - condensation dripping on exposed product;

- establishment not fully pest proof.

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 system

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.

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-based own control systems were in place, however not always checked during the controls and only a few shortcomings had been identified by the CA. The following observations were made by the FVO audit team:

- In one canton, the obligation to consider the HACCP based system in all establishments as part of the approval conditions will not be controlled before the expiry date of the validity of the existing approvals in 2015.
- In another canton, if during the initial evaluation of the HACCP based system it was considered as satisfactory, it is no longer included in the routine inspections and as a consequence it would be evaluated only during the five year full inspection.
- The HACCP based systems of three establishments were centralised in the parent company. However the verification was not included in the on-site inspection in these other two establishments, missing the opportunity to cross-check records with the on-site situation.
- In the establishments visited, where the HACCP plan was verified, systems were well designed and controlled and no major deficiencies were identified.
- Some weaknesses identified by the FVO audit team: In two establishments visited, the risk assessment of some products did not consider deviations from the described production flows and processing conditions. In practice intermediate products were not used as described and stored for longer periods. The documentation describing a cooking procedure was not amended.
- Microbiological testing:
 - Microbiological criteria contained in Regulation (EC) No 2073/2005 are in general complied with. However Swiss legislation foresees in a derogation that the FBO might apply reduced frequencies when there is a production of less than 500 kg of meat products per week.
- Carcass testing was carried out in the pig slaughterhouse with satisfactory results.
 - In one canton, in order to assist the FBOs in small slaughterhouses, it was decided that the carcass testing and swabs of contact surfaces are done by the OV for a small fee.

Conclusion

HACCP-based own control systems in line with the requirements of Article 23 of the LMG and in

Chapter 5, Sections 1 of the LGV 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. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

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 23 a 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

In response to recommendation no 5 of the previous audit report DG(SANCO)/2012-6350 (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*) the CCA informed the FVO that the cantons would be reminded in writing about the obligations concerning identification and labelling.

The CCA reminded the cantons in writing about the obligations concerning identification and labelling as announced.

In general, most of the products were correctly labelled. The following shortcomings were identified by the FVO team:

- In several establishments, some plastic crates or pallets with fresh meat were not correctly labelled.
- In two establishments, health marks were not legible or were missing on carcasses; for some large pieces of meat there were no mechanisms in place to ensure that this meat could be traced.
- A barrel with salted casings without an identification number.

The FBOs had established traceability systems, which could in general identify from whom they have been supplied and the other businesses to which their products have been supplied, and which are subject to verification during official controls and in most cases found to be reliable. However, in one meat processing plant traceability could not be fully guaranteed. The documentation of the in and out-going meat/meat products was not coherent.

Conclusion

Traceability systems were in place in the establishments visited and in most cases found to be

reliable. Identification marking and labelling of products were in most cases done in a satisfactory way. However, the FBO and the CA paid insufficient attention to the implementation of the labelling requirements.

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 hygiene rules 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*).

Ordinance of 23 April 2006 (TSchV, RS 455.1), as last amended on 9 May 2012.

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. 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 some of the shortcomings identified.
- The ante and post-mortem inspections in the two slaughterhouses visited were performed correctly by auxiliary meat inspectors and the OV.
- The provisions for food chain information are included in Articles 22-24 of the Swiss Ordinance on Slaughter and Meat Inspection (817.190). The system as demonstrated complied with the Swiss standards. The food chain information was verified by the OVs in the slaughterhouses visited.
- Equivalent provisions for the requirements of Regulation (EC) No 1099/2009 on the protection of animals at the time of slaughter is already in force since the beginning of 2010. The stunning equipment was well maintained and spare instruments were available in all slaughterhouses visited. Pigs and bovines were sufficiently stunned in the slaughterhouses visited and the process was regularly controlled by the FBO and the OV as required by Swiss legislation. However the FBO's procedures to verify the efficiency of the CO stunning allowed up to 25% deficiencies before action was required. In addition, the FVO audit team

identified a pig unable to walk and another with obvious clinical signs of illness. Neither the FBO nor the OV had identified these situations and no action had been taken.

- 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. The reports seen did not contain remarks from the OV concerning labelling and identification marking (see also 5.4.3).
- In one slaughterhouse visited, the OV responsible for the slaughter hygiene, ante-mortem, post-mortem and the cantonal supervisor did not demonstrate the expected knowledge and judgement concerning the slaughter hygiene and no immediate action was taken to address the hygienic deficiencies once pointed out by the FVO audit team.

Conclusions

The CA's performance was in general considered acceptable or good but with some individual weaknesses clearly identified, in particular in regard to the identification marking and animal welfare.

6 OVERALL CONCLUSION

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. The actions as announced in response to the recommendations of the previous report, are still in the process of implementation. Slow progress in the harmonization-calibration-standardization of the implementation of the requirements was noted, however not all of the recommendations from the previous audit have been fully addressed yet.

The establishments visited were in general compliant with the requirements.

However, shortcomings were identified in relation to the approval of some establishments, the inspection frequencies, labelling and traceability.

7 CLOSING MEETING

A closing meeting was held on 8 March 2013 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 problems identified in relation to establishment approvals and inspection frequencies.

8 RECOMMENDATIONS

The following recommendations are made to the CA of Switzerland and 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 one month of receipt of the report.

N°.	Recommendation
1.	To take appropriate action 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 that the effectiveness of the official controls are continued and finalised more timely.
2.	To ensure that the actions in the process of implementation are taken more timely in order 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 by 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 action be verified.
4.	To ensure that all listed food businesses in all cantons have a valid approval obtained in accordance with the requirements of Article 31 of Regulation (EC) 882/2004 and comply with the relevant Swiss requirements as quoted in Chapter I, appendix 6 of Annex 11 to the Agreement.
5.	To ensure that identification markings on products are applied in accordance with the requirements of Article 30 of the Swiss Ordinance on Identification and Advertising of Foodstuffs (Verordnung des EDI über die Kennzeichnung und Anpreisung von Lebensmitteln, LKV).
6.	In relation to internal or external audits carried out in accordance with Article 4 (6) of Regulation (EC) No 882/2004, to take appropriate measures in the light of their results, in all cantons, so as to ensure that they are achieving the objectives of this Regulation.

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=2013-6887

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 1825/2000	OJ L 216, 26.8.2000, p. 8-12	Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
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. 1099/2009	OJ L 303, 18.11.2009, p. 1-30	Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
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