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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SWITZERLAND

FROM 15 TO 25 OCTOBER 2013

IN ORDER TO EVALUATE THE FOOD SAFETY CONTROL SYSTEM IN RELATION TO  
RAW MILK AND DAIRY PRODUCTS UNDER THE AUSPICES OF THE AGREEMENT  
BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON  
TRADE IN AGRICULTURE 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 15 to 25 October 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 II 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)/2009-8217 (hereafter referred to as report 2009-8217).*

*The Swiss legal framework for the controls of raw milk and dairy products destined for human consumption is recognised as equivalent to European Union (EU) legislation and only minor differences exist when compared to EU legislation. The CAs are clearly designated for the official controls over milk and dairy products. The official staff met were generally qualified and motivated and training has been provided as necessary. While a functioning audit system has been put in place, the follow-up is weakened as the cantons are not legally bound to follow the recommendations and to take appropriate corrective actions. The official controls carried out by the cantonal authorities were generally effective and the performance of the CAs in relation to controls of dairy establishments and collection centres was in general satisfactory. However, the time allocated for the inspection and documentary checks was not always sufficient and the inspectors had not picked up some significant shortcomings observed by the FVO audit team. Although evidence of the use of enforcement tools was available in the cantons visited, in relation to one establishment visited, the enforcement action taken had been poor. However, the CA took immediate action and the approval of the food business operator (FBO) was withdrawn. Whilst evidence on official sampling of milk and dairy products by the Canton Food Safety Authority (CL) visited was available, in the establishments visited the frequency was low. Furthermore, the CCA do not have an overview of the situation at national level and lack a specific legal basis for national surveillance programmes.*

*Although the CAs had addressed the recommendations of the report 2009-8217 not all cantons have followed the instructions received from the CCA and the FVO audit team noted some shortcomings in relation to the approvals of three out of eight establishments visited. One of the FBOs visited, a major exporter of milk product for human consumption to the EU, was processing raw milk rejected by other dairies as raw material for feedstuffs for another FBO without an approval for such an activity.*

*Seven of the eight establishments visited largely complied with the Swiss standards for general and specific hygiene requirements and Hazard Analysis Critical Control Points (HACCP)-based procedures were in place in all except one FBO visited. However the FVO audit team noted some significant shortcomings that had not been picked up by the CAs. The documentation available on testing of potable water in the establishments visited was in most cases limited to microbiological parameters only. The microbiological testing carried out by the FBOs was in line with most aspects of the Swiss requirements and the results seen were in most cases satisfactory. However, some shortcomings were noted. In general, traceability systems were in place that were in line with Swiss requirements. The requirements for animal by-products (ABP) were largely complied with, with the exception of shortcomings concerning the application of the labelling requirements for ABPs. The quality control system for bovine raw milk is well established and functions adequately. However, no formal control system has been established for raw milk of other species and the FVO audit team noted shortcomings in relation of testing of raw goat milk for Total Bacterial Count (TBC) and antibiotic residues.*

*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

<b>Abbreviation</b>	<b>Explanation</b>
ABP	Animal by-products
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)
CFU	Colony Forming Units
CL	Canton Food Safety Authority ( <i>Kantonales Laboratorium</i> )
CVS	Canton Veterinary Service ( <i>Kantonales Veterinäramt</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</i> )
FOPH	Federal Office of Public Health ( <i>Bundesamt für Gesundheit</i> )
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
MANCP	Multi-Annual Critical Control Plan
OV(s)	Official Veterinarian(s)
SCC	Somatic Cell Count
SFVO	Swiss Federal Veterinary Office ( <i>Bundesamt für Veterinärwesen</i> )
TBC	Total Bacterial Count (Plate count at 30°C)
TPC	Total Plate Count

## 1 INTRODUCTION

The audit took place in Switzerland from 15 to 25 October 2013 as part of the planned audit programme of the FVO. The FVO audit team comprised three auditors from the FVO. The FVO audit team was accompanied throughout the audit by representatives from the Central Competent Authorities (CCAs), the Swiss Federal Veterinary Office (SFVO), the Federal Office of Public Health (FOPH) or the Federal Food Chain Unit (FFCU).

The opening meeting was held on 15 October 2013 in Bern with the CCAs and one of the cantonal authorities to be visited. 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, and in addition to evaluate the follow-up action taken by the CAs in response to the recommendations made in report 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 milk and dairy products.

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	5	Canton level/ 1 office visited
FOOD PRODUCTION/PROCESSING/DISTRIBUTION – ACTIVITIES			
Dairy establishments		7	The establishments visited were located in 5 cantons (Bern, Fribourg, Solothurn, Zug and "Urkantone" (Uri and Nidwalden)
Milk collection centres		1	
Dairy Holdings		2	Bovine holdings
Laboratory		1	Raw milk laboratory

## 3 LEGAL BASIS

The audit was carried out under the auspices of the Agreement between the European Community and the Swiss Confederation on trade on agricultural products and, in particular its Article 16 of Annex 11 on animal health and zootechnical measures applicable to trade in live animals and animal products, adopted by Council and Commission Decision 2002/309/EC (hereafter referred to as the Agreement).

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 milk and dairy products for human consumption 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 the report 2009-8217.

This report is accessible at: [http://ec.europa.eu/food/fvo/index\\_en.cfm](http://ec.europa.eu/food/fvo/index_en.cfm).

The action plan received from the Swiss authorities in response to the report's recommendations provided satisfactory guarantees in relation to six of the nine recommendations and was considered as overall satisfactory. The follow-up of the eight recommendations relevant for the controls on raw milk and dairy products is included in the respective chapters of the report.

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 was verified against the Swiss standards included in the Agreement, and the EU requirements included in the special conditions, relevant for the respective chapters. In addition, the corresponding EU requirements to Swiss standards are also included 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.

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 LEGISLATION**

#### **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 the Appendix.

The main Swiss standards in relation to animal health are the Law on Epizootic Diseases (916.40) and Ordinance on Epizootic Diseases (916.401).

The main Swiss standards in relation to public health sanitary requirements are the Federal Act on Foodstuffs and Consumer Products (Food Law, 817.0) and the Federal Ordinance on Foodstuffs and Consumer Products (Food Ordinance, 817.02) and the Ordinance on the Implementation of Foodstuffs Legislation (817.025.21).

The main legislation in relation to milk and dairy products and controls thereof comprises the

following:

- Ordinance on Hygiene ( 817.024.1);
- Ordinance on Food of Animal Origin (817.022.108);
- Ordinance on Primary Production (916.020);
- Ordinance on Hygiene in Primary Production (916.020.1);
- Ordinance on Hygiene in Milk Production (916.351.021.1);
- Ordinance on Hygiene in Alpine Premises (817.024.2);
- Enforcement Ordinance in Relation to Food Legislation (817.025.21);
- Swiss Ordinance on Labelling and Advertising of Foodstuffs (817.022.21);
- Ordinance of Co-ordination of Controls on Agricultural Holdings (910.15);
- Milk Testing Ordinance ( 916.351.0);
- Ordinance on Veterinary Drugs ( 812.212.27);
- Ordinance on the Qualification, Further Training and Continuing Education (916.402); and
- Ordinance on the Education and Examination of Staff Responsible for the Implementation of the Food Legislation (817.042).

### Special Conditions

According to Annex 11 to the Agreement, Appendix 6, Chapter I, Special Condition (1) 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.

According to Annex 11 to the Agreement, Appendix 6, Chapter I, Special Conditions (8) in application of the provisions of Article 2 of the Ordinance on Hygiene (817.024.1) the Swiss CAs may in particular cases allow adjustments to Articles 8,10 and 14 of the Ordinance (a) to meet the needs of establishments situated in mountainous regions (b) for the production of foods with traditional characteristics. The Swiss CA undertake to notify the Commission by written procedure of such adjustments.

### **Findings**

The FVO audit team received a comprehensive package on the relevant legislation, guidelines and instructions related to animal health and public health requirements over milk and dairy products.

The CCA informed the FVO audit team that the draft Food Law is still being discussed in the Parliament. The draft law, once passed through the Parliament, will, among others, provide the

central authorities with more power in relation to co-ordination and control of the cantons. It will in addition, strengthen the legal basis concerning the frequencies of official controls in establishments and introduce the precautionary principle.

The Ordinance on Hygiene in Alpine Premises lays down the requirements for hygienic milk processing in alpine premises. It includes structural derogations for natural caves and storage rooms and allows the use of wood on surfaces and shelves. It is also possible to process milk in rooms that are used for cooking and eating, provided there is a separation in time. Milk can also be heated up in a traditional way over the open fire. Milk has to be cooled within 2 hours after milking to 8°C. However, milk for processing into cheese can be stored at up to 18°C. In this case it has to be processed within 24 hours.

The FVO audit team noted the use of wooden shelves and copper vats in some of the establishments processing cheeses. These establishments were not considered as alpine premises. The CCA stated that the use of copper and wood was generally accepted and did not require a general or specific derogation.

## **Conclusion**

The Swiss legal framework for the controls of raw milk and dairy products destined for human consumption is recognised as equivalent to EU legislation and only minor differences exist when compared to EU legislation.

### **5.2 COMPETENT AUTHORITIES**

#### **Legal requirements**

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.

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. The CAs have 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 official controls are free of any conflict of interest. Article 5 of the Regulation lays down the requirements for delegation of specific tasks related to control bodies. 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 the CAs 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 the competent authorities 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 CAs which identify 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 Food Law is the main Swiss legislation regarding the organisation of the official controls and public health sanitary measures. The main requirements concerning professional qualifications for officials involved in controls are laid down in Article 63 of the Food Ordinance. Articles 24 and 25 of the Food Law provide the legal basis regarding the right of entry into food premises during official controls and requires that the FBOs shall assist the officials. The Food Law has in addition requirements regarding transparency as well as confidentiality in Articles 12, 42 and 43. Article 36 of the Law provides the legal basis for gathering information from the cantons on the official controls carried out and on enforcement actions.

The Ordinance of Co-ordination of Controls on Agricultural Holdings (910.15) lays down rules in relation to using control bodies for specific control tasks on agricultural holdings.

Article 56 of the Food Ordinance lays down the requirements for regulation and risk-based official controls and lists the relevant criteria to be taken into account. Article 62 of the Ordinance requires that official laboratories and private laboratories authorised to carry out official analysis must be accredited according to ISO/IEC 17025. Official inspection bodies have to be accredited under ISO 17020.

Chapter 7 of the Food Law comprises clear provisions for penalties regarding infringements of food legislation.

#### *5.2.1 Designation of Competent Authorities and operational criteria*

The structure and responsibilities of the CAs are described in the FVO audit report DG(SANC0)/2013-6887. It is foreseen that the two main central CAs responsible for the controls over the dairy sector, namely the Food Safety Division of the FOPH and the SFVO will merge 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: [www.mancp.ch](http://www.mancp.ch). Attached to the MANCP are the cantonal profiles which provide further data on the organisation of the individual cantons. 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 the cantons, the Canton Food Safety Authorities (CLs) represent the Food Safety Division of the FOPH and the Cantonal Veterinary Services (CVS) the SFVO. In some cantons these services are merged.

### **Audit findings**

In its response to recommendation no 1 of the report 2009-8217 (*The CCA should continue in their efforts to improve the monitoring and knowledge how the cantonal authorities are executing their supervisory and enforcement tasks, as foreseen by Article 36 of the Food and Consumer Products Law and Article 60 of the Food and Consumer Products Ordinance*) the CCA committed themselves to carry out audits of the cantonal enforcement authorities. A follow-up audit was planned for 2012.

In 2010 the FFCU carried out an audit round in all cantons on the implementation of legislation in the field of inspection and approval of meat and dairy establishments. The audits resulted in reports including recommendations. The CCA has analysed the action plans received. However, not all cantonal authorities had followed the recommendations. Evidence was available that the FFCU had carried out the audits on the approval and inspection of dairy and meat establishments in 2008-2010. The FFCU had also carried out audits on other topics in 2008-2012 concerning animal welfare, border inspection posts, animal health and feed. In the cantonal office visited, the CL staff could demonstrate that they had taken actions to follow the recommendations. The FFCU's audit plan no 5 planned for September 2013-May 2014 comprises follow-up audits of the previous "inspection and approval round".

At CCA level, evidence was available of co-ordination meetings between and within the services. Minutes of meetings between and within the services were available and the dairy topic was also discussed (for example, the test methods and results of raw milk for inhibitory substances were discussed during one meeting of the standing committee of food safety in 2012). The Cantonal Veterinary Offices organise conferences two to three times per year. Several steering groups exist, comprising staff of the central and cantonal authorities. There are four standing committees (animal health, animal welfare, food safety and veterinary medicinal products). The members of the Committees comprise staff of the SFVO and representatives from each cantonal region. The Cantonal Chemists organise conferences four times annually and the federal level also takes part.

Meetings between the FOPH and the SFVO are organised on an *ad-hoc* basis when the need arises.

The cantons have a Memorandum of Understanding to provide the FOPH with information on official controls. However, the Memorandum is not binding.

In addition to the CCA's office, the FVO audit team visited five cantons, including the cantonal authority office in one of the cantons. In this canton, controls on dairy holdings had been contracted to three external control bodies. The FVO audit team could verify that the national rules in relation to control bodies had been respected (three year contracts between the CA and the control bodies were available), the control bodies were accredited and independent, and the staff had to be trained and knowledgeable, and the control bodies have to report to the CAs about shortcomings detected. Evidence was available that the CAs had accompanied staff of the controls bodies during their inspections. However, the national legislation does not require CAs to carry out direct audits of the control bodies.

## **Observations**

The CCA are currently not receiving information from all cantons in relation to official controls carried out. For example, no information is available at central level in relation to official microbiological sampling and testing programmes of the cantons.

### *5.2.2 Staff performing official controls*

## **Findings**

In response to recommendation 2 (*The CCAs should take further measures in order to ensure that there are adequate staff resources in place at Federal level, in order to comply with the above (see recommendation no 1)*) the CCA stated in their action plan that they are aware of the resources problem and are working on it. High priority will be given to the follow-up-audits by the SFVO and

the FFCU.

In response to recommendation no 4 of the report 2009-8217 (*To increase their efforts to provide adequate training to improve the performance of the inspectors of the CLs over industrial processing establishments as foreseen in Article 41 of the Food and Consumer Products Law (817.0)*) the CCA stated that the FOPH would organise training for the cantonal enforcement authorities.

Evidence of training provided by the SFVO and the FOPH was seen at the central and cantonal levels. The SFVO has an annual training programme. The FOPH provided the FVO audit team with information on training activities carried out and evidence of staff participation.

The staff numbers at federal level has remained the same. In one canton visited there had been a slight increase in staff in recent years. The FVO audit team did not note any staff shortage in relation to the controls of the establishments and holdings visited.

The staff met by the FVO audit team were in general qualified and competent. Some of the staff met were official veterinarians (OVs), some had qualifications as official controllers or food inspectors and some had, in addition, the qualification of cheese master (*Käsemeister*). The inspectors met had participated in various training sessions (for example, Better Training for Safer Food courses, courses on HACCP and training organised by the cantonal authorities on milk and dairy products).

### 5.2.3 Organisation of official controls

## Findings

In response to recommendation no 3 of the report 2009-8217 (*The CAs should ensure that the planned inspection frequencies of inspections are met as foreseen in Article 56 of The Food and Consumer Products Ordinance*) the CCA stated that they have produced the technical basis for risk based-checks that will lead to standardised inspection frequencies.

The current procedure to calculate the frequency of controls in dairy establishments is risk based and was determined by the Swiss Cantonal Chemist Association in 2007. This guideline document should be replaced by a new guideline by the end of 2013 at the latest. The new guideline comprises minimum inspection frequencies for different categories of food establishments that have been established jointly by the federal authorities and cantonal food safety authorities of establishments. The FVO audit team received the latest version of the draft guideline that was published in March 2013. However, even the new guideline is not legally binding but a guidance document.

The CCA stated that all CLs have been accredited in accordance with Article 62 of the Food Ordinance. All CVS are accredited.

Evidence of internal audits carried out by the FFCU was available.

## Observations

In the cantons visited the CAs had used the risk-based procedure of 2007 to establish the inspection frequencies. All establishments visited had been subject to risk assessment and were inspected with the inspection frequencies based on the risk assessment.

Although the procedure takes into account relevant factors in determining the frequencies, in practice the scoring system and the resulting inspection frequency does not always work adequately (the numerous significant shortcomings in a small dairy visited did not raise the inspection frequency (inspected once in every two years)).

The FVO audit team noted that the time dedicated to the audits of the dairy establishments visited rarely exceeded three hours. The time allocated to the audits does not allow a thorough audit of the whole establishment and all relevant documentation. This is reflected by the finding that the FVO audit team noted several shortcomings in the establishments visited that the CA responsible for the controls were unaware of.

#### 5.2.4 *Enforcement measures*

##### **Audit findings**

In response to recommendation 1 of the report 2009-8217 (*The CCA should continue in their efforts to improve the monitoring and knowledge how the cantonal authorities are executing their supervisory and enforcement tasks, as foreseen by Article 36 of the Food and Consumer Products Law and Article 60 of the Food and Consumer Products Ordinance*) the CCA stated that the FFCU Unit carries out audits of the cantonal enforcement authorities.

Evidence was available in the cantons visited that enforcement measures had been taken. The Swiss legislation provides for different levels of enforcement, namely oral advice, written warning, orders (*Verfügung*) and initiating a court case. In relation to the establishments and holdings visited, the most common enforcement tools were oral advice and written warnings. However, the cantonal authorities in the one canton visited had also initiated four legal proceedings in 2012 in relation to food safety.

##### **Observation**

The FVO audit team noted that the enforcement action taken in relation to one establishment visited had been poor (long-standing significant deficiencies that had not been reacted to). However, the cantonal authorities reacted quickly and withdrew the approval.

#### 5.2.5 *Official sampling*

##### **Legal requirements**

Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation.

##### Swiss standards

Article 56 of the Food Ordinance provides for a general legal basis for risk based surveillance of foodstuffs. Articles 57, 58 and 59 lay down basic rates for official sampling.

##### **Findings**

It is up to the CLs to organise surveillance programmes based on their own risk assessment. The results of these sampling programmes are included in the annual cantonal report sent to the CCA. The 2011 annual report received for the cantonal office visited included data on official sampling. The results are given in the table below.

Testing of milk and dairy products for microbiological criteria 2012 in the CL visited.

<b>Product</b>	<b>Number of non-compliant result</b>	<b>Number of analysis carried out</b>
Cream based on pasteurised milk	0	31
Milk and dairy products	0	12
Cheeses made based on pasteurised milk	1 ( <i>Escherichia coli</i> )	148
Butter and cream made based on milk heat treated below pasteurisation temperature	0	11
Cheeses made based on raw milk	4 ( <i>Escherichia coli</i> , <i>Coagulase-positive Staphylococcus</i> )	164
Cheeses based on milk heat treated below pasteurisation temperature and mature cheeses	0	46
Milk based ice-cream	1 (total aerobic colony count)	26
<b>In total</b>	<b>6</b>	<b>438</b>

In the CL visited, in 2012, 438 microbiological analyses had been carried out on official samples taken of milk and dairy products and analysed for microbiological criteria. The products covered cream, pasteurised milk and dairy products, cheeses made based on pasteurized milk, cheeses, butter and cream based on milk that has been subject to a heat treatment below pasteurisation and matured cheeses, cheeses made based on raw milk and milk based ice-cream. Out of the 438 samples, 1.4 % (6) were non-compliant with regard to microbiological criteria. The above programme was deemed to have an appropriate allocation of testing within the different production groups.

The FVO audit team checked the corrective actions taken and the follow-up in relation to a rapid alert notification that occurred in 2013 related to dairy products. The actions taken were satisfactory.

### **Observations**

Except for the general legal basis given above the FVO audit team did not receive any other legal basis or instruction from the CCA on national surveillance programmes for food microbiology. The CCA stated that they lack a specific legal basis for such surveillance programmes.

The CCA do not have a national overview of the official microbiological sampling and testing carried out by the CLs.

The frequency of official sampling and microbiological analysis in the establishments visited to verify compliance of the FBO programmes with the Swiss requirements was very low. For example, in one large-scale establishment visited, the last official sampling had been carried out in 2010 in relation to a rapid alert notification.

## **Conclusions**

The CAs were clearly designated for the official controls over milk and dairy products. The official staff met were generally qualified and motivated and training has been provided as necessary. The draft Food Law has not yet been passed in the Parliament with the effect that there is insufficient feedback from the cantonal authorities to the CCA on inspection, official sampling and enforcement activities carried out by the cantons. While a functioning audit system has been put in place, the follow-up is weakened as the cantons are not legally bound to follow up the recommendations and to take appropriate corrective actions. The official controls carried out by the cantonal authorities were generally effective. However, the inspections of the establishments visited had some shortcomings. Although evidence of the use of enforcement tools was available in the cantons visited, in relation to one establishment visited the enforcement action taken had been poor. Whilst evidence on official sampling of milk and dairy products by the CL visited was available, in the establishments visited the frequency was low. Furthermore, the CCA do not have an overview of the situation at national level and lack a specific legal basis for national surveillance programmes.

The CA had addressed the recommendation of the audit 2009-8217 related to CA performance in the cantons visited. However, the FVO audit team noted some shortcomings which are partly due to a lack of a legal basis.

### **5.3 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS' LEGAL REQUIREMENTS**

#### **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.

#### 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

Articles 12 and 13 of the Food Ordinance provide the legal requirements for registration and approval of food businesses. Further rules for the implementation of Articles 12 and 13 on registration and approval of establishments are given in instruction No 7 of the FOPH.

## **Findings**

In response to recommendation no 6 of the report 2009-8217 (*To ensure that establishments do not operate without an approval, when needed, and that this approval covers the activities carried out as foreseen in Article 13 of the Food and Consumer Products Ordinance (817.02)*) and recommendation no 7 of the report 2009-8217 (*The CAs should take measures to ensure that the lists over approved establishments as published on the internet are up to date and accurate*), the CCA had developed and distributed a guideline to the cantonal authorities regarding the registration and approval of food establishments. Furthermore, the guidelines concerning Article 13 for approval were updated by the CCA in 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 SVFO website before the end of 2012. The implementation of the approval procedure was also included in the audits carried out by the CCA.

The approved dairy establishments are published on the webpage of the Swiss authorities.

## **Observations**

The information available on the webpage was correct in relation to the dairy establishments visited.

For four of the seven establishments visited by the FVO audit team updated approvals with accurate information was available, as well as evidence of inspections carried out for the purpose of approval.

The FVO audit team visited one of the major exporters of dairy products to the EU. The dairy establishment was also processing downgraded raw milk (not fit for human consumption) which was sent to another company as raw material for pet food. The FBO was unable to explain to the FVO audit team why the raw milk had been rejected. Furthermore, the dairy establishment visited had no approval to produce pet food. The two CAs responsible for the official controls of the establishment had not noted these shortcomings.

In one small canton visited, the CL staff met stated that no formal renewed approval documents for the five approved dairies in the canton existed. The two dairy establishments visited in the canton had both been inspected in 2013. However, no evidence was available that the CL had reacted to the request of the CCA in September 2012 to verify and to update the activities covered by the approvals.

## **Conclusion**

Although the CAs had addressed the recommendation of the audit 2009-8217 and the action plan had been considered as satisfactory by the FVO, not all cantons have followed the instructions received from the CCA and the FVO audit team noted some shortcomings in relation to the approvals in two of the five cantons and three out of eight establishments (including the collection centre) visited.

## 5.4 IMPORT CONTROLS

### Legal requirements

Council Directive 2002/99/EC lays down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

Council Directive 97/78/EC lays down the principles governing the organisation of veterinary checks on products entering the Community from Third Countries.

Chapter V of Regulation (EC) No 882/2004 lays down rules on official controls on the introduction of feed and food from Third Countries.

Regulation (EU) No 605/2010 lays down the animal and public health and veterinary certification conditions for the introduction into the EU of raw milk and dairy products intended for human consumption.

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.

### Swiss standards

The following Swiss legislation comprises the main rules for import and transit of milk and dairy products from Third Countries:

Ordinance on Import, Transit and Export of Animals and Animal Products (916.443.10);

Ordinance on Import and Transit of Products of Animal Origin by air (916.443.12)

The Ordinance over controls at import and transit of animals and products of animal origin (916.443.106). According to Article 3 and point 16 of Annex 1 the requirements of Commission Regulation (EU) 605/2010 and Commission Decision 2011/163/EU have to be followed.

In addition, Instruction no 7 of the FOPH requires the approved establishments to obtain food of animal origin only from approved establishments.

### Special Conditions

Chapter 1 of Appendix 6 to the Agreement requires Switzerland, as Special Condition (3), to apply the same conditions for imports as the EU.

### Findings

The FVO audit team received the statistics for imports of milk and dairy products from Third Countries to Switzerland. The total amounts imported from other Third Countries in 2012 and 2013 (until 17 October) were 1 111 263 tonnes and 1 476 177 tonnes, respectively. Whilst the majority of the imports originated from countries that are on the list of countries from where the EU Member States are permitted to import milk and dairy products, some larger quantities were also imported from other Third Countries which are not on the list of such countries (for example, in 2012 the



following amounts of milk and dairy products were imported to Switzerland: 1 508 kg from Philippines, 474 kg from Mexico and 354 kg from Brazil, and in 2013, 1 419 kg from the Arab Emirates, 1 084 kg from South Africa and 749 kg from China). The CCA explained that these imports comprised samples for technical purposes, special studies and analyses that can only be imported with an import permit. These batches were sent from FBOs in Third Countries that are part of multi-national FBOs, that have their research centres located in Switzerland. The imports are strictly controlled, can only be imported via the airports in Geneva or Zürich and the raw materials and products are handled as category 1 animal by-products (ABP) material and have to be destroyed or sent back. The establishments are in addition inspected annually in relation to these import restrictions. The FVO audit team received the approval procedure of the SFVO for such products and an example of one import permit.

Some of the FBOs visited used ingredients that had been imported from other Third Countries as raw materials for dairy products. The ingredients seen were all from establishments that were on the list of establishments from which the Member States are permitted to import milk and dairy products.

## **Conclusion**

No shortcomings were identified in relation to controls over imported products.

### **5.5 FOOD BUSINESS OPERATORS' COMPLIANCE WITH HYGIENE RULES AT ESTABLISHMENT LEVEL**

#### *5.5.1 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 Food Law is the main Swiss legislation regarding public health sanitary measures. The detailed rules in relation to the general and specific requirements of dairy establishments are laid down in the Food Ordinance and the Hygiene Ordinance.

#### **Findings**

In general, the seven dairy establishments and one collection centre visited were in line with the general and specific hygiene requirements.

## Observations

- In two establishments shortcomings in relation to cleaning were noted that had resulted in fungal growth.
- In one establishment the own-checks over efficacy of cleanliness was not documented for visual checks and microbiological testing of cleanliness was not carried out.
- In two small establishments visited, pest control programmes were not in place. However, some protection was established (e.g. use of insect nets and insecticides).
- In two small establishments visited the layout and housekeeping of changing rooms was inadequate.
- In one establishment exposed cheese was stored in an area with cleaning agents and other equipment.
- In the establishments visited water testing was carried out according to Swiss standards, which stipulates that the FBOs have to analyse the potable water once annually for microbiological parameters when supplied with municipal water and four times annually if they have their own supply. Nevertheless, the results of examinations for heavy metals and pesticides were not available in any of the establishments visited and not in all establishments in relation to basic chemical parameters.

Most of the above mentioned deficiencies were detected during the official supervision. However, in some cases they were noted only after the FVO audit team asked the CA to inspect additional facilities or documentation (for example, a separate cheese ripening building, controls on pasteurisation or own controls on raw material entry).

## Conclusion

Seven of the eight establishments (including the collection centre) visited largely complied with the Swiss standards for general and specific hygiene requirements. However the FVO audit team noted some significant shortcomings that had not been picked up by the CAs.

### *5.5.2 HACCP-based system*

## Legal requirements

On the basis of Article 5 of Regulation (EC) No 853/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

### Swiss standards

The general obligation for the FBOs to carry out own checks is laid down in Article 23 of the Food Law. The requirements in relation to HACCP-based procedures are laid down in Articles 51, 52 and 53 of the Food Ordinance. Article 51 of the Ordinance comprises the requirements for the seven main HACCP principles. According to Article 52 the FBO can apply an industry guideline for HACCP that has been approved by the FOPH. Article 53 requires the FBO to provide proof for the CA that he applies HACCP-based procedures or the industry guideline.

## **Audit findings**

Except for one establishment visited, HACCP based systems were in place in the establishments visited and the large majority of them generally complied with HACCP requirements. However, some shortcomings were noted:

- One small FBO was producing a variety of dairy products without a HACCP concept and had in general insufficient documentation of its own controls. This had been noted as a deficiency by the CAs already in 2009 but no action had been taken by the FBO and no enforcement action was taken by the CA to rectify the situation. In general there was a lack of documentation of own-checks carried out in this establishment. In particular, the pasteurisation parameters were not recorded and the process was neither verified nor validated. The FBO was producing for the local market only but the customers included vulnerable groups (e.g. the local hospital and nursing homes for old people). However, the CA reacted quickly during the FVO audit and the FBO's approval was withdrawn.
- One establishment producing melted cheese and fresh cheese had no specifications for the gelatine supplier to ensure the eligibility of the raw material.
- In one establishment producing whey concentrates, the processing and channeling of non-compliant raw milk with regard to raw milk quality (rejected by other establishments) was not addressed in the HACCP programme. The FBO could not explain to the FVO audit team the reason for the rejection. The FBO also used “white water” derived from the whey truck tanks for production of whey concentrate used as raw material for dairy products for human consumption. However, this raw material was not covered by the HACCP programme and the risks of the use of the “white water” for powder production had not been assessed. Furthermore, the time laid down for pasteurisation had not been validated.
- In one establishment producing yoghurts and drinking milk, the time laid down for pasteurisation to be validated and temperature control of incoming raw milk was not included in the HACCP programme.
- In one small establishment visited producing cheese, although it was established that the time of pasteurisation should be recorded, this was not done. Moreover, the verification of the pasteurisation process was not carried out. However, validation of the process took place once per year.
- In another small establishment producing cheeses, the hazard analysis was inadequate with regard to inhibitors presence, since aspects were missing such as the impact of anti-microbiological resistance and the presence of allergens. Moreover, the HACCP programme was not fully implemented, since water activity in different products was not measured although this was taken into account in the hazard analysis.
- In six out of the seven establishments visited adequate procedures were in place for recall of products.

## **Conclusion**

HACCP based systems were in place in all but one establishment visited. They varied in standard and level of detail and some shortcomings were noted concerning the lack of inclusion of some

production activities carried out in the HACCP programme and insufficient verification and validation of the pasteurisation process in some cases.

### 5.5.3 Microbiological criteria for foodstuffs

#### Legal requirements

Details on the microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. These cover a range of items with regard to requirements for raw milk and dairy products and other products of animal origin.

#### Swiss standards

The requirements for microbiological criteria are laid down in Article 5, chapter 5a and Annex 1-3 of the Hygiene Ordinance. Article 58a of the Hygiene Ordinance requires the FBO to ensure that food safety and process hygiene criteria are adhered to.

Article 56 of the Ordinance on Foodstuffs and Objects provides for a general legal basis for risk based surveillance of foodstuffs.

#### Findings

The FBOs visited are required to carry out microbiological testing and are required to follow Swiss legislation, which is considered as equivalent to EU legislation.

The CCA had sent out questionnaires in 2008-2011 on the implementation of food safety and process hygiene criteria by the dairy industry. The summary results for 2011 in relation to percentage of FBOs testing for microbiological criteria and the percentage of non-compliant results received is given in the following table:

Microbiological-logical criteria	Alpine premises		Commercial premises		Industrial premises		Cheese ripening and packing premises		Agricultural holdings with processing on-site	
	119 in total		150 in total		19 in total		8 in total		49 in total	
	% of FBOs testing for microbiological criteria	% of non-compliant results	% of FBOs testing for microbiological criteria	% of non-compliant results	% of FBOs testing for microbiological criteria	% of non-compliant results	% of FBOs testing for microbiological criteria	% of non-compliant results	% of FBOs testing for microbiological criteria	% of non-compliant results
<b>Food safety criteria</b>	53.00%	9.00%	90.00%	7.00%	79.00%	13.00%	100.00%	0.00%	63.00%	13.00%
<b>Process hygiene criteria</b>	62.00%	23.00%	87.00%	11.00%	84.00%	62.00%	50.00%*	0.00%	55.00%	63.00%

\*The establishments visited carried out a limited number of processing steps which makes this criterium less relevant for the ripening and packing premises.

According to the results of the survey the FBOs operating on alpine premises and the on-farm producers of milk and dairy products have the most shortcomings in relation to carrying out the required sampling. The results in relation to compliance of food safety criteria varied between 100 and 87 %, whereas in relation to process hygiene criteria the compliance level was lower (100-38 %) between the different types of FBOs.

## Observations

All laboratories used by the FBOs visited were accredited according to ISO 17025 by the Swiss Board of accreditation. In all establishments visited where microbiological testing was carried out either reference methods or alternative validated methods were used. In six out of the seven dairy establishments visited microbiological testing was carried out in line with the Ordinance on Hygiene (817.024.1).

However, some shortcomings were noted:

- The national survey 2008-2011 demonstrated that the FBOs have difficulties in reaching full compliance in relation to the implementation of microbiological criteria.
- In one establishment visited no microbiological sampling and analysis was carried out to verify the effectiveness of HACCP-based procedures, despite the fact that the FBO was producing cheese based on raw milk. This shortcoming had been noted already in 2009 by the CA. However, the situation had not improved since then.
- Trend analysis was not carried out in the establishments visited except for one.
- In all establishments visited the sampling for *Listeria monocytogenes* (*L. monocytogenes*) examination was limited to one unit, instead of the five legally required by the Ordinance on Hygiene (817.024.1). The decision on this reduction was not based on adequate justification as required by the Ordinance. In addition, in none of the establishments visited had the CA requested such a justification from the FBO.
- In three of the establishments visited environmental sampling for *L. monocytogenes* was not carried out although products were produced which might support the growth of the bacteria.
- Usually the absence criterium was used for *Listeria* testing. Only in two establishments was the enumeration method used, when the FBO was able to demonstrate that the product would stay below 100 cfu for *L. monocytogenes* during shelf-life.
- In an establishment producing whey concentrates the process hygiene criteria for whey after pasteurisation was defined as 1 000 000 Colony Forming Units (CFUs) instead of the 100 000 CFU as stipulated in legislation.
- The specification of the method used for enumeration of *L. monocytogenes* by an accredited laboratory was not precise enough.
- In relation to the establishments visited very limited official sampling had been carried out by the CAs in order to verify compliance with the microbiological criteria.

## Conclusions

In the majority of cases reviewed, the range of microbiological testing carried out by the FBOs was in line with most aspects of the Swiss requirements and the results seen were in most cases satisfactory. However, shortcomings were noted in relation to the number of samples taken for the food pathogen *L. monocytogenes*, environmental testing and shelf-life studies. Furthermore, the reduced number of samples taken by the FBOs without justification combined with the limited official sampling carried out on the microbiological control programmes of the FBOs raises a concern about the adequacy in general of the implementation of FBOs' programmes.

### 5.5.4 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 CAs 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.

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.

Directive 2000/13/EC lays down rules for labelling, presentation and advertising of foodstuffs.

### Swiss standards

The requirements regarding traceability are laid down in Article 23a of the Food Law. The requirements regarding labelling and identification markings are laid down in Article 26 of the Food Ordinance and the Ordinance on Identification and Advertising of Foodstuffs (817.022.21)

## Audit findings

In response to recommendation no 8 of the report 2009-8217 (*The CAs should take measures to ensure that deficiencies noted with regard to identification marking in connection with labelling and commercial documentation, and the poor performance of the Cantonal Authorities in detecting these are rectified and in compliance with Articles 30-32 of the Ordinance on labelling and advertising of foodstuffs (817.022.21)*), the CCA stated that they had informed the cantonal authorities of the problems in a letter sent out in 2009 and furthermore this topic had been discussed in meetings with cantonal authorities.

The CCA stated that for products on the national market, there will be no identification number as such on the products that can only be produced in non-approved establishments only.

In general traceability systems were in place in all establishments visited, which had been tested by

the CA in six out of the seven dairy establishments and deemed to be operating adequately. The FVO audit team verified that procedures were in place in all establishments visited that can provide for adequate forward and backward traceability. In addition, systems were in place for internal traceability which could support nutritional claims such as “lactose free” and freedom of certain allergens. Similarly the provisions for identification marking and labelling were largely complied with.

## **Observations**

The FVO audit team noted some shortcomings in relation to identification marking that were not complying with Swiss standards and had not been noted by the CA:

- In two establishments visited some products were seen without any identification mark (gelatine and whey and egg powder mix) and the FBO could not demonstrate the eligibility of these products as originating from approved establishments. This jeopardised the traceability of the finished products.
- In two other establishments, some identification marks were wrongly designed or difficult to read.

## **Conclusions**

The requirements for identification marking were largely complied with and recommendation no 8 of report 2009-8217 has been addressed satisfactorily. However, some isolated shortcomings were noted in four of the seven dairy establishments visited. In general, traceability systems were in place that were in line with Swiss requirements but in two cases they were jeopardised by the lack of identification marking of some ingredients used.

### *5.5.5 Animal by-products*

## **Legal requirements**

Article 4.1 of the Regulation (EC) No 1069/2009 requires the operator to identify ABPs as soon as they are generated and to ensure that they are dealt with in accordance with this legislation.

### Swiss standards

According to the Ordinance on Disposal of ABPs (916.441.22) the FBO is obliged to categorise products, as appropriate, as ABP and identify them as ABPs of the correct category before they are dispatched from the establishment.

## **Findings**

In the establishments visited, products that were decided not to be included in the food chain by the FBO or were unfit for human consumption were generally categorised as ABP.

## **Observations**

The FVO audit team noted the following shortcomings that had not been picked up by the CAs:

- In all establishments visited, the containers used for ABPs were in most cases indistinguishable from those used for dairy products intended for human consumption. In some cases these products were collected in containers bearing a label "for feeding purposes".
- In one establishment visited, cheese offcuts that were considered by the FBO not to be processed into dairy products for human consumption, were collected in transparent bags without any label. The FBO characterised this product as “waste” and it was collected by an external collector to be used as animal feed. However, there was no indication showing that such products were ABPs and as to whether such a product could be used for animal feeding or simply was unfit for human consumption.

## **Conclusion**

The requirements for ABP were largely complied with exception of shortcomings concerning the application of the labelling requirements for ABP.

### **5.6 MILK PRODUCTION HOLDINGS AND RAW MILK UPON COLLECTION**

#### **Legal requirements**

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004. The CA shall carry out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and monitor the checks carried out for plate count, somatic cell count (SCC) and residues of antibiotic substances.

#### Swiss standards

The general requirements for primary production holdings are given in the Ordinance on Primary Production (910.020). The Swiss animal health requirements for dairy cows, milking hygiene, storage, cooling and transport of raw milk and the requirements for raw milk are laid down in the Ordinance on Hygiene at Milk Production. The requirements for the control system in place for raw cow’s milk are given in the Ordinance of Milk Control (916.351.0). The laboratories testing raw milk in the framework of the control system are obliged to inform the milk producers and the cantonal authorities in case the national limit are exceeded or detection of antibiotic residues. In addition, the results must be sent to a central administration point. Article 12 of the Ordinance requires the raw milk laboratories to send annual reports of their activities to the FVO.

#### **Audit findings**

##### *5.6.1 Milk production holdings*

The FVO audit team visited two dairy cattle holdings. The holdings had adequate facilities, equipment and documentation.

#### **Observations**



The FVO audit team noted some shortcomings on both farms in relation to treatment registers, keeping and labelling of veterinary drugs. On the first farm visited there were some errors in the register of veterinary treatments (e.g. one treatment was missing, calves receiving milk with antibiotic residues were not recorded as treated, one veterinary label text was too small to read, one expired drug). On the second holding there were some shortcomings in relation to labelling of prescription-only veterinary medicines (one drug lacked the label of the veterinary practitioner). Another veterinary medicine for dry cow therapy did not have a withdrawal period for meat. It was stated that if the animal was slaughtered the meat should be tested for residues. This is incorrect as the meat from such an animal should not be used.

#### 5.6.2 Raw milk upon collection

Switzerland has established a centralised system for analysing raw cow's milk for SCCs, total plate counts (TPCs) and antibiotic residues. Milk is collected from approximately 24 000 producers, 1 200 sample collection points and using 70 collection tours. All approved dairy establishments receiving raw bovine milk have the milk analysed for the criteria of Chapter III, Section IX, Annex III to Regulation (EC) No 853/2004.

The Swiss requirements for the raw milk in relation to SCC and TBC differ somewhat from the EU requirements:

	<b>SCC (bovine milk)</b>	<b>TBC (bovine milk)</b>	<b>Inhibitors</b>	<b>TBC other species</b>
<b>Limit</b>	350 000/ml	80 000/ml	Absence	1 500 000/ml  (500 000/ml if used for raw milk products)
<b>Sampling frequency</b>	2 samples/month	2 samples/month	2 samples/month	2 samples/month
<b>Parameter used</b>	4 exceeding monthly geometrical averages in a 5 month period (no rolling averages used)	3 exceeding monthly geometrical averages in 4 months period (no rolling averages used)	Single positive result	

According to the statistics received, in 2012 98.9 % and 96.3 % of the bovine raw milk samples analysed complied with the national requirements for TBC and SCC, respectively (based on results of single tests). In relation to antibiotic residues, the compliance percentage reached was 99.3.

The laboratory visited by the FVO audit team had adequate facilities, equipment, quality control and documentation. The laboratory had a valid ISO 17025 accreditation certificate issued by the Swiss Accreditation Service and the methods used were accredited reference or validated alternative methods. Evidence was available that the laboratory had notified the cantonal authorities when antibiotic residues had been detected in the milk or the geometrical averages for TBC or SCC had

exceeded the national criteria. The laboratory visited collected and tested two samples from each farmer each month. This included farmers delivering milk to collection centres. The annual number of samples analysed for public milk quality testing is 625 000 samples. The laboratory had participated successfully in annual proficiency tests organised by commercial providers. In addition to raw milk analysis, the laboratory offers also milk content testing for breeders associations and mastitis diagnostics services to their customers.

The seven dairy establishments visited by the FVO audit team were all testing the raw bovine milk in the centralised laboratory and the results seen were in general satisfactory. The test methods and frequencies were all adequate. Evidence of actions taken in relation to non-compliant milk was available (e.g. sending of notification letters, follow-up visits carried out by the veterinary inspectors, re-sampling, delivery stop returning of antibiotic-positive milk to the farm etc.). The raw milk results were also available on the two holdings visited and the quality was adequate.

## **Observations**

No similar raw milk quality system has been established to analyse raw milk of other species (e.g. goat, sheep or buffalo milk). It is for the FBO to have the raw milk of other species analysed for TBC and antibiotic residues and this aspect was not controlled by the CA met in the three establishments visited producing dairy products based on goat milk. Only one of three FBOs visited producing goat milk cheese and yoghurt had their milk tested for TPC and none for inhibitory substances.

The CA in the cantons visited did not include the verification of the raw milk control system in their controls of dairy establishments.

## **Conclusions**

The dairy holdings visited had adequate facilities and equipment, herd management and documentation. Some shortcomings were noted in relation to labelling of veterinary drugs and documentation of treatments with veterinary medicines. The quality control system for bovine raw milk is well established and functions adequately. The quality of the bovine raw milk is in general satisfactory. However, no formal control system has been established for raw milk of other species. The FVO audit team noted shortcomings in relation of testing of raw goat milk for TBC and antibiotic residues.

### **5.7 OFFICIAL CONTROLS OVER APPLICATION OF HYGIENE RULES AT DAIRY ESTABLISHMENTS**

#### **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 Food Law is the main Swiss legislation regarding official controls in food businesses. In addition, more detailed rules can be found in *inter alia* the Food Ordinance, and the Ordinance on the Enforcement of Food Legislation. Further instructions are given in the Guidance for Inspection of Food Processing Establishments approved on the basis of Article 13 of the Food Law.

## **Findings**

In response to recommendation 5 of the report 2009-8217 (*The CAs should take further measures in order to ensure that the efficacy of controls over meat and dairy processing establishments is evaluated and the necessary corrective measures to improve its performance are put in place as required in Article 56 of the Ordinance on the Enforcement of Food Legislation*) the CCA stated that the efficacy of the checks is examined individually at canton level. The FOPH would write to the cantonal CAs to draw their attention to the FVO recommendations and request the required documentation, so that appropriate conclusions can be drawn at federal level and corresponding measures can be taken. The CCA also undertook to organise training by spring 2011.

Evidence was available in the cantonal office visited that the cantonal CAs are informed of the outcome and recommendations of previous FVO audits and that training had been provided in relation to meat and milk topics.

The establishments and the collection centre visited had been inspected regularly with the planned frequency and inspection reports, including recommendations and the follow-up of previous inspections were available for the establishments visited by the FVO audit team. The controls of the milk collection centre and dairy establishments visited were in general well organised, systematic, and well documented. All the inspectors used check-lists for the controls. The controls comprised documentary checks and verification of the FBOs' compliance with good hygiene practice and HACCP-based procedures, verification of the correctness of the approval and checking traceability and recall procedures. This was followed by an inspection of the premises and equipment. All the inspectors accompanied were using check-lists but stated at the start of the inspection that they would not cover all areas due to time constraints.

## **Observations**

The FVO audit team noted from the previous audit reports available that the time allocated for inspections was in general between one and three hours. It is not possible to carry out a full physical inspection and thorough documentary check in such a short time-frame.

Although the officials met carried out the controls in a generally adequate way, some significant shortcomings identified by the FVO audit team had not been identified by the inspectors responsible for the controls of the establishments (for example; errors in HACCP-concepts or not all products included in HACCP, incorrect and not plausible documentation of temperatures, processing of raw milk destined for feedstuffs without an approval for such activity, lack of own controls, lack of the environmental testing for *L. monocytogenes*, lack of shelf-life studies, shortcomings in relation to water testing).

## **Conclusions**

The performance of the CAs was in general satisfactory but with some shortcomings identified, in particular in related to the time allocated for the inspection and documentary checks.

Recommendation no 5 of report 2009-8217 has been addressed partly satisfactorily, as the inspections were not always sufficiently thorough and some significant findings had not been noted.

## **5.8 OFFICIAL CONTROLS OF MILK PRODUCTION HOLDINGS AND OVER RAW MILK UPON COLLECTION**

### **Legal requirements**

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004.

### Swiss standards

The main legislation in relation to controls on holdings is laid down in the Ordinance of Co-ordination of Controls on Agricultural Holdings (910.15). In addition the following technical guidelines and instructions on controls of dairy holdings are available: technical guidance on official controls in primary production (animals); manual for official controls of agricultural holdings; technical guidance on control of milk production hygiene; and the manual for control of milk production hygiene. The Ordinance on Milk Control (916.351.0) lays down the requirements for the control system of bovine raw milk, but not for sheep and goat milk.

### **Findings**

The above-mentioned Ordinance lays down a four yearly minimum inspection frequency for several types of controls on holdings, including controls on milk hygiene. The set frequency for controls on animal health aspects and veterinary medicines is one control in ten years.

The controls on animal health and welfare, animal identification and movements, udder health, hygiene in primary production, and on veterinary medicines are carried out during the “blue controls”, traditionally carried out by staff of the CVS, whereas the dairy hygiene aspects are checked during the “white controls” carried out traditional by CL staff. The blue controls are carried out on 10 % of the holdings annually. In future these will be combined controls with a minimum routine frequency of once in four years. In one canton visited the blue controls were contracted to a control body.

Evidence of regular controls of dairy holdings was available in the two cantons visited where these aspects were checked. Check-lists were available for both types of controls. The controls witnessed by the FVO audit team were thorough and well documented and resulted in some recommendations in relation to the veterinary drugs used and documentation of veterinary treatments.

### **Controls over raw milk upon collection**

The control system for raw bovine milk is functioning independently and not controlled by the CAs, who rely on the inspections carried out by the accreditation body. Evidence was available in the cantons and the raw milk laboratory visited that the CA are informed regularly of the results received. The CAs are notified if antibiotic residues are detected in the raw milk or if the SCC or TPC exceed the legal limits and the milk delivery to the dairy is stopped until the holding is inspected and re-sampled with an acceptable sample result.

### **Observations**

In the raw milk laboratory visited the control system for bovine raw milk quality control was functioning well.

No controls are carried out in relation to raw milk derived from other species.

## **Conclusion**

The performance of the CAs at central level and in the cantons visited in relation to controls on milk production holdings and raw milk upon reception was in general satisfactory, except the lack of controls on raw milk derived from species other than bovine.

## **6 OVERALL CONCLUSIONS**

The legislation, the organisation of the CAs and the operation of the official controls provide satisfactory assurances that the provisions of the Agreement in the milk and dairy sector can be met. Seven out of eight establishments (including the milk collection centre) visited were in general compliant with the legal requirements. One establishment had several significant, long-standing deficiencies and the enforcement measures taken in relation to the FBO had been weak. However, the CA took immediate action and withdraw the approval of the FBO. In relation to the controls over the other FBOs, some shortcomings were noted, mainly in relation to the FBOs' own controls, microbiological sampling and analysis, potable water, raw milk quality controls of raw milk derived from species other than bovine and identification of ABPs.

## **7 CLOSING MEETING**

A closing meeting was held on 25 October 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 FVO audit team had requested guarantees in relation to the non-compliant dairy establishment and satisfactory guarantees were received in the closing meeting.

The representatives of the CCAs acknowledged the problems identified.

## **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.

<b>N°.</b>	<b>Recommendation</b>
1.	To ensure that the official controls cover potable water, and that potable water complies with microbiological criteria, physical and chemical as required in Article 17 and Annex B of the Ordinance on Hygiene (817.024.1), Ordinance on Potable, Spring and Mineral Water (SR 817.022.102), and Ordinance on Impurities and Ingredients in Foods (817.021.23). Furthermore, to ensure that the complete analysis of potable water from waterworks are available for the food business operators, as required in Article 5

N°.	Recommendation
	of the Ordinance on Potable, Spring and Mineral Water.
2.	To ensure that the food business operators' systems in place for the control of raw milk and colostrum cover also raw milk of sheep and goat and that the official controls of dairy establishments, as required by Article 56 of the Food Ordinance (817.02) and the Enforcement Ordinance in relation to Food Legislation (817.025.21), respectively, cover also raw milk quality control.
3.	To ensure that the food business operators' Hazard Analysis Critical Control Points-based systems are in line with the requirements of Article 51 of the Food Ordinance ((817.2), to ensure that the official controls on Hazard Analysis Critical Control Points-based procedures are effective and that their effectiveness is evaluated, as required in Article 56 of the Enforcement Ordinance in relation to Food Legislation (817.025.21).
4.	To ensure that animal by-products in dairy establishments are subject to an adequate control system, including their collection and identification, as required in Article 16 of the Ordinance on Hygiene (817.024.1) and in Articles 20 and 38 of the Ordinance on animal by-products.
5.	To ensure that the official controls on food safety and process hygiene criteria are effective and cover the verification of the compliance of the food business operators with the rules and criteria of Article 58a, Chapter 5a and Annexes 1-3 of the Hygiene Ordinance (817.024.1).

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=2013-6888](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6888)

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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
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
Reg. 206/2010	OJ L 73, 20.3.2010, p. 1-121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Reg. 605/2010	OJ L 175, 10.7.2010, p. 1-24	Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption
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. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
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



<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Dir. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
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. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC