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FINAL REPORT OF AN AUDIT CARRIED OUT IN SWITZERLAND

FROM 10 TO 19 OCTOBER 2012

IN ORDER TO EVALUATE THE SYSTEM IN PLACE FOR ANIMAL HEALTH CONTROLS AND TO ASSESS THE PREPAREDNESS FOR OUTBREAKS OF ANIMAL DISEASES, 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

Report of an audit carried out in Switzerland from 10 to 19 October 2012, under the auspices of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products in order evaluate the system in place for animal health controls and to assess the preparedness for outbreaks of animal diseases

The audit team has drawn the following conclusions:

- The Swiss legal requirements for the control of animal diseases are, in general, essentially consistent with the EU legislation and aimed at producing the same results.
- Switzerland has a very favourable animal health status. The CA has implemented an excellent system of passive surveillance, a well-functioning risk-based serological surveillance programme for a number of diseases relevant in the context of trade with the EU, a reliable diagnostic laboratory network and is well prepared to tackle even major outbreaks of highly infectious diseases. However, the surveillance systems for bovine tuberculosis and for brucellosis cannot be considered sufficiently robust, due to inadequate design and operation of certain important components of those systems which could diminish their sensitivity and, consequently, undermine the position of the CA to provide assurances in respect of the health status of the Swiss ruminant population.
- A number of official control elements, such as the introduction of the concept of 'exclusion diagnosis' and the registration of equine holdings and the notification to the database of movement of equidae to another holding for more than 30 days, significantly enhance the effectiveness of the control system, which is further strengthened by the quality and frequency of official controls of animal holdings. However, other elements have the potential to weaken the system, such as the insufficiency of controls of assembly centres and animal dealers.

The CA, both federal and cantonal, operate efficient, effective and well co-ordinated control systems. While verification systems, including audit of the Cantons by the federal authority, are in place, there has not yet been any audit in the field of animal health and there is significant reliance on mutual trust between colleagues.

A sophisticated and well developed traceability system is in place. However, enforcement of Swiss requirements for notification of animal movements through markets and dealers was not fully efective and this could reduce the ability of the system to identify and trace contact animals in the case of a disease outbreak. The variety of activities which may take place on the same holding (assembly centre, dealership, commercial holding) also compromises traceability and disease control.

At the bovine SSC visited, the official controls of the animal health files were insufficient. This, coupled with deficiencies in pre-export inspection of consignments, weakens, to some extent, the reliability of the certification system.

The report makes a number of recommendation to the Swiss authorities aimed at fulfilling the commitments as set out in the Veterinary Annex to the Agricultural Agreement.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
AD	Aujeszky's Disease	
AHS	African Horse Sickness	
AI	Highly Pathogen Avian Influenza	
ALKVW	Office for food control and veterinary affairs of the Fürstentum Liechtenstein [Amt für Lebensmittelkontrolle und Veterinärwesen]	
ASF	African Swine Fever	
Blaue Kontrolle	Official controls on holdings including checks on animal identification, holding and movement records, records about use of veterinary medicines and milk production hygiene [10% of holdings per annum]	
BT	Bluetongue	
BVD/MD	Bovine Viral Diarrhoea / Mucosal Disease	
BVET	Federal Veterinary Service [Bundesamt für Veterinärwesen]	
C / T V	Centre / Team Veterinarian	
CA	Competent Authority	
CAE	Caprine Arthritis/Encephalitis	
CCA	Central Competent Authority	
СР	Contingency Plan / Planning	
CSF	Classical Swine Fever	
EBL	Enzootic Bovine Leukosis	
ECT	Embryo Collection Team	
EDAV	Regulation concerning the Import, Transit and Export of Animals and Animal Products [Verordnung über die Ein-, Durch- und Ausfuhr von Tieren und Tierprodukten 916.443.10 vom 18. April 2007]	
EHD	Epizootic Haemorrhagic Disease	
EIA	Equine Infectious Anaemia	
ELISA	Enzyme-Linked-ImmunoSorbent-Assay	
ERT	Emergency Response Team	
EU	European Union	
EVD	Swiss Ministry for Economic Affairs [Eidgenössisches Volkswirtschaftsdepartment]	
FFCU	Federal Food Chain Unit	
FMD	Foot and Mouth Disease	
FOAG	Federal Office for Agriculture [Bundesamt für Landwirtschaft]	
FVO	Food and Veterinary Office	
IBR/IPV	Infectious Bovine Rhinotracheitis / Infectious Pustular Vulvovaginitis	
IVI	Institute of Virology and Immunoprophylaxis [Institut für Viruskrankheiten und Immunprophylaxe]	

Joint Veterinary Committee	The Joint Veterinary Committee of the Swiss Confederation and the EU established by Article 19(1) of Annex 11 to the Agriculture Agreement is responsible for considering any matter arising in connection with the Veterinary Annex and its implementation and for carrying out the tasks provided for therein. As a rule the Joint Veterinary Committee meets once a year.	
KVA / KVÄ	Cantonal Veterinary Service [Kantonales Veterinäramt / Kantonale Veterinärämter; syn. Veterinärdienst, Amt für Veterinärwesen, Service de la sécurité alimentaire et des affaires vétérinaires, Ufficio del veterinario cantonale]	
LSD	Lumpy Skin Disease	
MS	Member State	
ND	Newcastle Disease	
NOSOS	Nation wide real-time simulation exercise on FMD in 2011	
NRL	National Reference Laboratory	
OIE	World Organisation for Animal Health	
OV	Official Veterinarian	
PCR	Polymerase Chain Reaction	
RP	Rinderpest	
PPR	Peste des Petits Ruminants	
RT-PCR	Real Time - PCR	
RVF	Rift Valley Fever	
SCC	Semen Collection Centre	
Sfr.	Schweizer Franken (Swiss currency)	
Sömmerung	Summer grazing mostly up on the mountains [transhumance]	
SOP	Standard Operational Procedure	
SSC	Semen Storage Centre	
Tb	Bovine Tuberculosis	
TRACES	Integrated computerised veterinary system	
TSG	Disease Control Law [Tierseuchengesetz 916.40 vom 1. Juli 1966]	
TSV	Disease Control Regulation [Tierseuchenverordnung 916.401 vom 27. Juni 1995; version 1. Juni 2012]	
TVD	Regulation Concerning the Animal Database [Verordnung über die Tierverkehrsdatenbank 916.404.1 vom 26. Oktober 2011]	
TW	Work Instructions [Technische Weisungen]	
Veterinary Annex	Veterinary Annex (Annex 11) to the Agricultural Agreement between the European Community and the Swiss Confederation	
Vetsuisse Faculty	Merger of the two veterinary faculties of Bern and Zürich in 2006	
VS	Vesicular Stomatitis	

1 Introduction

This audit took place in Switzerland from 10th to 19th October 2012. The audit was undertaken as part of the Food and Veterinary Office's (FVO) planned programme.

The audit team comprised three FVO auditors and one national expert. The audit teams were accompanied throughout the audit by representatives of the Central Competent Authority (CCA).

2 Objectives

The objectives of the audit were

- to evaluate the implementation of the Swiss legislation concerning animal health controls applicable to trade in cattle, pigs, sheep and goats and equidae and their germinal products in accordance with Veterinary Annex (Annex 11) to the Agricultural Agreement between the European Community and the Swiss Confederation, which recognises that the legal requirements of the EU and Switzerland for the control of animal diseases are essentially consistent with each other and produce the same results.
- to review the system put in place for contingency planning (CP) for exotic and/or emerging diseases, the action taken in the case of suspected disease and the procedures for disease notification;
- to evaluate the monitoring and surveillance programmes in place for animal health;
- to check the import requirements concerning animal health applicable to trade in live animals and their products from other Third Countries;
- to review the animal health certification system.

In pursuit of these objectives, the following meetings were held and sites visited:

VISITS / MEETINGS				COMMENTS
CA	Federal level:	Bundesamt für Veterinärwesen	2	Opening and closing meeting
	Cantonal level:	Kantonale Veterinärämter	12	Aargau, Bern, St. Gallen, Luzern, Jura, Neuchâtel, Vaud, Lausanne, Schwyz, Uri, Obwalden, Nidwalden
Laboratories		2	Institut für Viruskrankheiten und Immunprophylaxe, Mittelhäusern; Vetsuisse Faculty Zürich	
Animal database		1	Identitas AG, Bern	
Slaughterhouse		1	Bovine	
Animal holdings		5	Riding centre, studs, bovine holding, ovine holding	
FII-approved		2	Bovine, ovine, caprine, porcine	
		2	Bovine, ovine, caprine, porcine	
establishments	Animal transporters		2	Bovine, ovine, caprine, porcine
	Semen collection centres		2	Bovine and equine
	Quarantine	station	1	Bovine
	Embryo co	llection team	1	Equine

3 LEGAL BASIS

The audit was carried out

- under the auspices of the Agreement between the European Community and the Swiss Confederation on Trade in Agricultural Products and, in particular, its Article 16 of Annex 11 on animal health and zoo-technical measures applicable to trade in live animals and animal products adopted by Council and Commission Decision 2002/309/EC, Euratom of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation (O.J. L 114 of 30.04.2002) in agreement with Swiss authorities.
- under Article 46 of Regulation (EC) No 882/2004 which stipulates that EU controls in third countries shall verify compliance or equivalence of third-country legislation and systems with EU animal health legislation.

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

4 BACKGROUND

4.1 Animal population in 2009 and in 2011

According to the data of the Agrarian Report 2012 [*Agrarbericht 2012*] published by the Federal Department of Economic Affairs (*Eidgenössisches Volkswirtschaftsdepartment* – EVD) in 2009 [in 2011], 60 000 [57 000] horses are kept in 9 600 [9 000] holdings, 1 597 000 [1 577 000] cattle in 42 000 [40 000] holdings, 432 000 [424 000] sheep in 10 000 [9 400] holdings, 85 000 [86 000] goats in 6 900 [6 600] holdings, 8 741 000 [9 390 000] poultry in 13 500 [12 800] holdings and 1 557 000 [1 578 000] pigs in 9 100 [8 300] holdings.

4.2 Trade figures in animals and their germinal products from Switzerland to the EU

In 2009 [in 2010], following the data provided by the CCA (*Bundesamt für Veterinärwesen* – BVET), 2 131 [1 216] cattle, 84 [43] sheep, 73 [66] goats, 10 [22] pigs, 71 [177] chicken and 3 275 [3 272] horses; in addition to 230 [235] bovine and 10 [0] porcine semen doses and 16 [4] bovine embryos were traded from Switzerland into the EU. The cattle mainly originated from the Cantons St Gallen, Bern and Waadt, [Waadt, Genf and St. Gallen] and the horses from Zürich, Jura, Bern and Genf [Zürich, Jura, Bern and Waadt]. The destination of the vast majority of the consignments have been France, Italy and Germany.

4.3 Animal disease statistics

Switzerland has a very favourable animal health status as the country is free from all animal diseases with an impact on trade of live animals. The last occurrence of Foot and Mouth Disease (FMD) was in 1980, Classical Swine Fever (CSF) in 1993, Highly Pathogen Avian Influenza (HPAI) in 1930, Contagious Bovine Pleuropneumonia in 1895, Bluetongue (BT) in 2010, Bovine Tuberculosis (Tb) in 2000 [caused by *Mycobacterium bovis*; *Mycobacterium caprae* which was found in cattle and deer in a neighbouring country has not been reported in Switzerland for the time being], Brucellosis (*B. abortus* and *melitensis*) in 1996 and in 1985, respectively, Enzootic Bovine Leukosis (EBL) in 2005, Infectious Bovine Rhinotracheitis / Infectious Pustular Vulvovaginitis (IBR/IPV) in 2010, Anthrax in 1997, Rabies in 2003, Newcastle Disease (ND) in 2011, Swine Vesicular Disease (SVD) in 1975 and Aujeszky's Disease (AD) in 1993. The last occurrence of Equine Infectious Anaemia (EIA) is unknown. Brucellosis (*B. Suis*) was not reported since 2009, Trichinellosis is only sporadically reported in wild boars and Tularaemia has not been reported since 2008. On-going eradication programmes are launched for Bovine Viral Diarrhoea / Mucosal Disease (BVD/MD) and Caprine Arthritis / Encephalitis (CAE).

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements

Annex 11 to the Agricultural Agreement between the European Community and the Swiss Confederation – the Veterinary Annex – establishes that Switzerland and the EU have similar legislation leading to identical results with regard to measures for the control and notification of certain animal diseases and with regard to imports from third countries of live animals, their semen, ova and embryos. The Swiss standards and special conditions applicable are specified in Appendixes 1 and 3 to the Veterinary Annex respectively.

Art. 3 of the Veterinary Annex establishes that the trade in live animals, their semen, ova and embryos between Switzerland and the EU shall be carried out in accordance with the legislation specified in Appendix 2 to this Annex and subject to the special rules laid down in that Appendix.

Findings

As the Veterinary Annex determines that the EU and the Swiss requirements for animal health controls are essentially consistent with each other and produce the same results, a detailed review of the Swiss legislative framework for animal health controls has not been the subject of this audit.

The audit team noted that

- Article 2 and 3 of the Swiss Animal Disease Law [Tierseuchengesetz 916.40 of 1 July 1966
 TSG] ensure that the CA at federal and cantonal level have legal powers to carry out official controls in the field of disease control;
- consignments of live animals and the germinal products thereof, intended for trade to the EU must be accompanied during transportation to destination by health certificates which models are used for intra-Union-trade as set out in Article 23 of the Swiss Regulation concerning the Import, Transit and Export of Animals and Animal Products [Verordnung über die Ein-, Durch- und Ausfuhr von Tieren und Tierprodukten 916.443.10 vom 18. April 2007 EDAV];
- the main pieces of Swiss legislation covering the animal health controls are publicly available¹.

Conclusions

The Swiss legal framework for the control of animal diseases is comprehensive and provides a solid basis for these controls.

The BVET has sufficient power to enforce the implementation of commitments made in the Veterinary Annex, in particular, to meet the requirements for animal health and traceability as set out in the relevant health certificates.

5.2 Competent authorities' performance

Legal requirements

The Veterinary Annex determines that the EU and the Swiss requirements for animal health controls are essentially consistent with each other and produce the same results, in particular

- Article 8 of the Regulation of the Organisation of the Federal Department of Economic Affairs [Organisationsverordnung für das Eidgenössische Volkswirtschaftsdepartement, Stand 30. Juni 2010] empowers the BVET to ensure within the scope of this audit, based on scientific evidence, that the animals are free from diseases transmissible to other animals and to humans, and to open markets for animals and their products.
- 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

http://www.bvet.admin.ch

¹ BVET – website:

Swiss Confederation has undertaken to incorporate into its national legislation the provisions of Reg. (EC) No 882/2004

Findings

5.2.1 Structure and organisation of the Swiss veterinary service

The CCA for animal health in Switzerland is the BVET within the EVD. The activities and responsibilities of the BVET include the drafting of Federal legislation, monitoring and control of animal diseases, operation of the reference laboratory for highly infectious animal diseases (IVI), international negotiations, operation of Border Inspection Posts (for live animals and animal products) and the provision of training and advice to the cantonal administrations (Kantonales/e Veterinäramt/ämter – KVA/KVÄ).

According to the BVET, there are the 23 KVÄ which includes the particularities in respect of the 4 "*Urkantone*²" which run one common KVA and the Fürstentum Liechtenstein³ where there is one Office for Food Control and Veterinary Affairs [*Amt für Lebensmittelkontrolle und Veterinärwesen* – ALKVW]. Each of these veterinary offices is responsible for the implementation of animal health legislation within its territory.

Evidence was seen of good co-ordination and cooperation between the federal and cantonal administrations with regular meetings, extensive exchange of information and regular reporting of control activities.

The BVET stated that there was generally good compliance by the Cantons with federal legislation but that legal powers are available should a Canton postpone or refuse to comply (Article 59a of the TSG).

The audit team noted that

- there are variations in the organisational structure of the KVÄ within the Cantons: in some, the KVÄ constitute a separate organisation; in others the KVÄ are integrated with agriculture, public health and environment services;
- Swiss legislation contains a general requirement relating to the avoidance of conflict of
 interest for persons performing official tasks but BVET has not provided guidance on how
 this should be managed within the scope of animal health. For control activities covered by
 accreditation [Blaue Kontrolle, see below], provisions concerning avoidance of conflict of
 interest are included. For non-accredited activities, official control activities may be

http://www.llv.li/amtsstellen/llv-alkvw-tiergesundheit.htm

² The 4 "Urkantone" are Schwyz, Uri, Obwalden and Nidwalden.

³ The ALKVW cooperates very closely with the BVET and implements the Swiss veterinary legislation regarding animal disease control. See also the official website of the Fürstentum Liechtenstein:

performed by private veterinarians; in some cases these could be on farms of their clients. The degree to which such potential conflict of interest considerations were taken into account was dependent on the cantonal chief veterinarian;

• the extent to which official controls were performed by veterinary practitioners varied between Cantons.

5.2.2 Official controls and verification

Official controls on operators and animal keepers are carried out in accordance with Swiss legislation, in the field of animal health, mainly the TSG and TSV. In particular, following the work instruction [*Technische Weisungen über amtstierärztliche Kontrollen in Tierhaltungsbetrieben vom 1. Februar 2001* – TW] extensive and regular official controls on animal holdings are conducted, which are called the *Blaue Kontrolle*.

The audit team noted that

- the coverage of holdings under the *Blaue Kontrolle* which include checks on animal identification, holding and movement records, records of use of veterinary medicinal products and milk production hygiene, is 10% of holdings per annum, and it is intended to increase this to 25% per annum. EU legislation [for cattle: Commission Regulation (EC) No 1082/2003 and for sheep and goats: Commission Regulation (EC) No 1505/2006] requires MS to ensure that at least 3 % of the holdings, selected on basis of risk analysis, are checked for correct identification of the animals;
- there are no requirements or guidelines from the BVET on risk-based prioritisation of controls on animal holdings in the frame work of the *Blaue Kontrolle*;
- in accordance with Article 37b of the TSV, dealers' premises have to be controlled regularly and on a risk base. However, in all Cantons but one, the dealers were not subject to such controls:
- the extent of accreditation [EN 45 011] of control activities also varies between Cantons from those having all accredited to others where only those in the framework of the *Blaue Kontrolle* are accredited;
- for the time being, the equine sector has not been included in the framework of the *Blaue Kontrolle*⁴:
- concerning the verification of the effectiveness of official controls, it appears that although the management supervision on the control activities is a requirement of accreditation, the management supervision on the non accredited sector operates more on the basis of mutual trust between colleagues than on supervision and verification of the application of legal requirements and instructions.

⁴ In their response to the draft report the CA stated that in accordance with a new order [Verordnung vom 26. Oktober 2011; 910.15] which came into force on 1 January 2013 the equine sector has been included in the *Blaue Kontrolle*.

5.2.3 Internal Audits

The Federal Food Chain Unit (FFCU) operates under the shared responsibility of the BVET and the Federal Office of Agriculture of the EVD and the Federal Office of Public Health of the Federal Department of Home Affairs. The FFCU is responsible for auditing the implementation of relevant legislation by the federal and cantonal administrations.

The audit team noted that

- the FFCU operates a Quality Management System which is accredited to ISO 9001:2008.
 When an audit of a cantonal administration is completed, a report is produced and the
 Canton is required to provide an action plan detailing actions to be taken to address the
 recommendations of the report. These action plans are then passed to the BVET for followup;
- to date, with the exception of import controls, no audits of the implementation of animal health legislation have been undertaken.

5.2.4 Enforcement measures

The KVÄ may apply administrative measures including sanctions in the case of infringement of requirements or may initiate court proceedings.

The audit team noted that

- evidence was seen of a range of such sanctions having been used, including the issue of
 warning letters, withdrawal of the right to keep animals, the revocation of licenses of a
 veterinary clinic and a dealer. In addition, owners of animals presented for slaughter, whose
 movement history contains irregularities, are subject to financial penalties.
- police may impose on-the-spot fines when they find an empty vehicle which has not been cleaned and disinfected. Transporters and dealers met reported that they had been subject to such fines following delivery of animals to a location where cleaning and disinfection facilities were not available

Conclusions

The Competent Authorities, both federal and cantonal, operate efficient, effective and well coordinated controls systems. For the non-accredited sector, the management control system in place and procedures for avoidance of conflict of interest operate, in general, more on the basis of mutual trust between colleagues than on supervision and verification of the application of legal requirements and instructions. The variations in the organisation of the veterinary services in the Cantons are not significant, except in the few instances where they result in minor deficiencies in implementation.

Concerning official controls on animal holdings, while risk based prioritisation is not consistently implemented, the Swiss legislation sets very high standards in relation to the quantity and frequency of these controls. This enhances the already high standards of veterinary supervision and provides the veterinary service with a sound overview in animal health matters about primary production in Switzerland.

5.3 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL

Legal requirements

The Veterinary Annex determines that the EU and the Swiss requirements for animal health controls are essentially consistent with each other and produce the same results, in particular

• Articles 7 to 15 of the TSV set out the requirements on holding registration, animal identification and movement control and recording;

(corresponding EU requirements are laid down by Regulations (EC) No 1760/2000, 1082/2003, 21/2004, 1505/2006, 504/2008 and Directive 2008/71/EC and Decision 2006/968/EC).

Findings

There is a traceability systems for cattle, sheep, goats, pigs and equidae in place which is based on obligation and controls on holding registration, animal identification and movement notification. These controls are supported by a central animal database. The database has been developed and is managed by a company established as a public-private partnership ($Identitas\ AG$). This central database is linked to other CA databases and information systems.

5.3.1 Holding registration

Under Article 7 of the TSV, the Cantons are required to register all holdings keeping hooved animals. The Cantons must allocate an identification number [Kantonale Identifikatsionsnummer] to each holding (where necessary, more than one number may be assigned to a holding).

Common mountain pastures for *Sömmerung* and movement of animals to and from these pastures are registered in the animal database.

Where a holding consists of more than one location but all lands/animal housing are within 3 km. of the main holding, the holding is considered as a single entity. Where animal housing is more than 3 km. from the main holding, this should be registered as a separate holding.

When registering holdings with the cantonal authorities, animal keepers are, in most Cantons, required to provide the geographical reference (map coordinates) for the holding. They are not required to provide geographical references for any animal housing facilities within 3 km. of the main holding.

The audit team noted that

- the registration of pastures without animal housing by the Cantons is not required, even if they are more than 3 km. distant from the main holding, nor are they required to provide geographical references for pasture remote from the main holding (irrespective of its distance from the main holding);
- geographical references are not always passed from the KVÄ to the animal database. Currently, the database holds the data for 71% of all farms (84% in the case of bovine holdings);
- Article 3.1.b of the Swiss Regulation of the Database [Verordnung über die Tierverkehrsdatenbank 916.404.1 vom 26. Oktober 2011 TVD] requires the operator of the database to allocate to each animal holding including those of equidae a unique TVD number and each change of the holding and / or of the ownership of the equidae has to be notified to the animal database (Article 8 of and in connection with Annex 1 of the TDV). In contrast, Article 21 of Regulation (EC) No 504/2008 requires to only record in the database the name and address of the person to whom the identification document is issued.

5.3.2 Animal identification

The Swiss requirements for identification of cattle, sheep and pigs are similar to the EU requirements leading to the same results in the implementation.

Due to the small size of the sheep and goat population [less than 600 000 sheep and goats] electronic identification of these animals is not required in Switzerland, similar to what is foreseen in Article 9.3 of Regulation (EC) No 21/2004.

Tags are distributed to animal keepers by the company managing the central database. A record of tags distributed and used is maintained.

Identification of equidae is based on the application of microchips, passports for equidae and the recording of these data in the animal database. For the time being there are 15 passport issuing bodies for equidae which are based in Switzerland and have been approved by the Federal Office for Agriculture (FOAG *-Bundesamt für Landwirtschaft* [one is doing so for other than registered horses] and 4 German passport issuing bodies approved by the German CA and recognised by the FOAG for doing that in Switzerland.

The audit team noted that

• cattle, sheep and pigs seen in the course of the audit, in general, have been identified as

required;

• Article 315g of the TSV lays down that equidae born before 1.1.2011 have not to be identified by micro-shipping but their owners have to get a passport for these equidae by 31.12.2012. In October 2012, according to BVET, around 70% of the equidae have been registered/recorded in the database⁵, less than 70% of the equidae bear microchips and the number of issued passports of equidae has been lower than the number of applied microchips. Although the audit team identified that the Swiss model passport for equidae is not fully identical to the EU model passport as set out in Annex 1 to Regulation (EC) No 504/2008, the Swiss model contains the main elements as requested for the EU model.

5.3.3 Animal movement control

For all movements of animals, an accompanying document is required. The keeper of the holding of origin is required to provide, for all animals, information about the holding number, name and address, the species being moved, the name and address of the buyer or the dealer or the market or the slaughterhouse of destination, as appropriate, an animal health attestation (that the holding of origin is free of epizootic disease); and information on medicines administered, if any, to any of the animals concerned. In addition, for cattle, sheep and goats, the ear tag numbers of the animals, their date of birth and their sex and, for pigs, all holding numbers of the pigs comprising the consignment and the number of pigs bearing each holding number are required.

- For cattle, both parties involved in the transaction are required to inform the animal database. The movement history of each individual animal and the database registers of the holdings concerned are to be updated. Movement histories are classified as valid when they contain no unexplained movements. Prior to 25 August 2009, animal movements through markets and dealers where the transfer of the animals from one holding to another was completed within a single day, were considered as single holding to holding movements. It was not required that the involvement of the dealer/market and the movement to/from the dealer/market premises be notified to the database. The legislation was amended at that time and such movements should now be notified to the database and recorded therein.
- In the case of pigs, both parties to a transaction are required to send copies of the accompanying document to the database. For pigs, the movement is recorded in the database against the receiving holding or establishment only. For pig holdings, the database does not record the movement of animals off the holding.
- For sheep and goats, the parties to a transaction must keep copies of the accompanying documents and must update their flock/herd registers accordingly.
- For horses, the system for movement control is currently at a development stage (see above). According to Article 15c of the TSV the keeper of equidae have to notify to the animal database within 30 days the movement of equidae to other holdings if the equidae stay there longer than 30 days.

⁵ In their response to the draft report the CA stated that by the end 2012 around 90% of the entire equine population in Switzerland has been registered/recorded in the database.

The audit team noted that

• in cases where the stay at the intermediate premises was only for some hours, the movement in and out of the premises was often not notified to the database. In one case the OV stated that it is not necessary to record a market as an intermediate premises when the move from source holding to destination holding was completed within the same day. In another case the responsible OV had identified the practice some months prior to this audit and had instructed the dealer that the involvement of the dealer should be registered for all calves assembled and distributed, and their movement should be notified to the database.

Conclusions

In general, the traceability system in place is well established and implemented with the following exception: the requirement, introduced in Swiss legislation in 2009, that all movements through intermediate premises, even when the total movement form source to destination holding is completed in less than one day, must be notified to the database, is not effectively enforced. This compromises the entire traceability system as many contacts with cattle from other holdings are not recorded and these unknown contacts might cause, in the case of an outbreak, an epidemiological challenge and an obstacle to successful early disease eradication.

The Swiss requirements in respect of registration of equine holdings and the notification of equine movements strengthen the system for tracing of equidae.

5.4 DISEASE AWARENESS AND DISEASE NOTIFICATION

Legal requirements

The Veterinary Annex determines in Title I [Trade in live animals, their semen, ova and embryos] Article 2.1 that the parties hereby note that they have similar legislation leading to identical results with regard to measures for the control and notification of animal diseases. Appendix 1 to the Veterinary Agreement specifies the Swiss standards and special rules applicable

Findings

The level of disease awareness within the farming society is, in general, high due to targeted campaigns and continuous training of veterinarians, as well as by maintaining a well updated webpage where extensive information and adequate guidance can be found in relation to all these diseases⁶.

⁶ Information about animal health issues, in particular regarding highly infectious diseases and

There is a list of all notifiable and reportable diseases broken down by diseases being highly infectious, and diseases to be eradicated, to be controlled or to be monitored (Article 2 to 5 of the TSV).

All kind of animal handlers have to immediately inform a veterinarian about any suspicion of an infectious disease (Article 61 of the TSV). The BVET compiles the disease control data weekly, publishes it in the official journal⁵ (Article 65 of the TSV) and forwards yearly to the European Commission services details of the occurrence of diseases in accordance with Article 8 of Council Directive 64/432/EEC.

According to Point XII of Appendix 1 of Annex 11 to the Agricultural Agreement, Switzerland is integrated into the animal disease notification system [ADNS] provided for in Council Directive 82/894/EEC.

Following Article 129 of the TSV, animal keepers have to notify to the KVA abortions of cows more than 3 months pregnant and abortions of ewes, goats and sows at any time of pregnancy. The OV has to investigate the reason if the abortion happened in a dealer's premises, during summer grazing in mountain areas [Sömmerung] or if it is the second or more abortion in the holding.

The audit team noted that

- concerning the awareness campaigns, information has been made available to horse owners by BVET. However, amongst those met by the audit team, there was no knowledge about the threat posed by EIA, in general, or in particular concerning the recent case affecting several countries in Europe related to transmission of the disease through equine blood products; and this despite the fact that they are travelling routinely around Europe;
- the list of notifiable disease comprises all diseases which are supposed to be listed according to EU legislation;
- the number of notifications of abortions of ewes and goats is lower than would be expected in these population groups;
- early in 2011 the BVET introduced the concept 'exclusion diagnosis' which comprises the following:

According to EU legislation, in the case of a suspicion of a highly infectious disease such as FMD, the veterinary practitioner is obliged to notify to the CA any suspicion of FMD without delay [in the case of FMD Article 4 of Council Directive 2003/85/EC] and the CA has to apply immediately precautionary and restrictive measures. In Switzerland, following Article 62.2 of the TSV, the veterinary practitioner is obliged to notify to the CVA an outbreak or a suspicion of outbreak of a highly infectious disease. TWs detail the criteria for suspect cases for highly infectious diseases. Where, however, the presence of an epizootic disease, such as FMD, CSF, AI or ND, is not the most likely cause of the condition

⁵ the Official Journal [Mitteilungen BVET] are publicly available at the BVET – website:

encountered but cannot be unequivocally excluded, the veterinary practitioner submits samples of animals suffering from a disease to the IVI and discusses the case with the IVI experts. They examine the samples within 48 hrs. at latest and, should they consider at any moment that the case is likely to be any suspected exotic disease or the test result turns out positive, they inform the BVET immediately.

According to the BVET, this approach increases the sensitivity of the surveillance system and can surely contribute to the early detection of the incursion of an exotic or emerging disease. They added that since its advent this policy has demonstrated its effectiveness as there has been a significant increase in the number of cases notified and investigated in the context of this initiative; for instance, since February 2011, there have been 12 cases investigated to exclude the presence of FMD and 29 to exclude CSF.

According to representatives of the BVET and the IVI, the ND outbreak in Canton Neuchâtel in 2011 would have been delayed recognised without the tool 'exclusion diagnosis'.

Conclusions

Concerning the notification procedure of highly infectious diseases, the Swiss approach of the 'exclusion diagnosis' has the potential, on one side, to increase the likelihood of detection of an outbreak of a highly infectious disease at an early stage by increasing the number of samples submitted to the laboratory. On the other side, following the concept 'exclusion diagnosis', there may be a theoretical risk for delayed application and enforcement of appropriate disease control measures. However, the experience to date in Switzerland has proven that it even shortens the reaction period.

5.5 CONTINGENCY PLANNING

Legal requirements

The Veterinary Annex determines in Title [Trade in live animals, their semen, ova and embryos] Article 2.1 that the parties hereby note that they have similar legislation leading to identical results with regard to measures for the control and notification of animal diseases; and, in particular,

• Swiss contingency planning is set out in the TSV in a general way supported by specific emergency plans for the relevant diseases [Notfalldokumente für hochansteckende Seuchen]; (Corresponding EU legislation requires the MS to draw up CP taking into account certain criteria as laid down in Council Directives for FMD, AI, CSF, African Swine Fever (ASF), ND, African Horse Sickness (AHS), BT and SVD, which include the requirement [Article 21 of Council Directive 92/119/EEC] to prepare CP for following epizootics: Rinderpest

(RP), Peste des Petits Ruminants (PPR), Epizootic Haemorrhagic Disease (EHD), Sheep and Goat Pox, Vesicular Stomatitis (VS), Lumpy Skin Disease (LSD) and Rift Valley Fever (RVF)).

Findings

At federal level a general CP which includes Standard Operational Procedures (SOP) and TW is present and publicly accessible on the website of BVET. There are also available, protected by a password, more detailed CP's for FMD, CSF (including in wild boars), ASF and AI (including AI in wild birds) but for BT.

The audit team noted that

at federal level

- CPs were not elaborated for all epizootics covered by EU legislation. According to the BVET, the current general CP and the specific CPs cover a wide range of viruses and all action procedures, instructions, control measures, templates, contact lists etc. are part of the CPs;
- the BVET distinguish three alert levels: normal [= peace time], special [= outbreak of a highly infectious disease in a neighbouring country or a small local epizootic episode] and emergency [= outbreak of a highly infectious disease]. In the emergency case, a National Disease Crisis Centre is set up in the building of BVET and a special group, the Emergency Response Team (ERT) tackles the daily operation when combating the epizootic in accordance with the relevant CP;
- in order to guarantee a rapid and effective decision-making process for dealing with an epizootic, the ERT and the cantonal crisis centres are part of the chain of command;
- although ample expertise about various epizootics and their control is readily available at the IVI and at the Vetsuisse Faculty, no permanently operational expert group exists in the sense of the criteria for CP fixed in the various pieces of EU legislation laying down measures to control outbreaks of epizootic diseases (e.g. FMD, CSF, ASF, HPAI)⁷. The main weakness in this respect is that, according to those pieces of EU legislation, the expert groups need to be operational not only in case of an outbreak, but also in peace time, in order to maintain a formalised expertise for each and every relevant disease, and to assist the CAs in ensuring preparedness against any outbreak of highly contagious diseases.
- an independent evaluation of the nationwide real-time simulation exercise on FMD "NOSOS", performed in 2011, revealed some weak points which are still under internal discussion:

⁷ In their response to the draft report the CA stated that the IVI is affiliated to the BVET and the Swiss chief veterinary officer is member of the Vetsuisse Faculty Board [Fakultätskollegium]. Thus, the availability of experts is always ensured in the event of an outbreak of an epizootic disease.

- It was recognized that the rendering of carcasses might be the bottleneck of successful disease control. Some Cantons have already assessed the need for spare capacities of the two rendering plants operating in Switzerland in the case of major epizootics but nowhere has the veterinary service fixed, on contractual basis with the privately owned rendering companies, their obligation for disposal of the carcasses in a worse case scenario. In some Cantons, the BVET, in cooperation with the environmental authorities, and in agreement with the cantonal authorities has already determined appropriate sites for treatment or mass disposal of animal carcasses and animal waste in the event of an epizootic.
- As BVET considers that a "vaccination-to-live" strategy in Switzerland in an early phase of the epizootic has no benefit for a successful disease control (as long as culling on infected holdings is done within 1-3 days and commitment of farmers to movement restrictions is sufficient), the opportunity to train staff in emergency vaccination was not used during NOSOS.
- The insufficient cooperation of the Cantons involved in NOSOS in making available or sharing equipment necessary to tackle the outbreak has limited the successful response of the veterinary service to the challenges of the epizootic.
- The exchange of data related to control measures between the Cantons involved in NOSOS, as well as the data communication to the BVET and from the BVET to the Cantons, were not always sufficiently ensured.

at cantonal level

- the implementation of the federal CP is the responsibility of each Canton. In consequence, the adaptation of the CP to cantonal needs, the cooperation with other authorities such as the Cantonal Catastrophic Unit, the Chemical Emergency Group or a special unit of the police, and the documentation available and the availability of the documentation varies considerably between the Cantons. Thus, some Cantons visited refer to the information about CP on the BVET-website; other Cantons, in order to properly implement the federal CP, have developed their own "Pläne zur Seuchenwehr"; in some Cantons very well implemented plans were available to all staff on the Intranet and in one Canton the documentation was a single file directly available to the chief officer of the KVA;
- concerning human resources, in a few Cantons visited, teams for emergency culling were nominated and trained. In no Canton visited had vaccination teams been formed. It was explained that the KVÄ rely on the existing structure of veterinary practitioners who already perform other official tasks such as blood sampling for monitoring and certification of live animal for exports;
- concerning emergency kits, in all Cantons visited emergency suitcases delivered by BVET were available. In some Cantons, a lot of these suitcases are in storage but in other Cantons the quantity of equipment is suitable for the Index herd only. Moreover, in many cases the disinfectant or the tubes for sampling had expired and sometimes disinfectant was not present at all. No controls on the emergency equipment had been carried out at the Cantons

visited;

Swiss legislation requires animal transport vehicles to be cleansed and disinfected after use
and facilities are provided at slaughterhouses. Concerning biosecurity at the assembly
centres, dealers' premises and at the slaughterhouse visited, the cleaning and disinfection of
the animal transport vehicles was poor, not recorded and not supervised by the operator or
by the OV.

Conclusions

The Swiss veterinary service, federal and cantonal, is, in general, well prepared to tackle even major epizootics.

The implementation of the contingency requirements by the KVÄ varies to the extent that it could be an obstacle to the successful combating of an epizootic. For some epizootics (BT, AHS, PPR, LSD and VS etc.) no tailor-made CP have been developed but it appears that the use of the existing tools for disease control are sufficient to address such challenges properly.

Whilst the BVET has already taken or will take measures in order to address the weak points in contingency planning as identified in the course of the NOSOS simulation exercise such as carcass treatment and disposal and emergency vaccination (both protective and suppressive), other deficiencies identified by the audit team may limit the efforts made by the CA to successfully combat any epizootic occurring on the Swiss territory: (1) the poor biosecurity measures applied by animal transport vehicles delivering animals to assembly centres, dealers' premises and slaughterhouses might not avoid an unpredictable virus spread in the case of an outbreak, and (2) the absence of a permanently operational expert group overlooks the advantage of using this expertise and assistance in peace times in order to increase disease preparedness for all highly contagious diseases amongst all relevant stakeholders and mainly within the BVET.

5.6 DISEASE SURVEILLANCE AND MONITORING

Legal requirements

The Veterinary Annex determines that the EU and the Swiss requirements for animal health controls are essentially consistent with each other and produce the same results, in particular

 Article 291 to 312 of the TSV set out the conditions for disease surveillance and monitoring (corresponding EU requirements are contained in Council Directives 64/432/EEC (cattle and pigs), 91/68/EEC (sheep and goats), 2009/156 (equidae) and 2009/158/EC (poultry) and for disease control Council Directives 92/35/EEC (AHS), 92/66/EEC (ND), 92/119/EEC (SVD, PPR, VS, LSD, RP, RVF and EHD), 2000/75/EC (BT), 2001/89/EC (CSF), 2002/60/EC (ASF), 2003/85/EC (FMD) and 2005/94/EC (AI)).

Findings

Switzerland has a very favourable animal health status (see also Chapter 4.3 of this report) and the epidemiological surveillance of animal diseases has been well developed for years.

5.6.1 Active surveillance

The audit team noted that

- BVET has set up adequate risk-based serological surveillance for a number of diseases that have been eradicated for many years in Switzerland, such as brucellosis in small ruminants, EBL, IBR/IPV and Aujeszky's disease. The detailed annual plans for serological surveillance are effectively implemented by the KVÄ;
- in the context of the above mentioned risk-based approach to disease surveillance, the BVET was in the process of developing a new comprehensive epidemiological data management and analysis set of tools that were already facilitating the continuous adaptation of the epidemio-surveillance systems in place to the evolution of the situation for different diseases and their related risk factors throughout the country.

5.6.2 Laboratory performance

The audit team noted that

- the entire laboratory network is well organised, which includes the appointment of an OV as laboratory coordinator, the maintenance of a high level of expertise, technical valid results and the use, at least at the National Reference Laboratories (NRLs), of validated SOPs which are accredited according to ISO 17025;
- in addition to the NRLs, the BVET has set up an extensive network of other NRLs for other diseases, such as brucellosis, bovine tuberculosis, EBL, IBR/IPV and Aujeszky's disease. It has also authorised a number of other laboratories, mainly accredited cantonal veterinary laboratories, to perform diagnosis of particular diseases;
- for most diseases and, with some exceptions, for most of the standard diagnostic techniques, the NRLs had organised inter-laboratory comparison tests to verify the operation of the other authorised laboratories. In all cases evaluated, these tests had been organised in a satisfactory manner and their results showed the good performance of the laboratories involved

5.6.3 Surveillance of particular diseases

The audit team noted that

- the surveillance system for brucellosis in place is based on investigation of abortions in cattle and, mainly, small ruminants. However,
 - there is in use a restricted diagnostic protocol followed by laboratories other than the NRL authorised to perform this diagnosis;
 - the number of investigations carried out in sheep and goats is limited (see also chapter 5.3 of this report); and
 - the test method used by authorised cantonal laboratories [microscopy with Køster staining as a preliminary screening test] is neither described in Annex C to Council Directive 64/432/EEC nor in the relevant chapters of the OIE Manual⁸.

In the case of a negative result, the presence of *Brucella spp*. infection is excluded. Where results are inconclusive, they perform an ELISA test on blood from the aborted animal and, if the result is negative, the presence of brucellosis is excluded too. These laboratories do not perform bacteriological culture to try to isolate *Brucella spp*. from uterine discharges, placental tissues or aborted foetuses;

- very limited attention is paid to surveillance of Tb in the context of inspection of carcasses in slaughterhouses as, according to data provided by the BVET, no cases are submitted for further investigation to the laboratory. Moreover, only the NRL, which receives just part of those few samples to be investigated, follows a diagnostic protocol sensitive enough to exclude the presence of the disease, with other involved laboratories not being in a position to do the same as they cannot use PCR or bacteriological culture to exclude the presence of *Mycobacteria spp*.. Representatives of the NRL met by the audit team conceded that investigations carried out by other laboratories using acid-fast staining of tissue samples sent from slaughterhouses as the screening diagnostic method before submitting the samples to the NRL for further investigation may not be sensitive enough to detect the disease;
- for years the BVET, in co-operation with the ovine and caprine sectors, has been implementing eradication programmes for Maedi-Visna and for CAE. The latter has been compulsory since 1998 and has been very successful as the incidence of flocks affected by the disease is very low and no clinical case has been found since 2009. Concerning the former, the eradication programme has gradually reduced the incidence of the disease, in particular in dairy flocks;
- a similar initiative is carried out to exclude the presence of AI in free-range poultry populations and a random serological survey is implemented throughout the year in a number of slaughterhouses. This is complemented by targeted surveillance on sentinel ducks populations in areas considered to bear a higher risk of introduction of the disease; e.g. around the *Bodensee*. In addition, there is a very extensive network of professionals

⁸ OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2012 accessible at

covering surveillance of poultry diseases that is centralised in, and organised from, the NRL for diagnosis of AI and ND in the Vetsuisse Faculty Zürich. This NRL provides extensive training to veterinary practitioners involved in the poultry sector and is the laboratory that also centralises most post-mortem disease investigations carried out in poultry in Switzerland:

• with regard to bluetongue, the BVET considers that the Swiss territory has been free of the disease since March 2012. The first case of bluetongue virus due to BTV serotype 8 in Switzerland was diagnosed in October 2007. Until the end of 2010, more than 70% of the target populations were vaccinated; until the end of 2011, in total 76 cases [160 animals from 70 different holdings]. The last virus positive animal was detected in winter 2010. Since January 2011, vaccination has been voluntary and the Cantons keep implementing serological surveillance in accordance with Regulation (EC) No 1266/2007.

Conclusions

The system set up by the BVET ensures systematic collection of pertinent epidemiological data that are orderly consolidated and evaluated in order to further refine and better organise disease surveillance for most infectious animal diseases relevant in the context of trade with MS of the EU. The main pillars of the system are an excellent system of passive surveillance, a well-functioning risk-based serological surveillance programme for certain diseases and a network of NRLs that can ensure adequate and prompt diagnosis for relevant exotic diseases.

However, the surveillance systems in place for brucellosis in ruminants, in particular sheep and goats, and for bovine tuberculosis, showed some gaps that could undermine their sensitivity. Diagnostic protocols in place to exclude the presence of both brucellosis [*B. abortus and melitensis*] and tuberculosis [*M. bovis*] in ruminants cannot be considered sufficiently sensitive⁹ and are not fully in line with international standards laid down in the OIE Manual. This compromises the position of the CAs to provide assurances in respect of the officially brucellosis free status of the Swiss bovine, ovine and caprine populations in accordance with EU requirements laid down in Annex A(II)(7) to Directive 64/432/EEC and Chapter 1(II) of Annex A to Directive 91/68/EEC and to run an effective surveillance system for bovine tuberculosis.

5.7 REQUIREMENTS FOR TRADE IN LIVE ANIMALS AND THEIR GERMINAL PRODUCTS

Legal requirements

Title I of the Veterinary Annex covers trade in live animals, their semen, ova and embryos. In

⁹ In their response to the draft report the Swiss CA stated that the surveillance of brucellosis and tuberculosis comprises different components, which undergo a permanent up-grading process. They added that any statement provided by the BVET in respect of the disease free status of any of the animal populations mentioned would be based on the information delivered by these different components of the brucellosis and tuberculosis surveillance system.

particular:

- Article 3 establishes that trade shall be carried-out in accordance with the legislation specified in Appendix 2 to the Annex. That legislation shall apply subject to the special rules and procedures laid down in that Appendix.
- Article 4 determines that with regard to imports from third countries the EU and Switzerland have similar legislation leading to identical results. The legislation applicable is specified in Appendix 3 to the Annex and is subject to the special rules and procedures laid down in that Appendix."
- Art. 6 establishes that checks on imports from TCs shall be carried out in accordance with the provisions set out in Appendix 5;
- Point 1 B. I. of Appendix 2 of the Annex to the Decision No 2/2004 of the Joint Veterinary Committee¹⁰ obliges the BVET to approve assembly centres as defined in Article 2 of Directive 64/432/EEC, to draw up lists of approved assembly centres, transporters and traders and to communicate them to the Joint Veterinary Committee.

Swiss requirements for animal transporters are set out by Article 25 and 26, for markets by Article 27 to 31, for dealers by Article 34 to 37*b* and for SCC, SSC and ECT by Article 50 to 58 of the TSV, each of them combined with specific TWs.

According to Point 1 of Chapter 1 of Appendix 5 to the Annex to the Agricultural Agreement, the KVÄ may, at the places of destination of animals and products, establish by means of non-discriminatory veterinary spot checks.

(corresponding EU requirements concerning trade of live bovine and porcine animals, animal health, hygiene and the traceability are laid down by Council Directive 64/432/EEC (Article 11 relates to assembly centres, Article 12 to animal transporters and Article 13 to dealers); concerning trade in live ovine and caprine animals by Council Directive 91/68/EEC (Article 8 a, b and c); concerning trade in live equine animals by Council Directive 2009/156/EC (Article 7); concerning trade in bovine semen and embryos by Council Directive 88/407/EEC and Council Directive 89/556/EEC, respectively, and concerning trade in equine semen and embryos by Council Directive 92/65/EEC.)

5.7.1 Requirements for trade in animals and their germinal products to the EU

5.7.1.1 Approval of establishments for trade with the EU

Findings

The approval of establishments for participation in export of live animals and their germinal products of the bovine, ovine, caprine, porcine and equine species to the EU is granted by the

¹⁰ The Joint Veterinary Committee of the Swiss Confederation and the EU established by Article 19(1) of Annex 11 to the Agriculture Agreement is responsible for considering any matter arising in connection with the Veterinary Annex and its implementation and for carrying out the tasks provided for therein. As a rule the Joint Veterinary Committee meets once a year.

competent KVA following an official inspection. In the case of a positive outcome of the inspection, an approval document will be issued where the permitted activities and their location are determined. The KVÄ are also responsible for the accuracy and weekly updating of their entries in the list of national EU approved establishments. These lists are displayed at the BVET website with a link to the SANCO website.

The audit team noted that

- Swiss legislation contains provisions for dealers' premises including the official supervision thereof [Article 34 to 37b] but does not contain similar requirements for assembly centres. The BVET has approved 14 assembly centre and has issued approval documents for the assembly centres visited containing some of the conditions set out in Council Directive 64/432/EEC. However, these approval documents do not contain a number of the requirements of Directive 64/432/EEC, particularly those contained in Articles 6.3 and 11, including:
 - the period during which the assembly of the cattle and pigs may take place outside the holding of origin is not limited to 6 days;
 - the assembly centre is not required to be under control of an OV who should determine the cleaning and disinfection procedures applied at the centre before use;
 - there is no requirement for the assembly centres to be regularly inspected to verify that the requirements for approval continue to be fulfilled
 - there is no requirement to keep records on animal health and for traceability.
- the approval for trade with the EU has been, in general, granted as required to the other establishments visited with the exception of the requirement that a dealer, within a maximum of 30 days of purchasing animals has to resell them or relocate them from the first premises to other premises [Article 2q of Council Directive 64/432/EEC];
- the lists of EU approved establishments¹¹ [version June 2012] contain several inaccuracies such as (1) two studs (equine) are twice mentioned in the list of approved ovine and caprine embryo collection teams (ECTs), (2) the name of the bovine SCC visited by the audit team differs from the actual one, (3) several indications of the species permitted to be transported or to be kept at dealers' premises are lacking.

5.7.1.2 Animal health controls on establishments approved for trade with the EU

There is a system of animal health controls in place on EU approved assembly centres, dealers, dealers' premises, animal transporters, SCCs, semen storage centres (SSCs) and ECTs.

The audit team noted that

11 The lists of EU approved establishments are published on the BVET website:

http://www.bvet.admin.ch/themen/ausfuhr/index.html

concerning dealers' premises

- at one EU approved dealers' premises visited, various activities take place such as keeping cattle permanently, trading cattle, performing markets / auctions / exhibitions and functioning as assembly centre. This latter activity was undertaken occasionally when a stable would be temporarily designated as the assembly centre and used exclusively for that purpose:
 - all these activities were operated under a single holding registration number [kantonale Identifikationsnummer] and movements within / between these facilities / activities were not recorded or notified to the database making it impossible to distinguish between cattle kept at the permanent herd, the dealers' premises, market and at the assembly centre;
 - at one of the two centres visited, no official controls have been performed to verify that assembling operations take place exclusively in designated stables;
 - although, according to the operator, the facilities were regularly cleaned and disinfected, no procedures in that respect were issued and no records have been kept;
 - some cattle were moved off the premises to own or rented pastures one of which was 15 km. distant from the premises. Also these movements were not notified to the database although the animals kept at these different locations do not longer form an epidemiological unit. Moreover, the responsible OV was not aware that cattle of the approved dealers' premises were kept on pastures far away from the premises;

concerning SCCs and the ECT visited and

- the centre / team veterinarians (CV / TV)
 - CV / TV have been approved and fulfil largely their duties as required by the TW for SCC and SSC [Technische Weisungen über sanitarische Anforderungen an Produktion, Lagerung, Abgabe und Übertragung von Samen der Rinder-, Schaf-, Ziegen- und Schweinegattung vom 12. März 2012] and ECT [Technische Weisungen über seuchenpolizeiliche Anforderungen an die Durchführung des Embryotransfers und die Gewinnung von Eizellen von Rindern, Pferden, Schafen / Ziegen und Schweinen vom 8. September 2008];
 - the arrangements for visitors are satisfactory, in particular the solution not to allow visitors access into the facilities but to show the bulls outside, separated from the visitors by the boundary fence;
- the infrastructure of the facilities including the quarantine accommodation was adequate and contact with livestock outside was prevented;
- the hygiene conditions at all locations seen were satisfactory with some minor exceptions:
 - outdoor collection of bovine semen is permitted without having issued a strict hygiene protocol;
 - the cleaning and disinfection of the small containers used for insulation of the fresh

semen transferred from the 'dirty' part (collection area) to the 'clean' part (processing laboratory) do not form part of the relevant SOP. The laboratory staff confirmed that these transport containers were never cleaned and disinfected. This may cause a risk of microbiological contamination of the tube filled with fresh semen;

 although the semen storage rooms present also a high standard of hygiene, the observed practice of handling the semen straws with uncovered fingers is poor hygienic behaviour.

animal health tests

- at the bovine SCC visited, the animal health tests of the bulls during the prequarantine and quarantine period and the routine testing of the bulls have been correctly performed using a test protocol which complies with Swiss (and EU) requirements;
- the movement record of one bull kept in the SCC was invalid (containing a number of unresolved and conflicting movements). As a consequence, its health status should have been considered suspect;
- when checking the requested print-out of the animal health files of the bulls present at the SCC, the audit team detected the report of one bull in the SCC tested positive for BT virus in blood. Requesting clarification, the BVET could demonstrate by submitting the original laboratory result that the positive result was a typing mistake by the SCC staff when transposing the laboratory results into the bull database of the SCC. The BVET explained that in the case of a positive test result of a highly infectious disease the IVI would immediately inform the BVET, but this would not happen in a case of BVD/MD serum conversion: a typing mistake "negative" instead of "positive" could have serious implications.

official supervision of the SCC

- inspections by the responsible OV have been carried out twice per year, using a detailed check-list, which has been, in general, duly completed. However, some entries in the check-list of the last official inspection do not match with the observations of the audit team:
 - the confirmation that the nitrogen has not been previously used for products of animal origin was provided by the cryogenic agent supplier only following the request of the audit team;
 - as the OV checks the animal health file from one bull only in the course of his half year inspections, the validity of the given statement in the check-list that health status of the bulls whose semen have been stored is in compliance with requirements is limited even when taking into account the obligation to notify to the competent KVA of any conspicuous health event at the SCC (No 40 of the TW).

5.7.1.3 Requirements for trade from the EU to Switzerland in live animals and their germinal products

Animals and the germinal products thereof can be imported if they meet the requirements for intra-Union trade;

The BVET is integrated in the Traces system;

The BVET is entitled to refuse the import of live animals into the Swiss territory, for example, due to disease outbreaks in the region / holding of origin;

The audit team noted that

- a non legally binding working instruction ["Spezielle Arbeitsanweisung für den Import von Rindern"] contains the obligation, in the sense of a strong advice, to take care that imported cattle were tested, on private bases, for BVD/MD prior to shipment into Switzerland. The BVET explained that, in such a way, both the introduction of persistent infected cattle into the Swiss territory and, on the other hand, trade obstacles [additional testing in a discriminatory manner] could be avoided.
- according to Point III of Chapter 1 of Appendix 5 to the Annex to the Agricultural Agreement, in order to preserve and promote mountain farming, in Switzerland special rules for movements of cattle when sent for Sömmerung apply, mutatis mutandis, as set out in Decision 2001/672/EC. The simplified model health certificate for bovine animals sent for grazing in border areas contain the requirement that the holding of origin of these cattle is not subject to restriction in connection with cattle diseases in accordance with EU or national legislation. The OV at the place of destination has to check the cattle and has to ensure that they comply with the standards laid down in this Annex. That means all cattle kept for Sömmerung on a cross-border pasture/s have to be checked for freedom of BVD/MD antigen, which makes, from a veterinary point of view, sense but, from a legal point of view, these checks could not be considered to be conducted in a non-discriminatory manner.

5.7.2 Requirements for the import from third countries into Switzerland of live animals and the germinal products thereof

Animals and germinal products thereof originating from third countries have to undergo the border inspection procedure either at the outer border of the EU or at the airports

- Zürich: animals [with the exception of ungulates and bi-ungulates] and animal products
- Genf: animals [with the exception of ungulates and bi-ungulates] and animal products
- Basel: pets exclusively

The audit team noted that

• at the SCC visited bovine semen was stored which originated from the United States,

Canada and New Zealand. The labelling on the semen straws checked by the audit team met the requirements and the corresponding the animal health documentation provided data about the EU eligibility of the semen;

• the report on an audit of the border inspection posts at the airport Zürich and Genf in 2010 carried out by the FFCU, provided by BVET to the audit team revealed minor weak points which were addressed within the granted period.

Conclusions

Establishment approvals for trade with the EU been granted by the KVÄ largely in accordance with conditions specified in the Agriculture Agreement, except that assembly centres and dealers premises have been approved without specifying some of the conditions necessary for such trade (e.g. maximum residency periods and separation of activities) with a consequent increased of risk of disease transmission due to a high level of animal contacts.

In addition the lists of EU approved establishments contain several inaccuracies.

At the SCCs and ECT visited, the performance of the centre / team veterinarian has been, in general, sufficient and the infrastructure and equipment are fit for purpose. The hygiene conditions have been in general satisfactory with some exceptions.

In general, the health testing of the bulls and its recording was satisfactory. However, official controls of the bovine SSC were insufficient, in particular, due to the very limited evaluation of information pertaining to the health status of the animals kept in the centre carried out during the routine half year inspections.

5.8 CERTIFICATION

Legal requirements

The Veterinary Annex determines that live animals and their germinal products traded between the EU and Switzerland shall be accompanied by health certificates in accordance with models set out in EU legislation.

Article 6 of Dir. 96/93/EC establishes that in the context of the audits to be carried out under the equivalence agreements between the Community and third countries, the Commission shall ensure that the rules and principles applied by third-country certifying officers offer guarantees at least equivalent to those laid down in this Directive.

Article 3 to 5 of the Regulation of import, transit and export requirements for animals and their germinal products [Verordnung über die Ein-, Durch- und Ausfuhr von Tieren und Tierprodukten 916.443.10 vom 18. April 2007] cover the conditions of certification of live animals.

Article 23 of the EDAV requires the KVÄ to launch a TRACES message and to issue a health certificate which has to accompany the consignment to its destination in the EU.

Findings

Health certification for export of live animals and their germinal products can be carried out by veterinary practitioners appointed by the CA as OV for export certification.

The audit team noted that

- in the Cantons visited, the certifying OVs had not received special training for certification. On the BVET web-site, advice is given to complete the certificates correctly and in cases of doubt to check the relevant EU legislation if the consignment is intended for trade with the EU¹²;
- there is no accessible and updated information system established ensuring that the certifying OV receive all necessary animal health information in time and in all cases;
- at the bovine SCC visited, the certifying OV does not [1] carry out physical verification of the consignment of bovine semen prior to sealing and shipment, and [2] does not check any animal health file of the bulls whose semen will be exported including his residency history and his current health status.

Conclusion

The certification procedures in place for the export of live animals and their germinal products to the EU are reliable, even though some of the principles of certification were not fully respected.

6 Overall Conclusions

The Swiss legal requirements for the control of animal diseases are, in general, essentially consistent with the EU legislation and aimed at producing the same results.

Switzerland has a very favourable animal health status. The CA has implemented an excellent system of passive surveillance, a well-functioning risk-based serological surveillance programme for a number of diseases relevant in the context of trade with the EU, a reliable diagnostic laboratory network and is well prepared to tackle even major outbreaks of highly infectious

¹² In their response to the draft report the Swiss CA stated that in 2012 the BVET has offered training regarding certification procedures in the course of the annual training session for OVs.

diseases. However, the surveillance systems for bovine tuberculosis and for brucellosis cannot be considered sufficiently robust, due to inadequate design and operation of certain important components of those systems which could diminish their sensitivity and, consequently, undermine the position of the CA to provide assurances in respect of the health status of the Swiss ruminant population.

A number of official control elements, such as the introduction of the concept of 'exclusion diagnosis' and the registration of equine holdings and the notification to the database of movement of equidae to another holding for more than 30 days, significantly enhance the effectiveness of the control system, which is further strengthened by the quality and frequency of official controls of animal holdings. However, other elements have the potential to weaken the system, such as the insufficiency of controls of assembly centres and animal dealers.

The CA, both federal and cantonal, operate efficient, effective and well co-ordinated control systems. While verification systems, including audit of the Cantons by the federal authority, are in place, there has not yet been any audit in the field of animal health and there is significant reliance on mutual trust between colleagues.

A sophisticated and well developed traceability system is in place. However, enforcement of Swiss requirements for notification of animal movements through markets and dealers was not fully effective and this could reduce the ability of the system to identify and trace contact animals in the case of a disease outbreak. The variety of activities which may take place on the same holding (assembly centre, dealership, commercial holding) also compromises traceability and disease control.

At the bovine SSC visited, due to the limited number of animal health files checked by the OV, the official controls of the animal health files were insufficient. This, coupled with deficiencies in pre-export inspection of consignments, weakens, to some extent, the reliability of the certification system.

7 CLOSING MEETING

A closing meeting was held on 19th October 2012 in Bern with representatives of the *Bundesamt für Veterinärwesen*. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team.

8 RECOMMENDATIONS

The Swiss authorities are invited, in the light of the findings described in this report and the conclusions drawn upon them and the special rules established in the Agriculture Agreement, to address the following recommendations:

N°.	Recommendation
1.	To strengthen the approval conditions applicable to assembly centres, dealers' premises

N°.	Recommendation
	and SCCs.
2.	To further improve the control systems in place in line with the principles established in Reg. 882/2004, in particular, in relation to prioritisation of controls, supervision of the performance of controls and measures to avoid conflict of interest.
3.	To further develop the quality of contingency planning, taking into account the lessons learned from the 2011 NOSOS exercise, in particular, in respect of the coordination of the implementation measures by the Cantons, the mass disposal or treatment of carcasses, the preparation for protective or suppressive vaccination and the establishment of expert groups.
4.	To enhance and to officially control basic biosecurity measures at animal holdings, slaughterhouses, dealers' premises, markets and assembly centres.
5.	To improve the surveillance system in place for brucellosis [Brucella abortus and melitensis] and tuberculosis [Mycobacterium bovis] in order to strengthen the assurances given in respect of the brucellosis and tuberculosis free status of Switzerland.
6.	To enforce movement notification requirements for cattle and to optimise the traceability system in place for cattle, pigs and sheep intended to be exported to the EU.
7.	To further improve the standards applied at SCC, in particular in respect of hygiene conditions and the official supervision of the SCC.
8.	To provide additional guidance to certifiying officials and to ensure that all necessary information is available to or checked by them.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6389

Annex 1 - Legal References

Legal Reference	Official Journal	Title		
General legislation	General legislation			
Reg. 882/2004	p. 1, Corrected and	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		
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		
Animal Health require	ements relating to trade			
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine		
Dir. 91/68/EEC	OJ L 46, 19.2.1991, p. 19-36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals		
Dir. 82/894/EEC	OJ L 378, 31.12.1982, p. 58-62	Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community		
Dir. 2004/68/EC	p. 321-360. Corrected	Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC		

Legal Reference	Official Journal	Title		
Dir. 2009/156/EC	OJ L 192, 23.7.2010, p. 1-24	Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae		
Dir. 88/407/EEC	OJ L 194, 22.7.1988, p. 10-23	Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra- Community trade in and imports of deep-frozen semen of domestic animals of the bovine species		
Dir. 89/556/EEC	OJ L 302, 19.10.1989, p. 1-11	Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species		
Reg. 599/2004	OJ L 94, 31.3.2004, p. 44-56	Commission Regulation (EC) No 599/2004 of 30 March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin		
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		
Dec. 2004/292/EC	OJ L 94, 31.3.2004, p. 63-64	2004/292/EC: Commission Decision of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC		
Epizootic disease conti	Epizootic disease control			
Dir. 2003/85/EC	OJ L 306, 22.11.2003, p. 1-87	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC		
Dir. 2000/75/EC	OJ L 327, 22.12.2000, p. 74-83	Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue		

Legal Reference	Official Journal	Title
Dir. 2001/89/EC	OJ L 316, 1.12.2001, p. 5-35	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
Dir. 2002/60/EC	OJ L 192, 20.7.2002, p. 27-46	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever
Dir. 92/119/EEC	OJ L 62, 15.3.1993, p. 69-85	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
Dir. 92/35/EEC	OJ L 157, 10.6.1992, p. 19-27	Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness
Dir. 2005/94/EC	OJ L 10, 14.1.2006, p. 16-65	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Dir. 92/66/EEC	OJ L 260, 5.9.1992, p. 1-20	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease
Animal identification	and movement control	
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. 1082/2003	OJ L 156, 25.6.2003, p. 9-12	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals

Legal Reference	Official Journal	Title
Reg. 21/2004	OJ L 5, 9.1.2004, p. 8-17	Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC
Reg. 1505/2006	OJ L 280, 12.10.2006, p. 3-6	Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals
Dec. 2006/968/EC	OJ L 401, 30.12.2006, p. 41-45	2006/968/EC: Commission Decision of 15 December 2006 implementing Council Regulation (EC) No 21/2004 as regards guidelines and procedures for the electronic identification of ovine and caprine animals
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae