EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2014-7212 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BOSNIA AND HERZEGOVINA

FROM 21 TO 31 JANUARY 2014

IN ORDER TO EVALUATE THE CONTROLS OVER THE PRODUCTION AND PROCESSING OF DAIRY PRODUCTS INTENDED FOR EXPORT TO THE EU

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 Bosnia and Herzegovina (BiH) from 21 to 31 January 2014. The objective of the audit was to evaluate the operation of controls over the production of dairy products for human consumption intended for export to the European Union (EU), as well as certification procedures.

The organisation of the veterinary service with its veterinary departments and inspectorates reflects the constitutional organisation of BiH. On 17 July 2013, a Protocol was signed between the various entities appointing the State Veterinary Office (SVO) as the body responsible for organising official controls of milk and dairy products for export to the EU. Further developments (contracts and agreements) are necessary to give full effect to this Protocol.

Currently, the organisation of official controls is neither efficient nor effective. No detailed instructions are in place and controls are not consistent. The lack of efficient supervision and power to ensure that corrective actions are taken weakens the performance of controls.

The quality of raw milk is of a major concern. Only very few milk production holdings meet the EU raw milk quality criteria for which the quantity of raw milk produced cannot cover the production of dairy products intended for export the the EU.

The animal identification and registration system as it stands today is not robust and reliable.

While major efforts have been made to identify non-compliances on milk production holdings and to implement and verify corrective actions, this work has started only recently and not all holdings have been evaluated.

The laboratory services are technically capable of testing for the raw milk quality parameters specified in Regulation (EC) No 853/2004. However, there are deficiencies in the report of results to dairy processing establishments and the CAs which hinder the implementation of effective controls.

The certification procedures in place are not robust and cannot be considered reliable. Misleading statements indicating that dairy products exported to other countries meet relevant EU requirements are certified.

The report makes a number of recommendations to the Competent Authorities (CAs) to assist the further development of the control systems so as to be in a position to export milk and dairy products to the EU.

Table of Contents

1 Introduction 1
2 Objectives 1
3 Legal Basis 2
4 Background 2
4.1 Background 2
4.2 Production and trade information (provided by the CCA) 2
4.2.1 Livestock 2
4.2.2 Dairy production 2
5 Findings And Conclusions 3
5.1 Legislation and competent authorities 3
5.1.1 Legislation 3
5.1.2 Competent Authorities 4
5.2 Animal health situation 8
5.2.1 Notification of disease outbreaks 8
5.2.2 Foot-and-mouth disease 9
5.2.3 Tuberculosis 9
5.2.4 Bovine brucellosis 9
5.3 Approval and listing of establishments 10
5.4 Official controls over food business operator at establishment level 11
5.4.1 General and specific hygiene requirements 11
5.4.2 HACCP-based systems 11
5.4.3 Traceability, labelling and identification marking 11
5.4.4 Health requirements and criteria for raw milk 11
5.5 Holding registration, animal identification and movement controls 12
5.5.1 Holding registration 12
5.5.2 Animal identification and registration 13
5.5.3 Movement controls 13
5.6 Application of hygiene rules on milk production holdings and official controls 14
5.7 Laboratory services 15
5.8 Official certification 16
6 Overall Conclusions 17
7 Closing Meeting 17
8 Recommendations 17
Annex 1 - Legal References 19

Abbreviations and definitions used in this report

Abbreviation	Explanation
The Agency	The animal identification and movement control agency
BD	Brčko District
BiH	Bosnia and Herzegovina - comprising the entities RS and FbiH and the Brčko District (the ISO 2 letter code used in Regulation (EU) No 605/2010 is BA)
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
DG(SANCO)	Health & Consumers Directorate General
EC	European Community
EU	European Union
FBiH	Federation of Bosnia and Herzegovina
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
Model certificate HTC	Model Certificate for heat treated dairy products from cow milk (Column C of Regulation (EU) No 605/2010)
OIE	*Organisation International des Épizooties*
RS	Republic of Srpska
SCC	Somatic Cell Count
SVO	State Veterinary Office
TPC	Total Plate Count

1 Introduction

The audit took place in Bosnia and Herzegovina (BiH) from 21 to 31 January 2014 as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO.

The FVO audit team was accompanied during the audit by representatives from the Central Competent Authority (CCA), the State Veterinary Office of BiH (SVO).

The opening meeting was held on 21 January 2014 with the CCA in Sarajevo. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

2 Objectives

The objective of the audit was to evaluate the operation of controls over the production of dairy products for human consumption intended for export to the EU, as well as certification procedures.

The scope of the audit covered:

- Competent Authority (CA) organisation and operation;
- official controls over food business operators at dairy processing establishments and milk production holdings;
- the correct implementation of the chain of certification.

In particular, controls over raw milk and dairy products in the framework of Regulations (EU) No 605/2010 were subject to this evaluation.

In pursuit of these objectives, the mission itinerary included the following:

MEETINGS/VISITS	NO	COMMENTS
COMPETENT AUTHORITIES		
Central and regional CA	4	Opening and closing meetings, meetings with the CAs from the entities the Federation Bosnia and Herzegovina (FBiH) and the Republic of Srpska (RS)
Local CA	8	Meetings with the cantonal (FBiH) and municipality CAs (RS) at the sites visited
Food production / processing / distribution – Activities		
Central Bovine Database	1	
Laboratories	2	One laboratory in the FBiH and one laboratory in the RS, both performing milk testing
Milk production holdings	4	Three farms considered as being compliant with EU requirements, one farm withdrawn from proposed list
Dairy processing establishments	4	Candidates for export to the EU

3 Legal Basis

The audit was carried out under the general provisions of European Union (EU) legislation and, in particular Article 46 of Regulation (EU) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

A full list of EU legal references referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

4.1 Background

This was the first audit on this topic and it took place after the CCA proposed five establishments to be listed for export of heat treated dairy products from cow milk to the EU (column C of Regulation (EU) No 605/2010).

Commission Decision 2011/163/EU indicates that the National Residue Monitoring Plan of BiH is approved for milk amongst other commodities.

4.2 Production and trade information (provided by the CCA)

Prior to the accession of Croatia to the EU, Croatia represented a significant market for the export of milk and dairy products from BiH. As a consequence of Croatia's accession, milk exports from BiH must satisfy the relevant EU requirements and no exports have taken places since 1 July 2013.

The SVO supplied detailed production data, which are summarised below.

4.2.1 Livestock

207 270 holdings are registered with a total of 1 264 600 bovine animals recorded in the central bovine database of which 1 148 487 are considered as alive in the central bovine database.

Based on information provided at the opening meeting, the livestock population is 445 000 cattle of which 109 425 are dairy cattle.

4.2.2 Dairy production

There are 36 authorised dairy processing establishments in BiH which provided the following production information for 2013:

Liquid milk (l)	143 046 355
Milk powder (kg)	18 027
Butter (kg)	498 157
Cheeses (kg)	4 641 882
Creams (kg)	16 175 022

Spread creams (kg)	405 663
Fermented products (kg)	27 047 029

5 Findings And Conclusions

5.1 Legislation and competent authorities

Legal basis

Article 46.1 of Regulation (EC) No 882/2004 stipulates that official controls by Commission experts in third countries shall verify compliance or equivalence of third country legislation and systems with EU feed and food law, and EU animal health legislation. These controls shall have particular regard to points (a) to (e) and (g) of the aforementioned Article.

5.1.1 Legislation

Findings

At central level, several laws and implementing measures covering different areas within the scope of the audit have been put in place aiming to harmonise BiH with EU legislation, amongst them:

- Veterinary Law in BiH (BiH official gazette no 34/02);
- BiH Food Law (BiH official gazette no 50/04) – corresponding to Regulation (EC) No 178/2002;
- Book of Rules on the hygiene of foodstuffs (BiH official gazette no 4/13)- corresponding to Regulation (EC) No 852/2004;
- Book of Rules on the hygiene of food of animal origin (BiH official gazette no 103/12) – corresponding to Regulation (EC) No 853/2004);
- Book of Rules for the organisation of official controls on products of animal origin intended for human consumption (BiH official gazette no 103/12) – corresponding to Regulation (EC) No 854/2004;
- Book of Rules for official controls performed to ensure the verification of compliance with food and feed law, animal health and animal welfare (BiH official gazette no 5/13) – corresponding to Regulation (EC) No 882/2004;
- Book of Rules on microbiological criteria for foodstuffs (BiH official gazette no 11/13) – corresponding to Regulation (EC) No 2073/2005;
- Decision on monitoring certain substances and residues thereof in live animals and animal products (BiH official gazette no 1/04, 40/09 and 44/11) – corresponding to Council Directive 96/23/EC;
- Decision on the ban of use on animals of certain beta-agonists and substances with hormonal and tireostatic effect (BiH official gazette no 74/10) -corresponding to Council Directive 96/22/EC;
- Book of Rules on the manner of approving establishments dealing with breeding of live animals, production, treatment, processing and storage of products of animal origin for the purpose of export to the EU market (BiH official gazette no 102/12);
- Rules on drinking water safety (BiH official gazette no 40/10, 43/10, 30/12) - corresponding

to Council Directive 98/83/EC;

- Decision on the veterinary certificate certifying the health status of animals and products of animal origin in domestic and international trade (BiH official gazette no 33/03, 14/04 and 35/05) – corresponding to Council Directive 96/93/EC, but not entirely. It also regulates certification within BiH;
- Book of Rules on general labelling of pre-packaged food (BiH official gazette no 87/08) – corresponding to Directive 2000/13/EC and the Rulebook on providing information to the consumers about food (BiH gazette no 68/13). Certain parts of this rulebook came into force on 1st January 2014, some will come into force on 13 December 2014 and some on 13 December 2016;
- Book of Rules on food additives save for food colourings and sweeteners (BiH official gazette no 83/08) – corresponding to Regulation (EC) No 1333/2008;
- Book of Rules on plastic materials and articles intended to come into contact with food (BiH official gazette no 42/10 and 82/11) – corresponding to Regulation (EU) No 10/2011;
- Rules on animal tagging and animal movement control scheme in BiH (BiH official gazette no 28/03);
- Rules on animal tagging and movement control in BiH (BiH official gazette no 13/10);
- Rules on amendments to the Rules on animal tagging and movement control in BiH (BiH official gazette no 79/10, 25/1, 103/11 and 41/12);
- Decision concerning contagious animal diseases (BiH official gazette no 44/03);
- Order concerning measures of control of contagious and parasitic animal diseases, implementation and funding thereof in the year 2013 (BiH official gazette no 6/13);

The transposition of Regulation (EC) No 1162/2009 into a Book of Rules has been drafted and has been sent to the entities awaiting their comments/consent.

Conclusions

A solid legal basis has been established for the production of dairy products intended for export to the EU, in line with relevant EU requirements.

5.1.2 Competent Authorities

Findings

The organisation of the veterinary service reflects the constitutional organisation of BiH and comprises the following institutions:

5.1.2.1 The SVO

The SVO operates as the CCA under the Ministry of Foreign Trade and Economic Relations. In December 2000 the SVO was established as an umbrella institution at state level in order to ensure integrity in the functioning of veterinary services in BiH. The SVO has five operational Departments: the Departments for Animal Health and Welfare, the Food Safety and conditions in Establishments, the Veterinary Inspection, the Border Veterinary Inspection and the Animal Identification and Movement Controls Agency (hereafter referred to as the Agency). Within its jurisdiction the SVO amongst other tasks, proposes legislation based on the Veterinary Law in BiH and co-operates with the international veterinary health and related institutions and associations.

5.1.2.2 The CAs at the entity and district levels

The CAs at the entity and district levels are as follows:

- The Ministry of Agriculture, Forestry and Water Management – veterinary sector in the entity of the Republic of Srpska (RS) and the inspectorate of the RS;
- The Ministry of Agriculture, Forestry and Water Management – veterinary sector in the entity of FBiH and the Federal administration for inspection – veterinary inspectorate;
- The veterinary sector of the Department of Agriculture in the Brčko District (BD) and the inspectorates at the offices of the mayor.

The primary responsibility of the relevant entity, the BD and the ten cantonal Ministries of Agriculture in FBiH (see chapter below) is development and promotion of animal breeding and plant cultivation, fishery and hunting, agriculture and forestry, food and feed industry, water protection, veterinary and phytosanitary issues, as well as public health protection for products of animal origin

These CAs in the veterinary field apply and implement the state level legislation and the Ministries enact their own legislation reflecting the specific characteristics of the areas of their responsibility.

5.1.2.3 The competent authorities at local level

The FBiH consists of 10 cantons, each covering several municipalities. Cantons have their own cantonal governments and ministries. Similar to the organisation of the CA at federal level there are veterinary sectors within the cantonal Ministries of Agriculture and veterinary inspectorates within eight independent cantonal administrations for inspection affairs. In two cantons, the veterinary inspectorate forms part of the cantonal Ministries of Agriculture.

The competent veterinary inspection authorities are organised within inspection administrations at entity level and cantonal, respectively municipality/city authorities. They are responsible for inspections/enforcement of veterinary legislation.

Federal legislation has stipulated that cantonal veterinary inspectorates shall report *inter alia* to the Federal Veterinary inspectorate (the veterinary inspection department of the SVO); however this provision has been made void by a decision of the Constitutional Court of the FBiH. In some of the municipalities there are veterinary inspectorates to which cantons have delegated official control tasks. These municipal inspectorates report to their mayors and to the corresponding cantons.

The bigger municipalities and/or those with larger animal production have municipal veterinary inspectorates, who report to the RS Veterinary Inspectorate. In other municipalities official controls are carried out by RS veterinary inspectors.

The veterinary inspectorate of the BD covers the entire territory of the BD.

5.1.2.4 The veterinary organisations

The veterinary organisations are private practices in the RS and private or public practices in the FBiH and the BD. The veterinary organisations are responsible for primary health care, but also carry out tasks delegated by the entity CAs such as sampling and testing for bovine brucellosis and tuberculosis.

5.1.2.5 Organisation of veterinary controls

On 17 July 2013, a Protocol was signed between the Minister of Foreign Trade and Economic

Relations and the two entity Minsters of Agriculture, Forestry and Water Management with consents from the cantonal premiers and the BD.

Signing this Protocol, the Ministers expressed the political will that the SVO is the central body responsible for the organisation of official controls of milk and their products intended for export to the EU and that the veterinary inspectors in charge of carrying out official controls at local level report directly to the SVO.

The latter is in the process of being further regulated via contracts on co-operation mutually signed by the SVO and the local CAs in which territory the dairy processing establishments and/or milk production holdings are located. At present, 15 contracts have been signed, 5 with cantons in the FBiH and 10 with municipalities in the RS.

The local CAs must regularly inform the SVO about the implementation of official controls of milk production holdings and dairy processing establishments intended for export to the EU, while the SVO carries out regular audits to verify the fulfilment of all contractual requirements by the local CAs.

The collaboration contracts define the mutual rights and obligations, the legislation that ought to be implemented, goals, items and conditions, resources, the manner of communication and exchange of information and the implementation of audit procedures. The local CAs must assign veterinary inspectors responsible for the implementation of official controls at both establishment and holding level, which they will report about on a monthly basis to the SVO.

Under the contract, the SVO adopts a unique plan for official controls of milk and dairy products intended for export to the EU, uniform criteria determining the frequency of inspection at dairy processing establishments, official sampling plan and a guidance on procedures that veterinarians should conduct prior to certification.

The contracts require that the SVO conducts audits of veterinary inspections at local level at least annually. The CCA further clarified that the local authorities shall prepare an action plan to address audit findings where non-compliance with the Act or non-conformity with the Co-operation Treaty are detected. Implementation of corrective measures shall be monitored through the co-ordination process. Co-ordination meetings between the SVO and the local CAs must be held at least bi-annually. The CCA may decide to temporary ban certification or withdraw establishments approval for EU export.

The implementation of the contracts is not yet complete and not all aspects could be fully evaluated during this audit.

The FVO audit team made the following observations:

- Although the BiH Veterinary Act stipulates that one of the tasks of the SVO, relevant bodies at the entity levels and BD is to issue binding instructions to the entire veterinary sector and veterinary organisations in line with the provisions of this Act, the FVO audit team has been informed by the CA that recommendations, instructions and guidelines could be given between different CA levels: from the SVO to the entities and local CAs; from the entity CAs to local CAs; and within the entities between the veterinary sectors and veterinary inspectorates. It is, however, not compulsory for the CAs to use those recommendations, instructions and guidelines.
- The current legislation and organisation of veterinary controls in place do not foresee supervision of the veterinary controls within the entities.
- The set-up of the audit structure from the SVO to the local CA is not sufficiently developed. The SVO has recently carried out two audits but a report with the results has not yet been

produced. Procedures are not developed yet on how to follow-up non-compliances identified during the SVO audits.

- The FVO audit team observed little evidence of co-ordination and co-operation between the different CAs. For example, the approval of EU eligible milk production holdings is carried out by the entities' veterinary sector with little involvement of the entity inspectorates and the local CAs, responsible for the official controls at the milk production holdings.
- The local CAs did not receive detailed instructions from the SVO or the entities' CAs in order to verify whether food business operators meet all relevant EU requirements for official controls at dairy processing establishments and milk production holdings. In the FbiH, instructions were issued during the FVO audit by the entity veterinary sector, but as stated above, it is not compulsory for the local CAs to use them. Consequently different check-lists and documented procedures are in circulation and some of them seen by the FVO audit team did not ensure that all relevant EU requirements are being verified during official controls.
- A guidance on procedures veterinarians should conduct prior to certification is not yet in place, but is being drafted by the SVO.
- Follow-up of deficiencies identified during official controls was not always well documented and the CA did not always follow-up the food business operator's guarantees to remedy the shortcomings. Results of controls carried out by the regional CAs were not always reported to the local CAs.

5.1.2.6 Independence of staff carrying out official controls

Legal provisions governing the independence of official staff carrying out official controls are described in the regulations as follows:

- at BiH level
  - the Veterinary Law, Article 83 thereof
  - the administration of BiH Act, Articles 71 and 89 thereof
  - the Civil Service in the institutions of BiH Act, Article 3 thereof
- at the levels of the entities and the BD
  - the inspections in the FBiH Act, Articles 13 and 14 thereof
  - the inspections in the RS Act, Article 40 thereof
  - the inspections of the BD Act, Article 8 thereof

5.1.2.7 Legal / enforcement powers

The above-mentioned acts provide the official staff with legal powers to carry out official controls in the areas covered within the scope of this audit, to enter the premises and to take official samples. The acts provide tools for enforcement should the inspectors identify that the food business operator is not in compliance with the relevant regulations. Non-compliances should be recorded in an official report which should require corrective actions with prescribed deadlines. The official staff has also the power to seize and destroy products, to initiate safeguard measures and to impose administrative sanctions such as fines, and also forward relevant details to the CAs for further legal actions if needed.

5.1.2.8 Training of veterinary inspectors

The SVO provided information on training within the scope of this audit. The most recent training sessions were:

- Certification and requirements laid down in the model certificates for dairy products intended for export to the EU;
- Food hygiene related to the production and the quality of raw milk and certification of milk;
- Approval conditions and implementation of health measures at milk production holdings;
- Official controls at dairy processing establishments;
- Peer reviews – assessment of dairy processing establishments in co-operation with TAIEX.

The FVO audit team made the following observations:

- At different CA levels, the relevant EU requirements to guarantee the production of dairy products intended for export to the EU were not understood. As a consequence, a number of experts had been hired and these had been providing guidance and improving approval standards in the five dairy processing establishments proposed for listing and the eight dairy cattle holdings. Only a limited group of officials has acquired the necessary knowledge.
- The requirements laid down in the health attestations of the model certificate for ultra-heat treated products (hereafter referred to as the model certificate HTC) were not understood by some of the official veterinarians responsible for certification and some of the food business operators visited. Official controls did not take into account all aspects to ensure sufficient separation of EU and non-EU compliant production.

Conclusions

The protocol established in July 2013 is a first step in strengthening the organisation of veterinary controls. However there is a clear need for further co-operation and co-ordination between the CAs at different levels and to establish detailed instructions. The lack of efficient supervision and power to ensure that corrective actions are taken weakens the performance of controls.

The CA is not in a position to give assurances regarding compliance with, or equivalence to EU requirements. The CA reacted late in responding to the need to improve the knowledge and performance of the CA controls in the dairy sector with a particular view on the export of dairy products to the EU. Only a limited number of officials had sufficient knowledge of relevant EU requirements.

5.2 ANIMAL HEALTH SITUATION

Legal requirements

Point II.1. of the model certificate HTC in part 2 of Annex II to Regulation (EU) No 605/2010 requires that the raw milk comes from animals under the control of the official veterinary service, belonging to holdings which were not under restrictions due to foot-and-mouth disease or rinderpest; and subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and in Council Directive 2002/99/EC.

5.2.1 Notification of disease outbreaks

The CCA informed the FVO audit team that under Article 4 of the Decision concerning communicable diseases (BiH OF No 44/03)), notifiable diseases include the diseases from the

former OIE *(Organisation International de Épizooties*) lists A and B. Animal owners must report any change in the animal health status to the nearest veterinary organisation and prevent any contact of other persons or animals with the diseased animal(s). Any veterinarian who suspects a disease is required to notify the CA at entity level thereof. While awaiting the arrival of the relevant veterinary inspector, the competent veterinary organisation must undertake any measures to prevent the disease from spreading. The CAs at entity level are required to notify the SVO of the disease outbreak. Laboratories are required to report the results of diagnostic testing to the relevant veterinary inspector, who notifies the CA at entity level thereof. In case of a disease from the former OIE list A, and in case of an outbreak of any other disease, the laboratory must report it to the relevant veterinary inspector, the competent CA at entity level and the SVO. In case of other animal diseases, the laboratory is required to report the results on a monthly basis. In case of zoonosis, the relevant veterinary inspector is required to notify the relevant health care services as well. The SVO is responsible for notifying international organisations and neighbouring countries.

5.2.2 Foot-and-mouth disease

BiH is recognised by the OIE as "free from foot-and-mouth disease without vaccination". The last reported outbreak of foot-and-mouth disease was recorded in 1968.

5.2.3 Tuberculosis

The control of tuberculosis is based on an annual testing of cattle over six weeks of age, which is conducted by authorised veterinary organisations. Bovine tuberculin is used for the intra-dermal test, which is read 72 hours after injection. Procedures are in place for re-testing in line with relevant EU legislation. The CA informed the FVO audit team that four cases in four herds were identified in 2012 and one case in 2013. The reactor animals were slaughtered. Thereafter testing procedures are in place to confirm the animal health status of the herd.

5.2.4 Bovine brucellosis

The control of bovine brucellosis is based on an annual testing of cattle over 12 months of age. Serological sampling takes place by authorised veterinary organisations and testing is carried out in authorised veterinary diagnostic laboratories using the Rose Bengal Test as screening and the Complement Fixation Test as confirmatory method. The CA informed the FVO audit team that 48 cases in 42 herds were identified in 2012 and 41 cases in 20 herds in 2013. The reactor animals were slaughtered. Thereafter testing procedures are in place to confirm the animal health status of the herd.

The CA stated that milk of reactor animals for tuberculosis or brucellosis cannot be used for human consumption or for feed. Consequently the milk must be destroyed.

The FVO audit team made the following observations:

- The inspectors confirmed for two milk production holdings visited that the cattle in lactation were free of tuberculosis and brucellosis, but did not verify the data for the entire herd.
- For two of the milk production holdings visited, the testing for tuberculosis and bovine brucellosis had been carried out with favourable results for all eligible animals. However, in a third holding the veterinary organisation had to retest the entire herd for brucellosis and in a fourth holding one third of the eligible cattle population of a holding with more than 1700 cattle were retested for tuberculosis and brucellosis a few days before the FVO audit visit. For the latter holding the recent test results for the re-testing contained many corrections on animal identification, dates of testing, results for the re-testing and samples with duplicate test tube numbers.

Conclusions

The CA was not sufficiently familiar with the requirements related to the herd status for tuberculosis and brucellosis. The test results for tuberculosis and brucellosis could not be considered to be reliable for one milk production holding with a significant cattle population.

5.3 Approval and listing of establishments

Legal basis

Article 12 of Regulation (EC) No 854/2004.

Findings

The SVO informed the FVO audit team that establishments wishing to export dairy products to the EU must be approved for placing dairy products on the national market, must obtain a general export approval and, in addition, must obtain a specific approval for exports to the EU.

The entities' CAs approve the establishments for the national market and for general export and grant an approval number. The approval is renewed every second year following an inspection visit only in the FBiH, while in the RS the approval has no time limit. The CCA further clarified that in the RS a general approval was issued and the approval did not specify whether the approval was given for the national or export market. There is no legal requirement to report non-compliant results to the SVO even though these may affect the EU approval.

Official controls are carried out at approved establishments by the local veterinary inspectors.

Dairy processing establishments wishing to export to the EU must apply to the SVO via the entities' CAs for an additional approval to export to the EU. A committee is formed of four inspectors: two from the SVO inspection department and two veterinarians to carry out a pre-approval inspection. An inspection report is issued after the visit. If non-compliances are identified, the follow-up is monitored by the same committee following receipt of a corrective action plan from the food business operator.

Establishments approved for export to the EU are subject to bi-annual audits by the SVO to reconfirm that they meet relevant EU requirements.

The SVO informed the FVO audit team that after the initial CA response to the pre-audit questionnaire and following the discussion thereafter, the relevant committees revisited all establishments in order to re-evaluate them. Based on the results, conditional approvals have been granted for those establishments which still need to adapt or to establish certain procedures in order to be compliant with all relevant EU requirements.

The FVO audit team made the following observations:

- In one establishment visited, inspection reports from the committee were present.
- A conditional approval valid for three months was granted more than three months after the inspection visit. This inspection visited was followed by a re-inspection 14 days after the conditional approval had been granted. The inspection report was produced after one month.
- During the inspection visits by the committee, the results of the inspections carried out by the local veterinary services are not taken into account.
- The SVO did not conclude yet on any of the five dairy processing establishments proposed for listing meet the relevant EU requirements. Moreover certain procedures were not yet evaluated.
- The general approval for export granted by the entities' CA for establishments did not

specifically exclude exports to the EU. The template was corrected during the FVO audit in one entity.

Conclusions

The CA was not in a position to guarantee that any of the five dairy processing establishments proposed for being placed on the list of establishments from which imports of dairy products are permitted meet the relevant EU requirements. The delay between inspection and the issue of the conditional approval was excessive.

5.4 Official controls over food business operator at establishment level

Legal requirements

Point II.1 and Point II.2. of the model certificate HTC in part 2 of Annex II to Regulation (EU) No 605/2010 sets out the animal and public health requirements to be met.

5.4.1 General and specific hygiene requirements

Findings

- The dairy processing establishments visited, had in the areas evaluated by the FVO audit team, generally acceptable structures and lay-out and the equipment meets the EU standards, which was also confirmed during official controls.

5.4.2 HACCP-based systems

Findings

The HACCP-based systems were not evaluated in depth during this audit.

5.4.3 Traceability, labelling and identification marking

Findings

- All dairy processing establishments claimed to have dual production procedures in place in order to process separately milk which meets EU standards from milk which does not. This could not be confirmed by the FVO audit team for one dairy processing establishment producing matured cheeses where all cheeses were salted in the same brine.
- Where evaluated, the documentation on this dual production, separated in time, contained deficiencies. In one establishment the volume of raw milk received and processed did not match during different steps in the process. This was not reflected in the official control reports.
- The CA did not demonstrate during the official controls that they had verified the origin of ingredients other than the raw or heat treated milk used for the production of dairy products.

5.4.4 Health requirements and criteria for raw milk

Findings

- The dairy processing establishments did not have a system to react to the quality criteria of raw milk with regard to somatic cell count (SCC) and total plate count (TPC). There was no evidence of involvement of the official veterinarian in verifying the raw milk quality criteria results.
- EU legislation requires that raw milk from each supplier is tested monthly for SCC and the geometric average over a three month period must not exceed 400 000. This was not

confirmed for all proposed EU eligible milk production holdings and test results were not available for all milk production holdings at establishment level. Milk production holdings proposed for listing were found to be non-compliant for SCC during the second half of the year and one such farm had only been removed from the list immediately before the FVO audit.

- EU legislation requires that raw milk from each supplier is tested twice monthly for total bacterial count and the geometric average over a two month period must not exceed 100 000. This was not confirmed for all milk production holdings and test results were not available for all milk production holdings at establishment level.
- EU legislation requires the absence of any residual antibiotics in milk. There is no routine testing at milk production holding level, only on the bulk milk, which in most cases is mixed from different milk production holdings, on arrival at the dairy processing establishments. In case the bulk milk contains residual antibiotics, an investigation to the source is launched.
- One dairy processing establishment visited calculated the arithmetic average and not the rolling geometrical averages for SCC and total bacterial counts. The results of the external laboratory showed this, but the insufficient number of samples for total bacterial count were not taken into account.
- The SVO, the entities' CAs and the CAs at local level have no overview on whether the milk production holdings meet the quality criteria for raw milk or not.
- From records evaluated, the raw milk on arrival did not exceed 10 degrees Celsius.
- The FVO audit team was informed by two food business operators that the intended quantity of dairy products for export could be produced with imported raw or pasteurised milk from EU Member States until sufficient compliant raw milk is available from BiH milk production holdings.

Conclusions

The dairy processing establishments have generally acceptable structures and lay-out and the equipment meets the EU standards. Only very few milk production holdings meet the EU raw milk quality criteria. The quantity of raw milk produced cannot cover the production of dairy products intended for export to the EU. Veterinary oversight of raw milk quality was insufficient. Veterinary controls on the separation of EU eligible milk from non-EU compliant milk during production were not effective.

5.5 Holding registration, animal identification and movement controls

Legal requirements

Point II.2. of the model certificate HTC in part 2 of Annex II to Regulation (EU) No 605/2010 requires that the raw milk comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Annex IV to Regulation (EC) No 854/2004.

Findings

5.5.1 Holding registration

All holdings where cattle are kept must be registered in the central bovine database with a unique holding number.

In respect of the scope of the audit, in addition, all milk production holdings considered meeting relevant EU requirements and, in particular, the raw milk criteria, are authorised at entity level and are listed in a separate holding list. The entities' CAs approve and register these holdings. Official

controls are carried out at the approved holdings by the local veterinary inspectors.

In their response to the pre-audit questionnaire the SVO stated that 93 milk production holdings meet relevant EU requirements. After having reviewed the situation shortly before the start of the FVO audit, the CA considered that only 10 holdings meet the relevant EU standards.

5.5.2 Animal identification and registration

The cattle identification and registration system consists of identification of cattle with double ear tags with a unique identification number, up-to-date register of all cattle present on the holding, including birth and death records and movements in and out the holding, cattle passports and a bovine central database.

The Agency, set up in 2003 and operating under the SVO is the operational service and is responsible for issuing ear tags, passports and the bovine central database. Identification of cattle is the responsibility of the veterinary organisations following the owner's request. Calves must be identified within 20 days of birth.

The SVO informed the FVO audit team that the bovine central database is under review and a new information system is expected to be in place by 1 April 2014. The current central database contains information which is not reliable, mainly as a consequence of failures to report movements, deaths, births, slaughter of animals and the lack of cross compliance controls.

Access to the bovine central database is limited and the food business operators must send any change to update the system via the veterinary organisations and data entry offices to the Agency.

5.5.3 Movement controls

There is currently no procedure established to recognise herds free or officially free from brucellosis and tuberculosis. For movement of animals, the "Decision on Veterinary Certification of animal health and consignments of animal origin in domestic and international trade" applies. This decision stipulates that all animals subject to placing on the market must have the required health status certificate. The certificates are issued by the authorised veterinary organisation.

The FVO audit team made the following observations:

- One holding was listed at entity level and initially considered as being EU eligible. The CA did not have evidence that an inspection took place at the milk production holding concerned. The laboratory visited in the entity did not receive any milk samples for testing for SCC and TPC and only male bovine animals born in 2005 were registered in the central bovine database.
- An official report on controls for another holding was available, but the milk production holding was not registered at entity level.
- Two health certificates examined by the FVO audit team for a total of 25 animals moved into one EU eligible holding visited did not mention the required information on the diagnostic testing carried out for bovine tuberculosis. At the milk production holding of origin more incomplete health certificates were observed.
- In one holding visited, the records from the central database did not match the records present at the milk production holding. Imported cattle received replacement ear tags and both sets of tag numbers were registered in the central database as being live animals present on the holding. The milk production holding's records were kept up-to-date.
- While data are maintained by various authorities, there is no single source capable of providing accurate information on the number of milk production holdings, the total cattle

population and the number of dairy cattle.

Conclusions

The current animal identification and registration system is not robust or reliable. The sanitary certificates accompanying animals moving between holdings are incomplete and do not provide sufficient guarantees of tuberculosis freedom for the destination holdings.

5.6 Application of hygiene rules on milk production holdings and official controls

Legal requirements

Points II.1 and II.2 of the model certificates HTC in Part 2 of Annex II to Regulation (EU) No 605/2010 sets out the animal and public health requirements, including those related to the production of raw milk.

Findings

- None of the milk production holdings for which control reports were evaluated, did meet shortly before the start of the audit requirements for animal identification and registration system. Records of veterinary medicine treatments were not available and incomplete records on testing of the herds for tuberculosis and brucellosis were noted during the CA controls. The veterinary service was working very hard to verify the corrections of all shortcomings identified shortly before and during this audit for at least the 10 milk production holdings considered to be EU eligible. Regarding the health status of holdings visited supplying raw milk to the processing establishments see chapters 5.3 and 5.6.
- At the holdings visited, the facilities and equipment for milking and storage of raw milk were in a good condition with the exception of one holding where protection against vermin was insufficient, part of the milking equipment was not properly covered and the milking parlour was not up to standards. Cleaning and disinfection procedures of milking equipment are in place.
- In the holdings evaluated, no observations were made regarding the hygiene during milking or staff hygiene.
- Where evaluated, testing of potable water was not in line with the EU requirements. Results showed an absence of TBC or other parameters laid down in Council Directive 98/83/EC. In one milk production holding visited, the water reservoir collecting water from natural sources had been chlorinated, which was not taken into account by the official veterinarian during the sampling.
- Registers of veterinary treatments were present at the holdings visited, but were introduced late in two of the holdings visited; in one of the holdings only one week before the start of the FVO audit.
- Procedures are in place at the holdings visited to discard milk from treated animals during the withdrawal period.
- At one holding visited, temperatures of raw milk stored upon collection were recorded on two different registers, which did not match. Moreover it was observed by the FVO audit team that the temperature of the milk tank did not increase immediately after milking – as would be expected.

Conclusion

Milk production holdings initially announced to the FVO audit team meeting relevant EU requirements were not all subjected to veterinary inspection and the reduced number of milk

production holdings thereafter were only recently checked by the CA.

5.7 Laboratory services

Legal basis

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004 stipulate that Community controls shall have, inter alia, particular regard to the resources including diagnostic facilities available to competent authorities.

Points 41 and 42 of Guidelines of Codex Alimentarius CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Findings

The FVO audit team visited two accredited laboratories carrying out the testing of raw milk samples collected by the dairy processing establishments at milk production holdings or received directly from milk production holdings supplying raw milk to dairy processing establishments. The laboratories tested the milk samples for physico-chemical parameters as well as for TPC and SCC.

Both laboratories had trained the staff collecting samples from the milk production holdings to ensure that this was done in a reliable way. The dairy processing establishments were in most cases responsible for the sampling plans but samples could also be received directly from larger milk production holdings with their own trained sample collector. Labels to be attached to the milk samples were printed by the laboratories and sent via the dairy processing establishments to individual farmers.

Both laboratories used similar testing equipment for measuring TPC, which was based on flow cytometry technology and the electronic readings were converted to equivalent TPC values. This conversion to TPC values was done automatically by the equipment based on correlation factors entered into the system.

In one of the laboratories the correlation had been established by parallel test results from the equipment and from traditional TPC testing for more than 500 milk samples. The laboratory participated in international ring tests with satisfactory results proving the reliability of the test results.

The other laboratory participated in a twinning project with a milk testing laboratory in an EU Member State and the calibration of the equipment was done in cooperation with this laboratory without ever having carried out any parallel testing on local milk samples. The laboratory had never participated in ring testing but did consider signing up for ring tests in the future.

The same testing equipment was used for the counting of SCC in both laboratories which is also based on flow cytometry technology that counts and characterises particles and cells. Standard samples supplied by the producer of the equipment were included for each batch of samples tested to ensure the reliability of the test results.

The laboratories do not carry out inhibitor tests on individual milk samples received from the dairy processing establishments or directly from milk production holdings.

Both laboratories stated that they provided on-line access to the test results for dairy processing establishments, authorities and farmers at their request. The farmers receive individual test results by SMS and the monthly test results by post including geometric average calculations.

The FVO audit team noted the following:

- Some test results for SCC showed extremely low results from one of the laboratories. In one milk production holding the highest test result was 52 000 during a long period with values

as low as 12 000.

- Some of the test results for the past three months only included one sample tested for TPC and not the minimum two as required in order to establish EU compliance.
- In one laboratory samples with milk fat content of more than 5.5% were discarded and new samples were requested. The high milk fat content was seen as an indication of poor mixing of the milk before sampling and the SCC test results would, in these cases, be very high. In the other laboratory no official limit had been established but they would in most cases exclude samples with less than 2.5% or more than 5.0% milk fat.
- There was no system established for notifying the CA of unsatisfactory results. One laboratory stated that they sent the individual results by e-mail to the Entity Ministry, but the recipient was not the CA responsible for the official controls in the dairy processing establishments or the milk production holdings.
- In one laboratory it was found that the access to the electronic database with raw milk test results had only been provided to the CA from the middle of December 2013. Before that only paper versions had been available on request.
- It was not possible in any of the laboratories visited to extract statistical information relating to the number of samples tested for TPC and SCC, or to the quality of raw milk delivered to the dairy processing establishments. Only data relating to individual milk production holdings could be extracted, either as tables of individual test results or as tables of monthly geometric averages.
- Official samples were not taken to verify if raw milk meet the relevant EU standards.

Conclusion

The laboratory services available are technically able to test raw milk samples in order to ensure that raw milk meets the quality parameters in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004. However, better communication of test results to dairy processing establishments and local CAs are required in order to ensure efficient and effective controls.

5.8 Official certification

Legal requirements

Article 5 of Commission Regulation (EU) No 605/2010 requires that consignments of dairy products are accompanied by a health certificate drawn up in accordance with the appropriate model drawn up in Part 2 of Annex II to that Regulation and that the certificate is completed in accordance with the explanatory notes set out in Part I of that Annex.

Letter (h) of those explanatory notes requires that the CAs of the exporting third country shall ensure that principles of certification equivalent to those laid down in Directive 96/93/EC are complied with.

Findings

The FVO audit team observed the following:

- The local CAs issue certificates for neighbouring (non EU) countries with the same health statements as those laid down in the EU model certificates for export of dairy products to the EU. The certificates were signed even though there was evidence that the statements could not be supported, in particular the volume of milk meeting the EU requirements for the quality criteria of raw milk was insufficient to support the quantities certified.
- In one establishment visited, the number of certificates issued and received could not be

accounted for and blank signed certificates were present.

Conclusion

Although currently no certification for export of dairy products to the EU takes place, the certification procedure in place is not reliable. Misleading statements indicating that dairy products meet relevant EU requirements are certified.

6 Overall Conclusions

The organisation of the veterinary service with its veterinary departments and inspectorates reflects the constitutional organisation of BiH. On 17 July 2013, a Protocol was signed between the various entities appointing the SVO as the body responsible for organising official controls of milk and dairy products for export to the EU. Further developments (contracts and agreements) are necessary to give full effect to this Protocol.

Currently, the organisation of official controls is neither efficient nor effective. No detailed instructions are in place and controls are not consistent. The lack of efficient supervision and power to ensure that corrective actions are taken weakens the performance of controls

The quality of raw milk is of a major concern. Only very few milk production holdings meet the EU raw milk quality criteria for which the quantity of raw milk produced cannot cover the production of dairy products intended for export the the EU.

The animal identification and registration system as it stands today is not robust and reliable.

While major efforts have been made to identify non-compliances on milk production holdings and to implement and verify corrective actions, this work has started only recently and not all holdings have been evaluated.

The laboratory services are technically capable of testing for the raw milk quality parameters specified in Regulation (EC) No 853/2004. However, there are deficiencies in the report of results to dairy processing establishments and the CAs which hinder the implementation of effective controls.

The certification procedures in place are not robust and cannot be considered reliable. Misleading statements indicating that dairy products exported to other countries meet relevant EU requirements are certified.

7 Closing Meeting

A closing meeting was held on 31 January 2014 with the SVO. At this meeting the FVO audit team presented the main findings and preliminary conclusions of the mission and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA acknowledged the main findings and preliminary conclusions presented by the FVO audit team.

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.

N°.	Recommendation
1.	To strengthen the organisation of official controls, their powers, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively in order to assure compliance with, or equivalence to, relevant European Union requirements for the production of dairy products intended for export to the European Union.
2.	To ensure that staff in the performance of official controls in the dairy processing establishments and milk production holdings and staff responsible for certification procedures have sufficient knowledge of the requirements set out in Points II.1 and II.2 of the European Union model certificate HTC for export of dairy products to the European Union.
3.	To establish documented control procedures for official controls at dairy processing establishments and milk production holdings in order to ensure verification of the requirements set out in Points II.1 and II.2 of the European Union model certificate HTC for export of dairy products to the European Union.
4.	To ensure that dairy establishments are only listed for EU export that, together with milk production holdings where they source the raw milk, meet the relevant European Union requirements as set out in Article 12 of Regulation (EU) No 854/2004.
5.	To ensure that milk production holdings are inspected in line with the requirements set out in Point II.1 of the European Union ultra-heat treated (UHT) model certificate milk in Part 2 of Annex II to Regulation (EU) No 605/2010 and that the raw milk used for the manufacturing of dairy products meets the requirements set out in Point II.2 of the mentioned certificate.
6.	To take measures in order to ensure that principles of certification equivalent to those laid down in Council Directive 96/93/EC are applied.

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=2014-7212

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
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
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

Legal Reference	Official Journal	Title
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
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
Reg. 10/2011	OJ L 12, 15.1.2011, p. 1-89	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
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. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Legal Reference	Official Journal	Title
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
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. 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