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DRAFT REPORT OF AN AUDIT

CARRIED OUT IN

ISRAEL

FROM 24 NOVEMBER TO 05 DECEMBER 2013

IN ORDER TO EVALUATE THE OPERATION OF CONTROLS OVER RAW MILK AND DAIRY PRODUCTS INTENDED FOR HUMAN CONSUMPTION AND INFANT FORMULAE AND FOLLOW-ON FORMULAE (INCLUDING THE SUPPLY CHAIN), DESTINED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Israel (IL) from 24 November to 5 December 2013. The objectives of the audit were to evaluate the operation of controls over raw milk and dairy products intended for human consumption and infant formulae (IF) and follow-on formulae (FOF) (including the supply chain), destined for export to the European Union (EU).

IL is listed for export of heat treated dairy products in Commission Regulation (EU) No 605/2010. Official controls in this area are under the responsibility of the Israeli Veterinary Services and Animal Health, the Central Competent Authority (CCA). There is no Competent Authority (CA) designated for the control of IF and FOF to ensure compliance before marketing on the EU market. However, a high level of compliance of national legislation regarding the specific requirements for IF and FOF with EU requirements (Commission Directive 2006/141/EC) exists and controls carried out by the food business operators (FBOs) were adequate to meet the requirements.

The routine inspection of the establishments and export certification is carried out by six CCA accredited Veterinary Inspectors who are employed by the Israeli Dairy Board (organisation co-owned by economic operators and Ministries). Official controls are carried out as prescribed in the national procedures, which are generally in line with EU requirements, except for microbiological testing, where the prescribed sampling activity and the documentation of water testing is inadequate to meet EU requirements. The five establishments visited which are approved for the export of dairy products to the EU were found to be largely in compliance with EU requirements. Both milk production holdings visited, supplying EU listed establishments with raw cow milk, were operating in line with EU requirements. Official controls over hygiene conditions and animal health of milk production holdings is implemented in accordance with the national procedures. The operation of the database for cattle identification and related legislation was not adequate to support animal health controls.

The controls over raw milk criteria were stricter than in the EU. using arithmetical calculation were stricter than the geometric average used in the EU. The average limits of the national production of raw milk is far below EU permitted maximum limits. Dairy products exported to the EU were treated in accordance with one of the heat-treatments prescribed by Regulation (EU) No 605/2010. IL experiences recurrent foot and mouth disease (FMD) outbreaks. Detailed instructions are available for official staff for management of FMD outbreaks and these were followed. No evidence was seen that non-compliant raw milk had entered the export chain.

Raw materials (milk powders) were only sourced from EU listed establishments. However, in most cases, procedures and awareness were not fully adequate. According to the CCA, the export of dairy products takes place only from EU listed establishments. However, three facilities were used for the intermediate cold storage although they were not EU-listed.

Although some deficiencies were noted, a high level of compliance with the EU provisions is provided for in the IL control system which covers the whole production chain for dairy products. Currently, the control system implemented by the CA largely provides the guarantees required by the health certificate and the EU legislation.

A number of recommendations have been made to the CA in order to address the deficiencies identified during the audit.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AVI	Accredited Veterinary Inspector
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies) (the Israeli Veterinary services and Animal Health - IVSAH)
CCP(s)	Critical Control Point(s)
CVO	Chief Veterinary Office (Director of IVSAH)
DCAP	Department of Control of Animal Products
DFVS	Department of Field Veterinary Services
DG(SANCO)	Health & Consumers Directorate General
EC	European Community(ies)
EU	European Union
FBO(s)	Food Business Operator(s)
FMD	Food and Mouth Disease
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
ICBA	Israeli Cattle Breeders Association
IDB	Israeli Dairy Board
IDF	International Dairy Federation
IL	Israel
IF and FOF	Infant Formulae and Follow-on Formulae
ISRAC	Israeli Laboratory Accreditation Authority
IVSAH	Israeli Veterinary Service and Animal Health (the CCA)
MARD	Ministry of Agriculture and Rural Development
Milk-HTC	Health certificate drawn up in accordance with the relevant model in Part 2 of Annex II to the Commission Decision 2004/438/EC
MoH	Ministry of Health

NRL	National Reference Laboratory
OV	Official Veterinarian (employed by the IVSAH)
P.S.	Procedure sheet (instruction issued by the CCA)
RVO	Regional Veterinary Officer
SCC	Somatic Cell Count
SI 55	Israeli Standard 55 (laying down criteria for raw milk)
TPC	Total Plate Count (Plate count at 30 °C)
VO	Veterinary Officer

1 Introduction

The audit took place in Israel (IL) from 24 November to 5 December 2013 as part of the planned audit programme of the FVO. The audit team comprised three auditors from the FVO.

The audit team was accompanied by representatives from the Central Competent Authority (CCA), the Israeli Veterinary Service and Animal Health (IVSAH).

The opening meeting was held on 24 November 2013 with the CCA in Beit Dagan, Israel. At this meeting the 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 official controls related to production and storage of raw milk and dairy products and infant formulae (IF) and follow-on formulae (FOF), including the supply chain in IL intended for export to the EU with regard to:

- Competent Authority (CA) organisation and operation;
- official controls over food business operators' (FBO) compliance with general and specific rules on the hygiene of food of animal origin;
- some specific aspects in relation to the production of IF and FOF;
- the correct implementation of the chain of certification;
- follow-up the action taken in relation to recommendations of report DG(SANCO)/2009-8219 (previous audit of the FVO from 23 November to 3 December 2009 on official controls over the production of milk, heat treated milk and milk based products destined for export to the EU).

In particular, controls over raw milk and dairy products in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004, No 854/2004 and Commission Directive 2006/141/EC, Regulation No 882/2004 as well as Council Directive 97/78/EC were subject to this evaluation. In pursuit of these objectives, the audit itinerary included the following:

COMPETENT AUTHORITIES			Comments
Competent Authorities	Central	3	Opening and closing meeting and Field Veterinary Office
	Regional	1	District Field Veterinary Office
	Local		
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Public health laboratory		1	Kimron Veterinary Institute
Private public health laboratory		1	Central laboratory of the Israel Cattle Breeders Association
In-house laboratories		5	Annexed to dairy processing establishments
Dairy processing establishments		5	
Milk production holdings		2	One "moshav" , one "kibbutz"

3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular Article 46 of Regulation (EC) 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.

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

4 Background

IL is listed in Annex I, column C to Commission Regulation (EU) No 605/2010, laying down a list of third countries where there is a threat of Food and Mouth Disease (FMD) and from which imports of raw milk and dairy products for human consumption may be authorised if they undergo specific heat treatments or other specific treatments and is included in the list of third countries with approved residues monitoring programmes for milk. Thirteen establishments are approved by the IL CCA for export of dairy products to the European Union (EU), of which seven are currently exporting to the EU. IL exported 896 tonnes of dairy products to the EU in 2012 and 1 005 tonnes in 2013 (Information from TRACES).

The previous audit concerning the export of dairy products IL to the EU was carried out from 23 November to 3 December 2009, the results of which are described in report DG(SANCO)/2009-8219 – MR Final (hereafter referred to as report 2009-8219). This report is accessible at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

The action plan received from the IL authorities provided satisfactory guarantees in response to all of the report's recommendations.

5 Findings And Conclusions

5.1 Legislation and Competent Authorities

5.1.1 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.

Article 11 of Regulation (EC) No 178/2002 requires that food imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent.

5.1.2 Findings

5.1.2.1 Legislation

The following main pieces of national legislation are relevant for the scope of the current audit:

- for approval of export establishments: the Business Licensing Regulation of 1972, as amended, and the Public Health Ordinance of 1983, as amended;

- for certification procedures: the Control on Exports of Animals and Animal Products Law of 1957, as amended, the Regulation for the Control of the Export of Animals and Animal products of 1998, as amended;

- for animal health controls: the Animal Diseases Ordinance of 1985, as amended, the Animal Diseases Regulations;

- for public health controls: the Public Health Regulations (Sanitary Quality of Drinking Water) of 1974, as amended;

- for controls on specific requirements for IF and FOF: Public Health Regulations (Food-(Nutrition labelling for mother milk substitutions 1990), Circular of Ministry of Health concerning the preparations of food compounds, microbiological requirements for IF and FOF, Circular of Ministry of Health (MoH) concerning the requirements for infant nutritional composition 04/2011 (update), guidelines for heavy metals detection in baby food (11.2004);

- for raw milk criteria: the Israeli Standard SI 55 of 2000, as amended.

In addition, several circulars ("Procedure Sheets" - P.S.) have been published, covering certification and supervisory procedures, to provide official staff with the appropriate guidance during their routine supervisory activities.

Observations:

- the P.S. 2.3.60 (Government laboratory tests before exporting dairy products to the EU and/or the US), lists microbiological criteria to be used both by the FBO when verifying the Hazard Analysis Critical Control Points (HACCP) programme and by the Authorised Veterinary Inspector (AVI) when certifying defined batches after microbiological testing. The parameters chosen correspond to the parameters included in Regulation (EC) No 2073/2005. However, the number of sampling units to be tested when certifying batches for export is only three instead of the five as stipulated in the Regulation.

- the IL Standard SI 55 lays down criteria for raw milk which since 1 January 2011 are equivalent to those laid down in Annex III, Section IX, Chapter I.III to Regulation (EC) No 853/2004 (see 5.6.)

- the IL requirements for composition of IF and FOF, although slightly different from the requirements of Commission Directive 2006/141/EC, are similar to the Codex requirements on this issue. The specific labelling claims concerning the superiority of breast feeding and advertisement exist in an equivalent form. The requirements for contaminants in IF and FOF are similar. Since 7 October 2013 the specific requirements for pesticides in IF and FOF as laid down in Directive 2006/141/EC have been included in the overall requirements.

Conclusions:

The national provisions provide the necessary legal framework to manage the control system over the whole dairy sector. The national legal criteria for raw milk are equivalent to the Community requirements. However, the specific requirements put in place when certifying dairy products for export to the EU for microbiological criteria are not equivalent to the requirements of Regulation (EC) No 2073/2005.

National legislation regarding the specific requirements for IF and FOF are either similar to Codex requirements, or similar or equivalent to EU requirements.

5.1.2.2 Competent Authorities

5.1.2.2.1 Organisation of Competent Authorities

The CCA responsible for the export of dairy products is the IVSAH, within the Ministry of Agriculture and Development (MARD). The CCA is organised into several departments, of which the most relevant for the audit are:

- Department of Control of Animal Products (DCAP), represented at headquarters' level by the Division of Control of Milk Products and processing plants for Export, the Division for Updating and Training of Veterinary Staff and the Food Safety Manager. At territorial level there are two Regional Veterinary Officers (RVOs), and six AVIs in charge of official controls and certification for export in dairy plants; the latter are employed by the Israeli Dairy Board (IDB) (see below), but are trained and accredited by the CCA to carry out their tasks.

- Department of Field Veterinary Services (DFVS) which operates through 63 Official Veterinarians (OVs) and 19 animal inspectors located in the six RVOs. The DFVS is in charge of prophylaxis and control of animal diseases, movement controls on livestock and management of animal identification.

- Kimron Veterinary Institute is, in particular, in charge of the implementation of the national residues monitoring programme and operates as the National Reference Laboratory (NRL) for official microbiological testing in accordance to Regulation (EC) No 2073/2005.

- Department of import-export is in charge of drafting and approval of the export certificates.

In addition, the following organisations are relevant in relation to the control of the dairy sector:

- Israeli Dairy Board (IDB) (private organisation managed by the MARD, MoH, Finance, Industry-Commerce, Farmers' Associations, consumers and milk processing operators) is in charge of raw milk quality improvements, trade and management of production and export quotas.

- Israeli Cattle Breeders Association (ICBA), with its Central Laboratory which performs the controls on Total Plate County (TPC) and Somatic Cell County (SCC) for all IL holdings.

The Ministry of Health (MoH) is responsible for domestic processing plants, the marketing chain in IL and the import of dairy products (raw materials). In particular the competence also covers the control of the specific requirements with regard to marketing IF and FOF for the domestic market.

Observations:

- There is no CA for the control of IF and FOF to ensure compliance with the specific requirements, when marketed on the EU market.

5.1.2.2.2 Competent Authorities powers, independence and authority for enforcement

The six AVIs working in the dairy establishments approved for export, although employed by the IDB, are affiliated (full time) to the DCAP. The contract they sign with the CCA includes the prohibition to carry out private activities. The AVI and the CA have full enforcement powers.

5.1.2.2.3 Supervision

A programme of audits of supervisory activities of the AVIs in the export establishments was implemented in 2010; according to P.S. 3.0.7 (general), the Food Safety Manager, performs audits in all dairy establishments at least once per year. During this audit the performance of the veterinary inspection team will be evaluated. Another verification is carried out by the Assistant of the Head of the Division (Veterinary Officer - VO) of control of milk and dairy establishments who performs at least three audits in each authorised establishment per year.

5.1.2.2.4 Training of staff in performance of official controls

Training of the AVIs in charge of supervision of the dairy establishments includes annually updating training. During 2012 topics such as quality control in the dairy sector, HACCP design and HACCP verification and Sanitation Standard Operating Procedure programmes in the dairy sector were covered. Qualifications and professional basic training of AVIs are specified in P.S. 0.1.61.

5.1.2.2.5 Resources

No lack of resources was noticed by the audit team during the visits.

5.1.2.2.6 Organisation of control systems

There is no particular prioritisation of official controls over the dairy sector in IL: each processing establishment receives at least an annual visit by the food safety manager for audits of the FBOs and for internal audit. A similar type of control is carried out by the VO at least three times per year. The AVI visits the establishments at least once a week for certification tasks, supervision and controls.

5.1.2.2.7 Documented control procedures

The recording of the different steps of official controls (audit, non-compliances, report, corrective actions and their verification) is done through a computerised programme. In this way the department gets an overview of all official control activities, which can be used for supervision of the control activities.

In accordance with P.S. 3.0.7 specific reports are sent to the FBOs, in case of non-compliances, with an indication of the deadlines for submission of an appropriate action plan (in general one to two weeks). The FBOs should submit an action plan with a timetable for its implementation. Follow-up activities and close out of the recommendations are also documented by the AVIs.

There are no instructions including specific control activities related to the production and marketing of IF and FOF destined for export to the EU. The instructions available cover only the general aspects in relation to hygiene controls, traceability and HACCP verification controls.

In general (with some exceptions in one establishment) the deficiencies were correctly identified in the reports seen by the audit team, and the follow-up activities were carried out as prescribed.

5.1.2.2.8 Official controls on imports

Controls on imports of dairy products are under the responsibility of the MoH. Imports of dairy products must comply with the following conditions:

- An import licence is required.
- Documents must be provided which include an export permit, microbiological analysis, residue free declaration.
- The goods must be labelled according to Regulations.
- Imported dairy products (mainly milk powder), are only used in authorised establishments, only as raw material and are not being re-exported.

Observations:

- In the three establishments visited using milk powders for processing, a procedure stipulating that only imported milk powder from EU listed establishments could be used for the production of dairy products destined for the EU market was only adopted in one of the establishments. However, in the other establishments milk powders had not been imported since 2007 and at this time, this was imported from an EU listed establishment.

5.1.3 Conclusions

The overall organisation of the CA, its co-ordination with other organisations and associations in charge of certain controls over the dairy sector and the control system in place provide sufficient assurances that EU requirements for dairy for human consumption to the EU can be met. However, as regards the control of IF and FOF to ensure compliance with the specific requirements, when marketed on the EU market, there is no CA designated.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION

5.2.1 Legal Requirements

The veterinary certification requirements for the introduction into the EU of raw milk and dairy products are laid down in Regulation (EU) No 605/2010. Point II.2 of the model certificates, in Part 2 of Annex II to the Regulation, requires that 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.

5.2.2 Findings

The national legislation prescribes that cattle must be identified with a single brass eartag bearing a unique identification number and provided with a passport; data concerning the animal are entered into the central computerised database.

New legislation will come into force that will stipulate that new born animals will have to be eartagged 7 days and registered within 14 days after birth compared to the 6 months notice which is currently applicable to these activities.

Observations:

- At both milk production holdings visited some animals had missing ear-tags. However, all of them were additionally identified and marked by freeze branding on the skin. However, at one farm, several animals registered in the database, were not present at the farm. This concerned animals that had left the farm, mainly because of death and slaughter. The CCA explained that only recently (one year ago) the slaughterhouses and the incineration plant had received access to the database in order to be able to report incineration and slaughter. Consequently many animals were still recorded in the database as "floating" animals (approx. 10 % according to the CCA) for which no exit had been reported.

- At the other milk production holding visited, several young animals that were present were registered wrongly under another holding's registration number. This was due to a mistake at the District Field Office, where eartags handed over to the farm had been wrongly registered under another holding registration number.

5.2.3 Conclusions

The database and the legislation in place is not fully adequate to support animal health controls in a satisfactory way.

5.3 Animal Health Controls

5.3.1 Legal Requirements

Article 5 of Commission Regulation (EU) No 605/2010 requires that consignments of raw milk and dairy products are accompanied with the relevant model in part 2 of Annex II of the Regulation. In particular, consignments should comply with section II.1 of the Milk-HTC certificate.

5.3.2 Findings

Approximately four times per year the official service visits the holdings for FMD vaccination and prophylaxis of animal diseases (Brucellosis).

Private veterinary practitioners are contracted by the farmers and regularly visit (on average once a week) the holdings to perform clinical examination and prescribe medical treatments, when required.

5.3.3 Tuberculosis and brucellosis

IL is officially tuberculosis-free; one case of transmission of *Mycobacterium tuberculosis* from

humans to cattle occurred in 1998. Herds are tested once every three years and every animal undergoes an intradermal test before being moved from the holding, with the exception of animals sent to the slaughterhouse. A skin reaction of 3 mm or more is considered positive, and reactor animals must undergo a second comparative test at least after 6 weeks. The reaction is considered positive if there is an excess of 3 mm or more for bovine over avian tuberculin.

Bovine brucellosis has not been detected in recent years; at least three times per year a milk ring test is performed on the bulk milk of all herds. The vaccination of heifers between two and six months, vaccinated with B19 vaccine, will cease from January 2014 due to the favourable situation with regard to this disease

For both diseases the national legislation prescribes that milk which originates from infected herds shall be destroyed until free-status is recovered (following three consecutive negative tests one month apart for Brucellosis, and six months apart for Tuberculosis).

5.3.4 Foot-and-mouth Disease and Rinderpest

Several outbreaks of FMD occurred in IL in 2011 (February-June), in the north of the country close to the borders with Lebanon and Syria. On 17 November 2013, one outbreak was reported in a feedlot close to the border with Syria. However, no milk production holdings were located within the Protection Zone of 3 Km radius and the Surveillance Zone of 10 Km radius.

Vaccination is mandatory for cattle, sheep and goats, which are vaccinated every year (young cattle receive two boosters in their first six months, small ruminants should be vaccinated from two months on (vaccinated mother) or at birth, when the mother is un-vaccinated. Calves should not be moved for fattening to other farms unless vaccinated at least once. Second vaccination at the farm of destination should be administered within six weeks of arrival; small ruminants are vaccinated with a bivalent vaccine (A+O), and cattle with a trivalent one (A+O+Asia1).

In case of an outbreak of FMD, a Protection Zone of 3 Km radius and a Surveillance Zone of 10 Km radius are imposed, but no stamping out is applied. Restrictions are lifted after one month has elapsed from the last clinical signs; during this period, milk produced in both zones is sent to dedicated dairies (not approved for export, or in which export approval is temporary suspended) in order to undergo a specific heat-treatment under official control. It was demonstrated to the audit team that the processing establishments were informed in a timely manner, by e-mails sent by the CCA, of the evolution of the FMD outbreaks (including the most recent one in November 2013) and subsequent changes in the definition of restricted areas and municipalities and on which preventive measures should be taken. Actions were taken by the FBO to identify its suppliers within such areas.

5.3.5 Conclusions

As stated already in the report 2009-8229, although IL experiences recurrent FMD outbreaks, detailed instructions and procedures are available for official staff and were followed. No evidence was seen that any non-compliant raw milk had entered the export chain.

5.4 LABORATORY SERVICES

5.4.1 Legal Requirements

The animal and public health and veterinary certification conditions for the introduction into the EU

of raw milk and dairy products intended for human consumption are laid down in Regulation (EU) No 605/2010. Point II.2 of the model certificates, in Part 2 of Annex II to the Regulation, sets out the public health requirements to be met, including the requirement to meet the criteria for raw milk laid down in Chapter I of Section XI of Annex III to Regulation (EC) No 853/2004, and to meet the relevant microbiological criteria laid down in Regulation (EC) No 2073/2005. When imported into the EU IF and FOF have to comply with the following requirements or requirements at least equivalent to those of:

- Commission Directive 2006/141/EC on IF and FOF laying down specific rules on composition, presence and level of certain pesticides and labelling of the IF and FOF.
- Regulation (EC) No 1881/2006 covering contaminants in foods including IF and FOF.

5.4.2 Findings

5.4.2.1 Laboratories testing microbiological criteria for foodstuffs

Testing for microbiological criteria of dairy products and IF and FOF intended to be exported to the EU takes place in the Food Microbiology Laboratory within the Kimron Veterinary Institute. The Kimron Veterinary Institute is part of the MARD. It is accredited by the Israeli Laboratory Accreditation Authority (ISRAC) and the accreditation scope includes the reference methods provided by Regulation (EC) No 2073/2005 for *Listeria, Salmonella, E. coli, Staphylococcus aureus* and alternative methods for these parameters. It participates regularly and in general with good results in privately organised proficiency tests for those and other parameters. When an unsatisfactory performance was noted root cause analyses were carried out and follow-up actions were taken. The laboratory uses the LIMS system and reports the test results to the CCA and to the AVI performing official controls in the establishment, where the sample was taken.

Observations:

- The accreditation scope of the Kimron Institute Food Microbiology does not include the methods for testing *Enterobacteriaceae.* Tests for detection and/or enumeration of *E. sakazakii*, *Bacillus cereus* and Staphylococcal entero-toxins are not carried out in this laboratory.

- The dairy matrix used for the proficiency tests was almost exclusively milk powder.

Tests for SCC and TPC are carried out in the laboratory of the ICBA. The laboratory is accredited by ISRAC according to ISO 17 025 and the relevant tests are included within the accreditation scope. It participates in internationally organised proficiency tests four times per year and has a good quality management system in place. They produce the calibration samples for all dairy establishments in IL according to International Dairy Federation (IDF) standard 141C:2000. Tests for the presence of antibiotic inhibitors are carried out at establishment level in FBOs' private laboratories (see chapter 5.6).

Observations:

- The FBOs' laboratories testing for the presence of antibiotic inhibitors and visited by the audit team had good quality management procedures in place.

- One of the laboratories participated in international proficiency testing with satisfactory results.

5.4.2.2 Laboratories for the control of pesticides, contamination and composition of IF and FOF

IVSAH

The residues laboratory within the Kimron Veterinary Institute performs the testing for pesticides and contaminants in raw milk and final products according to an annual monitoring programme. The programme for raw milk testing includes 300 samples which are each tested for the different parameters included. A monitoring programme for residues in final products is in place and consists of one sample per establishment taken each month and tested for three parameters which are rotated on a yearly basis.

Observations:

- From 2012 the monitoring programme for residues in raw milk does not include heavy metals.

- The residues monitoring programme covers neither the specific parameters concerning pesticides which should not be used in the agricultural products intended for the production of IF and FOF as provided for by Annex VIII of Directive 2006/141/EC nor the maximum residue levels of pesticides or metabolites of pesticides in IF and FOF provided by Annex IX of the same Directive.

Public Health Services

- National surveillance of pesticides and contaminants in IF and FOF takes place but is not, in particular, focused on products eligible for export to the EU.

FBO

- The FBOs' controls for pesticides and contaminants in IF and FOF are mainly based on supplier controls managed by audit programmes, including some testing activities. It was noted during a review of documentation that all substances were analysed for and including, as regards pesticides, the application of detection limits ensuring compliance with the requirements of Directive 2006/141/EC.

- In addition, evidence in the contracts with the suppliers was seen with regard to specifications given for pesticides and contaminants.

5.4.3 Conclusions

The laboratory network for microbiological testing and testing for raw milk control was adequate in

terms of competence, capacity and compliance with EU requirements.

The official monitoring programmes for contaminants and pesticides cannot be considered to be adequate for monitoring purposes of IF and FOF destined for the EU market. However, the only establishment in IL producing IF and FOF had an adequate monitoring programme for monitoring compliance with Commission Directive 2006/141/EC as regards pesticides and with Regulation (EC) No 1881/2006 as regards contaminants.

5.5 Control of milk production holdings

5.5.1 Legal requirements

Point II.1 of the model certificates, in Part 2 of Annex II to Regulation (EU) No 605/2010, requires official controls of milk production holdings.

5.5.2 Findings

Official controls of milk production holdings are carried out by OV from the District Field Veterinary Office three to four times per year. The purpose of such controls relates mainly to animal health. According to the CCA, documented official controls for dairy hygiene aspects using a dedicated check-list started to be introduced in 2010. A frequency of on-farm inspections for dairy hygiene aspects will be established when the exercise of checking each farm once has been completed.

Observations:

- In the District Veterinary Field Office visited approximately 30 to 40 documented controls have been carried out in the 253 bovine milk production holdings in the district. The milk production holding visited by the audit team had previously been controlled by the CA only prior to the audit team's visit on the spot.

- For animal identification controls see chapter 5.2.

- The structures, equipment and procedures in place at holding level were largely satisfactory at both holdings visited except that and the milk tank storage area not being vermin proof. In one of the holdings visited, no wash-basin facilities were present in the milking area either.

- Both farms visited had a system in place for recording the temperature of the milk in the tank and the values seen by the audit team ensured compliance with the requirements of Regulation (EC) No 853/2004.

- For the two dairy establishments receiving raw milk visited by the audit team, the milk collection trucks were equipped with an automatic system which did not allow the loading of the milk above 6C in one case and 7C in the other case.

- At both holdings visited the records for medical treatment of animals were incomplete in terms of indicating the dosage and withdrawal period. It was explained to the audit team that according to IL requirements recording of treatments are not obligatory at holding level. Nevertheless, a system was in place identifying treated animals for which milk could not be delivered to the dairy for human consumption.

- A check-list for on-farm controls for hygiene of milking adopted after the previous audit in 2009 was recently amended to include controls over the records for medical treatments of the animals. Nevertheless, for non-compliances identified by the CA no enforcement action can be taken as the Israeli provisions currently in force do not require medical treatment records. This was identified already during the audit DG(SANCO)/2010-8433 on residues controls and consequently a recommendation (no 8) was issued.

5.5.3 Conclusions

The system of control of milk producing holdings was adequate to provide for the guarantees under Point II.1 of the model certificates, in Part 2 of Annex II to Regulation (EU) No 605/2010.

5.6 CONTROL OF RAW MILK UPON COLLECTION

5.6.1 Legal requirements

Point II.2 of the model certificates, in Part 2 of Annex II to Regulation (EU) No 605/2010, requires that raw milk is produced in accordance with the provisions of the Hygiene Package.

5.6.2 Findings

In response to recommendation No 1 of the report 2009-8219 *(To ensure that only raw milk complying with the criteria for TPC and SCC prescribed in Section 11.1.a.vi of the Milk-HTC export certificate laid down by Commission Decision 2004/438/EC is processed into milk-based products intended for export to the EU)* the CCA undertook to revise IS 55 as soon as possible and before the beginning of 2011 so that TPC and SCC limits will correspond to the EU regulation.

The system of CA controls over FBOs procedures for ensuring compliance with the IL raw milk criteria comprises controls carried out by the ICBA (testing for SCC and TPC - see chapter 5.4.2.1)) and controls carried out by the DCAP at establishment level (AVIs, VO and Food Safety Manager).

The IDB managing the National Service for Udder Health and Milk Quality is a private company jointly owned by the dairy industry, the milk producers, the consumers' organisations and the IL Government. It provides consultations free of charge to the farmers for milking management and improving the milk quality, performs laboratory tests, *inter alia*, also for mastitis pathogen diagnosis, antimicrobial sensitivity tests, water, bedding, towels, and teat dips concentrations. It has also an educative role for the farmers. Currently 70% of the farmers use their services.

According to national legislation, all dairy products produced in IL have to be produced from pasteurised milk.

Observations:

- In the two establishments receiving raw milk which were visited by the audit team, the FBO controls over the presence of antibiotic inhibitors in the raw milk were identified as a critical control point (CCP) and managed accordingly. The acceptance test was carried out with a test for beta-lactams in each compartment of the truck while after unloading a test for a wider spectrum of antibiotics was carried out for each farmer and silo. The system in place in both establishments visited required re-testing of the positive silo cases twice before

starting to take action. Nevertheless, no positive cases occurred in recent years.

- Tests for TPC are carried out three times per month from the bulk tank of each farm and a monthly arithmetical average is calculated. Testing for SCC is carried out at each delivery for each farm and a monthly arithmetical average is calculated. A bonus system is in place for monthly averages below 200 000 SCC and 10 000 TPC for cows milk. A penalty system of 10% for one month arithmetical average of 400 000 SCC or above and of 20% for two months arithmetical average in cows' milk is in place. When for three consecutive months the SCC arithmetical average exceeds 400 000 the farmers are subjected to a close supervisory system which requires an acceptance test prior to each delivery. If the SCC test before delivery exceeds 400 000, the milk is not accepted and has to be discarded. The same system applies when TPC average exceeds 100 000 per month. The compliance level in terms of results for SCC and TPC was satisfactory in all cases assessed by the audit team. The national average for SCC is currently below 190 000 while between 2010 and 2012 the highest average was 210 000. As regards TPC currently 50% of the monthly averages are below 10 000.

5.6.3 Conclusions

The system of control of raw milk upon collection is adequate to provide for the guarantees under Point II.2 of the model certificates, in Part 2 of Annex II to Regulation (EU) No 605/2010.

5.7 LISTING OF ESTABLISHMENTS

5.7.1 Legal requirements

Article 12 of Regulation (EC) No 854/2004 requires that products of animal origin may be imported into the EU only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up, kept up-to-date and communicated to the Commission.

5.7.2 Findings

Export approval procedures are described in Regulations for the Control of the Export of Animals and Animal Products of 1998; the establishment must have valid licences for the national market issued by the competent services of the MoH according to the Business licensing Law of 1968 and the Control of Commodities and Services Order of 1960.

P.S. Dairy 8.1.61 (Export of dairy products from IL - Principles) defines the general hygiene requirements applicable to dairy establishments approved for export, equivalent to those set out in Annex II to Regulation (EC) No 852/2004 and lays down procedures for the administrative procedure for granting the EU approval. The procedure includes application, visits by an approval committee from the department of animal products, which verifies structure and own-check programme. Export to the EU can only take place when the establishment has been EU listed.

Thirteen dairy establishments are currently listed for export to the EU, according to the list published on the Health and Consumers Directorate General (DG SANCO) website. According to the CCA, seven establishments are currently exporting dairy products to the EU.

Observations:

- The audit team reviewed the files of one establishment withdrawn from the list of export-approved establishments by the CCA in January 2013. The CCA stated that the procedure can take a long time as first the plant is suspended from certification for export and time is given to the FBO to bring the non-compliances under control. If this is not the case, formal de-listing communication is sent to the FBO and the Commission Services. In the case seen by the audit team, the whole process took more than one year.

- During the storage period some dairy products are stored temporarily in storage sites outside the EU listed establishments. In total four storage sites are used, three of them operating under controlled temperature conditions and one operating at ambient temperature conditions which are all registered by the CA. None of the three storage facilities operating under controlled temperature conditions was EU listed as required by Article 12 of Regulation (EC) No 854/2004. Moreover, this was not considered by the CA. Nevertheless, export certification of consignments only takes place when the products have been returned to the EU listed establishments. Moreover, the establishments are controlled every second week by the AVI for storage conditions and the presence of the products.

5.7.3 Conclusions

Procedures and responsibilities for granting and withdrawal of export approvals are adequate to ensure that only EU compliant establishments are listed.

Although exports only take place from EU listed establishments, storage under controlled temperature conditions takes place in some cases in facilities outside the EU listed establishments, which are not EU listed, contrary to the requirements of Article 12 of Regulation (EC) No 854/2004.

5.8 Official controls at establishment level

5.8.1 Legal requirements

Article 12 of Regulation (EC) No 854/2004 lays down that the CA of a third country of origin has to guarantee that establishments placed on the list of establishments from which imports of specified products of animal origin to the EU are permitted, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant EU requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that are determined to be equivalent. It also lays down that an official inspection service supervises the establishments and has real powers to stop the establishments from exporting to the EU in the event that the establishments fail to meet the relevant requirements.

The animal and public health and veterinary certification requirements for the introduction into the EU of products of animal origin intended for human consumption are laid down in the product specific Commission Regulations covered by the scope of the audit, i.e. Commission Regulation (EU) No 605/2010.

When imported into the EU, IF and FOF have to comply with the following requirements or requirements at least equivalent to those of:

- Commission Directive 2006/141/EC on IF and FOF laying down specific rules on composition, presence and level of certain pesticides and labelling of the IF and FOF.

- Regulation (EC) No 1881/2006 covering contaminants in foods including IF and FOF.

- Directive 2000/13/EC regarding labelling of foodstuffs.

5.8.2 Findings

5.8.2.1 General and specific hygiene requirements

Official controls in relation to the general and specific hygiene requirements are part of the AVI duties and subject to verification during the CCA supervisory visits on the spot. Instructions for such controls are included in several P.S.s, Standard Operating Procedures and Sanitation Standard Operating Procedures issued by the CCA.

Observations:

- Although the official controls on these issues in general were adequate and a high level of compliance with the general and specific hygiene requirements was noted, the following shortcomings were noted:

    - In one establishment visited which underwent partial reconstruction at the time of the audit team's visit, several maintenance and pest control issues throughout the factory were noted. In another establishment where several maintenance issues were scheduled to be addressed by long-term effective investments, a lack of intermediate actions to prevent contamination of products from above by rusted pipes and peeling paint was not noted by the CA. In two establishments the cleaning procedures were not fully effective in a few isolated areas where exposed products could be present.

5.8.2.2 HACCP – based procedures

Official controls in relation to the FBOs' HACCP-based systems are part of the AVI duties and subject to verification during the CCA supervisory visits on the spot. Extensive instructions for controls on FBOs HACCP-based systems are available for the three levels of controls. The FBOs HACCP-based systems are certified by the CCA Food Safety Manager once per year.

Observations:

- In the establishments visited by the audit team, official controls in relation to the FBOs' HACCP-based systems were largely satisfactory. All FBOs visited had implemented HACCP-based procedures, identified CCPs, monitored them and had procedures in place for corrective actions, when the critical limits were not adhered to. Pasteurisation was a CCP in most establishments visited (except for one powder plant using pasteurised whey as raw material where pasteurisation was not defined as a CCP) but in practice managed as a CCP. Critical limits for pasteurisation were in all cases set more strictly than prescribed by Regulation (EU) No 605/2010 and supporting documentation, for monitoring and action to be taken when the limits were exceeded, was available.

- All establishments visited pasteurising raw milk applied the Alkaline Phosphatase test as a

verification of the pasteurisation process using the ISO Standard 11816-1:2006/IDF 155-1:2006, applying a higher sensitivity than prescribed in EU legislation.

5.8.2.3 Microbiological testing

Official controls in relation to FBOs' microbiological testing are part of the AVI duties and subject to verification during the CCA supervisory visits on the spot. The Food Safety Manager assesses mainly the suitability of the FBOs' sampling and testing programmes for microbiological criteria while the AVI and the VO assess mainly its implementation.

The AVI takes yearly official samples which are tested in the Kimron Institute for verification of the FBOs' HACCP based procedures in each of the dairy establishments approved for export to the EU.

In addition, in accordance with the P.S. 2.3.60, samples from each batch exported to the EU are tested in the Kimron Veterinary Institute. The Kimron Institute test results are a prerequisite for signing the export certificate by the AVI and they were available on the spot for all certificates assessed by the audit team.

Observations:

- According to the P.S. 2.3.60 only three units have to be sampled and sent for microbiological testing of dairy products in Kimron Institute to verify compliance with the previsions of Regulation (EC) No 2073/2005 before certification, instead of the five stipulated in the said Regulation when microbiological verification of batches takes place. The methods indicated on the analysis certificate were ISO reference methods or ISO/Israeli standards making it unclear whether the IL standard was used or the ISO reference method. No documentation was available to demonstrate that the IL standard methods were validated against the ISO reference method as required by Article 5(5) of Regulation (EC) No 2073/2005. Nevertheless, the CCA stated that for export to the EU only the ISO reference methods are used. In the P.S. 2.3.60 the relevant criteria of Regulation (EC) No 2073/2005 were included except for the food safety criteria for *Listeria monocytogenes* for infant foods, which implies that powdered IF and FOF, where recontamination in fact is possible after a heat treatment effective to eliminate *Listeria monocytogenes* was not sampled and tested for this species.

- In two out of the five establishments visited, FBOs also carry out batch verification of the production with only three samples. In the three other establishments sampling was carried out in order to verify the proper operation of the HACCP programme.

- In the establishment producing IF and FOF official batch verification did not cover *E. sakazakii*. Nevertheless, batch verification was carried out by the FBO covering this parameter, using an FDA parameter, where it could not be demonstrated that it had been validated against the reference method. In addition, the process hygiene criteria *enterobacteriaceae* and *Bacillus cereus* were covered.

- In one establishment visited, the FBO procedure for taking action in case of non-compliant food safety test results did not adequately address the risk and the CA undertook to ensure that this procedure would be changed. Nevertheless according to the CA, the procedure had not been used as no non-compliant food safety test results were identified in that establishment.

5.8.2.4 Water Testing

Official controls in relation to FBOs water testing are part of the AVI duties. Specific instructions for such controls are laid down in P.S. Nos 5/2009 and 15/2008. The FBOs are required to test for the microbiological parameters (Part A of Annex I to Council Directive 98/83/EC) and to demonstrate compliance with the monitoring parameters (Part C of Annex I to Council Directive 98/83) either through own testing or by making the municipal water test results available to the CA.

Observations:

- In all establishments visited by the audit team, the FBOs had a water sampling and testing plan in place. Satisfactory test results were seen by the audit team in all cases verified for microbiological parameters. Testing for the chemical parameters in Part B (contaminants and pesticides) of Annex I to Commission Directive 98/83/EC is not required by the CA. However, in one establishment the parameters of Part B were tested for instead of the parameters of Part C and in three of the other five establishments visited testing for some of the parameters of Part B was also carried out. Nevertheless, documentation for testing of all the Part B parameters (for instance by providing the compulsory test results from the water suppliers) were not available in four out of five establishments visited.

- Testing for *enterococci* was not carried out in two out of five establishments.

5.8.2.5 Traceability and identification marking

Official controls in relation to FBOs' recall system are carried out by the AVI yearly and verified by the VO and food safety manager during visits on the spot.

Official controls in relation to the identification marking are carried out by the AVI at the time of the pre-loading checks for exports to the EU.

Observations:

- During the visits on the spot the audit team noted that the ID marking was correctly applied. The partial traceability exercises carried out by the audit team during the visits on the spot were largely satisfactory.

- In one establishment the traceability exercise was difficult and the connection between the different production steps was ambiguous. The FBO and CA had already identified gaps in the traceability system and a new system was under development at the time of the audit team's visit.

5.8.2.6 Special requirements for IF and FOF

Compositional criteria were verified by the FBO mainly by extrapolation from recipes but also in several cases by analyses. According to the own-check programme, Directive 2006/141/EC has to be observed in this respect for products destined to the EU market. A randomly selected recipe for IF reviewed by the audit team confirmed this procedure.

For products to the EU market, compliance with the requirements for contaminants was ensured by observing the IL legislation which includes the requirements for the limits of contaminants in food

stuffs as laid down in Commission Regulation (EC) No 1881/2006 and with regard to pesticides by observing Directive 2006/141/EC. This was done by requiring products declarations from suppliers, and some audits of certain suppliers. In addition, sampling and testing took place under the FBO's monitoring programme. All required parameters were covered and the detection limits were adequate to ensure that verification of compliance with Directive 2006/141/EC was ensured.

Official controls of the specific requirements of IF and FOF destined for export to the EU was carried out by the AVI despite no CA being designated for this task.

Official monitoring of IF and FOF for composition, contaminants, pesticides and microbiological contamination is carried out by the MoH services at the level of the domestic market without specifically focusing on products from the exporting establishment.

5.8.2.7 Documentation of official controls

Official controls at establishment level are carried out in accordance with the CCA instructions (P.S.s)**.** The minutes of the meetings between the CA and the FBO, the non-compliances identified by the CA, the action taken by the FBO and the follow-up are recorded in the food inspection IT programme and consequently verified by the VO and food safety manager respectively. Each level of control may open new non-compliances and the follow-up of the action taken by the FBO to address them is carried out by the AVIs. All these steps are recorded in the same IT programme which gives a structured overview of the compliance history in each plant and the activity of each of the three levels of control.

Observations:

- Official controls for dairy hygiene at farm level started to be documented only since 2010 (see chapter 5.5). Both holdings visited by the audit team have been subject to such controls prior to the audit team's visit on the spot.

5.8.3 Conclusions

A high level of compliance with the EU provisions is provided for in the Israeli control system which covers the whole production chain for dairy products. Some deficiencies were noted with regard to microbiological testing for verification of compliance with Regulation (EC) No 2073/2005 (reduced number of sample units for batch verification) and there are no requirements for testing for *L. monocytogenes* in IF and FOF and documentation of water including testing for the parameters of part B of Council Directive 98/83/EC.

Although, as regards the control of IF and FOF to ensure compliance with the specific requirements, when marketed on the EU market, there is no CA designated, national legislation regarding the specific requirements for IF and FOF is either similar to Codex requirements, or similar or equivalent to EU requirements. Moreover, the controls carried out by the only FBO producing and exporting IF and FOF to the EU were adequate to meet the specific EU requirements when these products are marketed on the EU market.

5.9 Official certification

5.9.1 Legal requirements

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

The specific animal health, public health and veterinary certification requirements for the introduction into the EU of products of animal origin intended for human consumption, are laid down in the product specific Commission Regulations (see point 5.7.1).

The specific health and veterinary certification requirements for the introduction into the EU of certain composite products intended for human consumption, are laid down in Commission Regulation (EU) No 28/2012.

5.9.2 Findings

In response to recommendation No 2 *(To ensure that the conditions for certification of milk-based products exported to the EU comply with the requirements of Council Directive 96/93/EC and with the conditions stated in the Milk-HTC export certificate laid down by Commission Decision 2004/438/EC. In particular, the CCA should ensure that certifying officers must complete the Milk-HTC export certificate laid down by Commission Decision 2004/438/EC in accordance with the notes at Annex II, and that copies of the Milk-HTC certificates is clearly different from the originals and that all certified products have undergone one of the HTCs indicated in Section 11.1.c of the Milk-HTC export certificate laid down by Commission Decision 2004/438/EC)*, the CCA undertook to correct the deficiencies in the certification procedures identified during the audit. The CCA issued an urgent instruction (dated 25 November 2009) to all the veterinary inspectors and officers in dairy plants approved for export and at the borders in order to rectify the situation. All recommendations were accepted and implemented immediately.

Procedures for certification of consignments for export to the EU are described in P.S. 3.3.61 (Health certificates for export of animal products-Principles and procedures) and in P.S. Dairy-3.3.66 (Food export certificate approved by Veterinary inspectors). According to the instructions, the health export certificate shall be prepared in four identical copies, all signed as original copies in blue ink: two are for the OV at the border (who has to certify Part I - Animal health attestation before loading of the consignment), one for the certifying AVI of the establishment, and the fourth is the original export certificate. The audit team noted that only the latter was indicated as "original". Copies of the signed certificates by the OV are faxed back to the certifying AVI at the establishment.

Observations:

- It was verified that copies of the signed certificates by the OV were faxed back to the certifying AVI.

- It was verified that dairy products exported to the EU had been treated in accordance with one of the treatments prescribed in Article 4 of Regulation (EU) No 605/2010. However, there was no procedure available at the FBOs visited, apart from at one FBO visited (the establishment producing IF and FOF), nor at the CA, stipulating that sourced raw materials such as processed animal products (milk powders) should be obtained from EU listed

establishments as required by Article 12 of Regulation (EC) 854/2004. Nevertheless, in all establishments using milk powders these were obtained from only EU listed sources. Moreover, the awareness about this requirement amongst FBOs and some AVIs was limited.

- A specific numbering system is in place for issued certificates in each establishment in order to control the certification procedure.

5.9.3 Conclusions

Dairy products exported to the EU had been heat-treated in accordance with one of the heat-treatments prescribed by Article 4 of Regulation (EU) No 605/2010.

Sourced raw materials such as processed animal products (milk powders) were only obtained from EU listed establishments in accordance with Article 12 of Regulation (EC) No 854/2004. Nevertheless, procedures were not established amongst most FBOs visited and by the CA guaranteeing that raw materials sourced would be obtained from EU listed sources complying with relevant EU requirements, in particular those of Regulation (EC) No 853/2004. Moreover the awareness about this requirement was not high.

6 Overall Conclusion

A high level of compliance with the EU provisions is provided for in the Israeli control system which covers the whole production chain for dairy products. As regards the control of IF and FOF to ensure compliance with the specific requirements, when marketed on the EU market, there is no CA designated. However, national legislation regarding the specific requirements for IF and FOF is either similar to Codex requirements, or similar or equivalent to EU requirements. Moreover, the controls carried out by the only FBO producing and exporting IF and FOF to the EU were adequate to meet the specific EU requirements, when these products are marketed on the EU market.

Some shortcomings were noted with regard to the operation of the cattle identification database in order to support animal health controls, the lack of listing of storage facilities used for intermediate storage of dairy products before export, microbiological testing, documentation of water testing and procedures and awareness about EU requirements for sourcing of animal products (milk powders) used in the production of dairy products destined for the EU market.

Nevertheless, currently the control system implemented by the CA largely provides the guarantees required by the health certificate and the EU legislation.

7 Closing Meeting

A closing meeting was held on 5 December 2013 with the CCA, the IVSAH in Beit Dagan. At this meeting the audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA acknowledged the findings and conclusions presented by the audit team. In addition, information on action already taken and planned, in order to address particular findings in the establishments visited, was provided.

8 Recommendations

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

No.	Recommendation
1.	To designate a Competent Authority for ensuring compliance with the specific requirements for infant formulae and follow-on formulae, when marketed on the EU market as provided for in Article 46 (1(b)) of Regulation (EC) No 882/2004.
2.	To pursue the proposed amendments to the legislation on identification of cattle and to ensure that controls on the bovine identification and registration system, including the cattle identification database will be implemented effectively so that the Israeli Veterinary Service and Animal Health can provide fully reliable guarantees based on the relevant animal health monitoring programmes that the animal health situation of the animals supplying milk intended to be exported as dairy products to the EU comply with the requirements listed in Point II.1 of model milk HTC of Part 2 of Annex II of Regulation (EU) No 605/2010.
3.	To update the requirements for microbiological criteria in order to ensure full compliance with the requirements of Regulation (EC) No 2073/2005 when certifying export of consignments of dairy products as provided for in Point II.2 of the milk-HTC of Part 3 of Annex II to Regulation (EU) No 605/2010.
4.	To ensure that the official controls on potable water cover all requirements of Council Directive 98/83/EC when certifying export of consignments of dairy products as provided for in Point II.2 of the milk-HTC of Part 3 of Annex II to Regulation (EU) No 605/2010.
5.	To ensure that storage facilities, when operated under temperature controlled conditions being used for intermediate storage of dairy products comply with European Union requirements and are European Union listed as provided for in Article 12 (1(a)) of Regulation (EC) No 854/2004.
6.	To ensure that procedures and awareness are adequate to guarantee that sourcing of animal products for production of dairy products destined for export to the EU will be obtained only from European Union listed sources complying with relevant European Union requirements in particular those of Regulation (EC) No 853/2004.

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. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

Legal Reference	Official Journal	Title
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. 28/2012	OJ L 12, 14.1.2012, p. 1-13	Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
Dir. 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
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. 2006/141/EC	OJ L 401, 30.12.2006, p. 1-33	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC