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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE NETHERLANDS

FROM 03 TO 14 SEPTEMBER 2012

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MILK AND DAIRY PRODUCTS

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in the Netherlands from 3 to 14 September 2012. The main objective of the audit was to evaluate the official controls related to the production and storage of milk and dairy products and the follow-up action taken by the competent authorities (CAs) with regard to official controls related to the safety of food of animal origin, in particular milk and dairy products.

The CA of the Netherlands have addressed all but one of the recommendations of the report DG(SANCO)/8146/2006 (hereafter referred to as 2006-8146) related to milk and dairy products.

The system for official controls on milk and dairy products is well established. The COKZ is implementing a risk-based control system in line with the requirements of Article 3 of Regulation (EC) No 882/2004. However, the COKZ did not carry out all of the planned audits of dairy establishments in 2011.

The procedures for registration and approval of establishments were in line with the European Union (EU) requirements and were documented adequately in the industrial scale dairy establishments visited by the audit team. However, in relation to the small-scale establishment visited, the implementation of the approval procedure did not guarantee compliance with the approval conditions at the time of the FVO audit.

The CA's soft line taken in relation to enforcement is reflected in the statistics on enforcement measures, with only a few strong actions taken.

The official controls over the food and business operator's (FBO) compliance with the hygiene rules at establishment level were carried out regularly and were adequate in relation to most aspects. The official controls included the Hazard Analysis Critical Control Points (HACCP)-based procedures and own control programmes. Nevertheless, the official controls on potable water did not cover all the relevant aspects and the FBOs' own control on potable water had some shortcomings. The FBOs' testing schemes and the official controls to verify compliance with the microbiological criteria as laid down in Regulation (EC) No 2073/2005 were adequate.

The system used in the Netherlands to verify that the health requirements for raw milk and colostrum production, and, in particular, the health status of the animals and the use of veterinary medicinal products are being complied with on milk production holdings is based on controls carried out by private veterinary practitioners (PVPs) instead of official controls. This is not in line with point 1 of Chapter I, Annex IV to Regulation (EC) No 854/2004. The controls on milk production holdings were carried out as planned. The system for raw milk quality control was functioning adequately.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ABP(s)	Animal by-product(s)
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
CFU	Colony forming units
COKZ	Controlling Authority for Milk and Milk Products *(Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel)*
DG(SANCO)	Health & Consumers Directorate General
EC	European Community
E. coli	*Escherichia coli*
E & LI	Ministry of Economic Affairs, Agriculture and Innovation *(Ministerie van Economische Zaken, Landbouw n Innovatie)*
EU	European Union
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Points
HP	Hygiene Package; Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
NVWA	Netherlands Food and Product Safety Authority *(Netherlandse Voedsel- en Warenautoriteit)*
PVP	Private veterinary practitioner
SCC	Somatic Cell Count
TBC	Total Bacterial Count (Plate count at 30 °C)
VWS	Ministry Of Public Health, Welfare and Sports *(Ministerie van Volksgezondheid, Zelzijn)*

1 Introduction

The audit took place in the Netherlands from 3 to 14 September 2012 as part of the planned audit programme of the FVO. The audit team comprised two auditors from the FVO.

The audit team was accompanied throughout the audit by representatives from the Central Competent Authority (CCA), the Netherlands Food and Consumer Product Safety Authority (NVWA) and the Controlling Authority for Milk and Milk Products (COKZ).

The opening meeting was held on 3 September with the NVWA and the COKZ in Utrecht. 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 main objective of the audit was to evaluate the official controls related to production and storage of food of animal origin and the follow-up action taken by the CAs in response to the recommendations made in report 8146-2006 with regard to:

- CA organisation and operation; and
- official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over milk and dairy products in the framework of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 were subject to this evaluation.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

COMPETENT AUTHORITIES			**Comments**
Competent authorities	Central	2	NVWA and COKZ
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Storage facilities		1	
Laboratories		1	
Milk processing plants		7	
Dairy holdings		2	

3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 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.

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

4 Background

The previous audit concerning the safety of food of animal origin in the Netherlands was carried out from 30 January to 10 February 2006, the results of which are described in report 8146-2006. This report is accessible at:

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

The report included 13 recommendations, of which 9 were relevant for the controls over milk and dairy products. The action plan received from the Netherlands authorities provided satisfactory guarantees in response to all but one of the report's recommendations in relation to controls over milk and dairy products. The recommendations and a summary of the CA response can be found under the relevant headings of this report.

5 Findings And Conclusions

5.1 Competent Authorities

5.1.1 Legislation

The Decree of the Ministry of Health, Welfare and Sports (VWS) on Hygiene of Foodstuffs of 3 October 2005 stipulates that raw milk from cows can be sold on farm for direct sale only if it is labelled that is has to be cooked before use. Raw milk derived from other species can be put on sale as raw (for example, goat, camel or horse milk).

5.1.2 Designation of Competent Authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

Audit findings

The country profile for the Netherlands provides an overview of the official control systems in place over foodstuffs in the Netherlands, based on the information provided by the CA. The country profile is available under the following link: http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=NL

The Ministry of Economic Affairs, Agriculture and Innovation (E & LI) and the VWS are responsible for the policy making over milk and dairy products and other foodstuffs. The NVWA is the central authority for food production and is responsible for the implementation of the Hygiene Package (HP). The NVWA has been restructured and the new organisation started its operations on 1 January 2012. The previous VWA has joined with the plant Protection Service and the General

Inspection Service. In addition, a new division, the Division of Criminal Investigation has been created with 110 staff. The total number of staff of the NVWA is 2 150 and the current budget is 230 million Euro.

The NVWA has six divisions and one Division is the Consumer and Safety Division which is responsible for milk and dairy products.

The COKZ is the central authority for milk and dairy products. It is an independent governmental body under government supervision and its tasks are stipulated in the Dutch legislation. The COKZ rules have to be approved by the E & LI and the VWS. The COKZ is under the responsibility of the NVWA and they approve its annual plan for official controls. The COKZ is accredited to ISO 45004.

On 1 July 2012 the COKZ received additional tasks as the Supervisory Board for Poultry, Eggs and Eggs products joined the COKZ. The COKZ took over the staff from the Supervisory Board. Thus in addition to the milk and dairy products the COKZ are responsible for the control and supervision of the quality aspects of these commodities. The annual work programme of the COKZ has to be approved by the NVWA. The total number of staff is 60, of which 45 are working in the milk and dairy products sector.

The audit team received the 2012 annual work plan of the COKZ. In 2012, the COKZ will no longer have staff allocated especially to supervise establishments producing special foods (reduction of the COKZ working days for this sector from 45 to 20) and the number or working days allocated to controls on animal by-products (ABPs) will be reduced from 40 to 20.

The COKZ is running the following programmes:

- Supervision and control of dairy farms – audits of FBOs' farm quality schemes;
- Supervision and control over the milk payment system;
- Supervision and control over residues and contaminants in farm milk;
- Controls on Infant formula/Food for Specific Medical Purposes;
- Control programmes for assuring compliance with food legislation;
- Sampling dairy products for further processing sourced outside the Netherlands; and
- Export certification.

Recommendation 5 of the report 2006-8146 concerned the training and information provided to staff carrying out official controls. Evidence was available that the NVWA and the COKZ had organised training for its staff performing official controls. The training covers different topics, ranging from communication skills to technical topics (for example, HACCP, microbiological criteria). In addition to their participation in the training courses, the inspectors are accompanied once a year by senior auditors during their audits of dairy establishments to ensure a harmonised approach.

5.1.3 Co-operation and co-ordination between and within Competent Authorities

Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between CAs. Article 4(5) of the Regulation requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-

operation shall be ensured between the different units.

Audit findings

In response to Recommendation 1 of the report 2006-8146 to put in place appropriate co-ordination and co-operation procedures between the different units of the VMA responsible for carrying out official controls, the CA indicated that they were improving the intranet information system and providing training to staff. Evidence of co-ordination and co-operation between the different authorities was available. The NVWA and the COKZ have regular meetings. The COKZ officials have monthly meetings with the senior COKZ auditors. A clear line of reporting has been established within the COKZ and between the COKZ and the NVWA.

5.1.4 Registration/approval of food business establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Audit findings

The NVWA has authorised the COKZ to register and approve FBOs. The dairy collection centres (30) are registered whereas the dairy establishments are approved. The total number of dairy establishments including baby food under the COKZ supervision is 750 (162 industrial scale dairy establishments, 336 on farm and small scale dairy producers, 105 dealers, 37 storage facilities, 9 establishments producing baby food, and 101 on farm dairy producers with direct sale only (registered). Evidence was available that the FBOs visited by the audit team had been inspected against the requirements of the HP before the approvals.

The establishments can have several approvals. The FBO can, for example, use a different approval number for products produced for a certain customer. Once the establishment has been approved the approval is valid until further notice. In case of major refurbishments, the CA has to carry out an additional inspection over the new facilities. The scope of the approvals is not given in the approval letter but is available in the COKZ inspection database.

Documentation in relation to the approval procedure was available for the establishments visited.

The audit team made the following observations:

- A small-scale dairy establishment visited, processing milk from its own cows only, had undergone major refurbishments (a new production building had been constructed with partly new equipment). The pre-approval inspection of the new premises and the own controls carried out at the start of September 2012 had revealed significant deficiencies in relation to the hygiene requirements, equipment and HACCP-based own control programmes. The plant had not been in operation during the inspection thus the processing hygiene could not be assessed. However, the FBO could still continue the production in the new premises without any additional measures being taken to ensure the safety of the products produced. The deadline given for the corrective actions was three months and the inspector planned to carry out a follow-up visit within one month after the deadline for corrective actions. In addition, the audit team noted several additional deficiencies during the audit (during which the plant was in operation, see chapters 5.2.1 and 5.2.2).

5.1.5 Prioritisation of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

Audit findings

The COKZ establishes the control frequencies in dairy establishments on an annual basis. The frequency of inspections and sampling depends on the inherent risk of the product or process and the FBO's compliance history. The basic frequency comprises one complete audit over the period of three years and annual partial audits. The partial audits are targeted to specific areas. In 2011 the audits focussed on the checking of installations and equipment, in 2012 the audits focus on personal hygiene, and the prevention of cross-contamination. In addition to the annual regular audits, the COKZ 2012 control plan comprises unannounced inspections of 50 industrial scale dairy establishments and in 90 establishments of small-scale producers and 50 extra (follow-up) audits in both types of establishments. In 2011, the total number of audits and inspections in dairy establishments was 997 in a total of 750 establishments under the COKZ supervision (including 9 routine audits to establishments approved for processing of special foods). The total number of audits planned was 1 070.

Exporting dairy establishments are audited annually in relation to the specific requirements of the importing countries and the final products destined for export also sampled and tested according to the importing countries' requirements.

In case serious shortcomings are detected during a routine audit, a follow-up audit will take place during the next four months.

The sampling frequency is established based on historical data and takes into account the type of products and the inherent risk of the product.

The audit team verified that the audits in the establishments visited had been carried out according to the annual programme and that follow-up inspections had been carried out when necessary. The audit reports seen also covered HACCP-based systems and microbiological criteria.

The audit team made the following observations:

Not all of the routine audits and unannounced audits planned were carried out, whereas the number of follow-up audits carried out in relation to small-scale dairies was higher than planned as more shortcomings than were estimated were found in the small scale-dairies.

Planned/implemented routine audits in 2011	Number of routine audits planned/ carried out	Number of follow-up audits planned/carried out	Number of unannounced audits planned/carried out
Industrial scale dairies	341/294 (86 %)	50/38 (76 %)	50/34 (68 %)
Small-scale dairies	339/310 (91 %)	49/75 (153 %)	90/88 (98 %)

5.1.6 Official sampling and laboratory analysis

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for the laboratories so designated.

Audit findings

The COKZ has designated a laboratory owned by the dairy industry to carry out microbiological analysis of official samples. The laboratory has been accredited according to ISO/EN 17025 by the Dutch Accreditation Council. The accreditation body carries out annual visits and every four years a major audit is carried out for the renewal of the accreditation. The audit team received the list of the accredited methods. The laboratory sends the results to the COKZ and they send the results to the dairies. The COKZ relies on the accreditation system in relation to guaranteeing the impartiality and integrity of the analysis.

The laboratory visited by the audit team had adequate facilities, equipment and quality control measures in place.

The COKZ authorities take official samples once annually in the dairy establishments. The results of the 2011 sampling and analysis and official sampling plan for 2012 were received. The results of the 2011 official sampling of final products in industrial dairy establishments are given below:

Microbe analysed	**Number of analyses**	**Number of samples exceeding the limit***	**Remarks**
Listeria monocytogenes	1 369	7	None of the results exceeded 100 CFU/g
Salmonella	408	0	Absent
Coagulase-positive *staphylococci*	581	9	
Escherichia coli (E.coli)	588	9	
Enterobactericeae	262	16	14 of the exceeding results concerned ice cream

* The limit used is the respective m-value of Annex 1 to Regulation (EC) No 2073/2005.

The results of the official sampling of final products in small-scale dairy establishments are as follows:

Microbe analysed	Number of analyses	Number of samples exceeding the limit*	Remarks
Listeria monocytogenes	1207	11	The value of 100 CFU/g was exceeded in one sample
Salmonella	796	0	
Coagulase-positive *staphylococci*	695	125	
Staphylococcal enterotoxins	27	0	
E.coli	204	10	
Enterobactericeae	385	40	
Campylobacter	65	0	Analyses comprised horse and camel raw milk

* The limit used is the respective m-value of Annex 1 to Regulation (EC) No 2073/2005.

The CA stated that based on the results above, the microbiological quality of dairy products produced in industrial dairy establishments except for ice cream was in general in line with the requirements of Regulation (EC) No 2073/2005. In relation to dairy products produced on farm and in small scale establishments, raw milk cheeses relatively often exceeded the limit for *Staphylococcus aureus* (125 samples of 515 tested) and of 20 ice cream samples tested for *Enterobacteriaceae* 10 samples exceeded the limit.

In the 2012 official sampling plan the sampling frequency set is higher in establishments producing grated and grinded cheeses as these products are considered more of a risk in relation to microbiological contamination.

Evidence was available of root-cause analysis in the case of exceeding the limits and actions taken where limits are exceeded (for example, follow-up inspections and additional sampling, increased own controls).

The COKZ samples 1-4 samples of dairy products/type of dairy products/month sourced outside the Netherlands and destined to be used for further processing. The products are sampled for different parameters comprising antibiotic residues, foreign material/dirt, heavy metals, pesticides, PCBs, dioxines, chloramphenicol, aflatoxin M1, radioactivity and microbiology.

The audit team made the following observations:

- According to the information received from the CCA the official sampling plan for 2012 does not cover sampling of liquid milk products and butter as the historical results have been satisfactory.

5.1.7 Procedures for performance of control activities

Legal requirements

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Audit findings

The CCA had established several procedures for the performance of official controls. The procedures comprise guidelines, working instructions and check-lists. For example, the COKZ has established a guideline and a check-list on the requirements of the HP in relation to dairy holdings and dairy establishments.

The private organisations carrying out checks on the dairy hygiene on holdings had issued a guidance document and check-lists for these controls. The audit team verified that the COKZ auditors met used harmonised check-lists and that the report format was harmonised. The reports seen included shortcomings and deadlines for corrective actions.

In response to Recommendation 7 in report 2006-8146 concerning the establishment of procedures to inspect products of animal origin that need to be certified in order to ensure that the information in the certificate is accurate and authentic as required by Regulation (EC) No 882/2004, Article 30(2), the CA stated that the COKZ is carrying out intensive control programmes in exporting establishments that are visited at least once a month for sampling and administrative checks. This CA response to the recommendation of the report 2006-8146 on certification had not been considered as satisfactory.

5.1.8 Enforcement measures

Legal requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation. Article 55 of the Regulation states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Audit findings

The COKZ's approach to enforcement measures is “soft where possible, hard as necessary”. Minor deficiencies are followed by oral intervention, whereas medium deficiencies are followed by written intervention and by a re-inspection and major deficiencies by a penalty and official measures. The audit team could verify interventions taken in the case of medium shortcomings in relation to some of the establishments visited.

The number of enforcement measures taken in 2011 is given in the following table:

Type of dairy establishments	Number of establishments revisited in 4 months (medium deficiencies)	Number of establishments receiving written warnings	Number of establishments receiving fines	Total number of audits in 2011
Dairy plants with industrial production	54	9	2	394
Small scale dairy establishments or on farm dairy processors	93	16	4	590

5.1.9 Verification and review of official controls and procedures

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed. Under Article 4 of the Regulation CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Audit findings

In response to Recommendations 2 and 6 in report 2006-8146 concerning the implementation of audits, audits on the COKZ and implementation of a system to verify the effectiveness of official controls carried out, the CA indicated that the COKZ will be audited annually. The NVWA is subject to internal audits by its internal audit department.

Evidence of annual audits carried out by the NVWA over the COKZ and audits carried out by the COKZ over the industry-owned accredited laboratory carrying out analyses on raw milk and milk and dairy products and on dairy farm quality assurance schemes was available. The audit team received the NVWA 2011 audit report on the COKZ. The 2011 audit comprised one audit day at the the COKZ headquarters and 10 separate audits. The audit covered controls related to the HP, microbiological criteria, ABPs and animal health controls (including zoonoses) related to the dairy sector.

Conclusions on Competent Authorities

The CA of the Netherlands had addressed all but one of the recommendations of the report 2006-8146.

The COKZ is implementing a risk-based control system in line with the requirements of Article 3 of Regulation (EC) No 882/2004.

The system for official controls on milk and dairy products is well established. However, the COKZ

had not been able to carry out all the planned audits for 2011 in dairy establishments and for the industrial scale establishments the planned audit frequency has not been reached.

The procedures for registration and approval of establishments were in line with the EU requirements and were documented adequately in the dairy establishments visited by the audit team. However, in relation to the small-scale establishment visited, the implementation of the approval procedure did not guarantee compliance with the approval conditions.

The CA line taken in relation to enforcement is reflected in only a few strong enforcement measures taken.

The principal difference in relation to acceptance of systems-based certification remains.

5.2 Official controls over food Business Operators' compliance with hygiene rules at establishment level

5.2.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the FBO carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, sitting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify the FBO's compliance with these requirements.

Audit findings

In response to Recommendation 13 of report 2006-8146 concerning the implementation of controls on ABPs in the dairy sector the CA indicated that the COKZ and the VWA have made agreements that ensure that the COKZ officials carry out controls on ABPs in dairy establishments.

In all establishments visited the CA had carried out annual regular audits to verify certain requirements of the HP. The audits also covered the handling of ABPs. The audits had identified some shortcomings. In case the shortcomings were classified as medium, there was documentary evidence of the actions taken and the follow-up. However, if the shortcomings were minor, the follow-up was often not documented (as these were dealt with orally). The six industrial scale dairy establishments were in in compliance with most aspects of the general and specific requirements of the HP. However, one small-scale dairy establishment and on-farm producer had moved into new premises one week before the audit. The audit team noted several shortcomings during the FVO audit.

The audit team made the following observations during the visits to the establishments:

- The small scale establishment visited lacked a hygiene lock at the entry into the production.

The different production areas had not been divided into different risk zones. An ordinary plastic flower watering device was used for filling yoghurt into bags. The dishwasher for dirty equipment was used at the same time as glass bottles were filled with butter milk in the same room (no time separation between the use of the dish washer and the production and filling of dairy products). The FBO had not established product specifications except what was mentioned on the product labels. There were no procedures in place for staff entering the production facilities.

- In some of the industrial scale establishments rust was noted on some equipment.
- In three establishments visited the hand wash basins had hand-operated taps in the operating area.
- In three establishments visited there were problems with pest control (doors not pest-proof, several flies in one powder plant at the entrance to a medium area, pest control programme not well documented). In one establishment the problem had been long standing but the CA had not used any stronger enforcement measures.
- In one establishment visited there was a leak in the ceiling.
- In two establishments visited the storage rooms for wrapping and packing materials were not clean (mouse droppings in one of them).
- In two establishments visited wooden pallets were used in the production area with a risk of cross-contamination of the product.
- In two dairy establishments visited the staff changing rooms had not been properly cleaned.
- In two dairy establishments visited, the buckets /crates were not identifiable to be used for ABPs or waste.
- Some of the above-mentioned deficiencies had not been noted by the CAs responsible for the audits in the plants.
- In some of the industrial establishments visited comprising several separate buildings with production of different types of dairy products the time that had been allocated for routine audits was not sufficient for a thorough audit.

Conclusion

The official controls of the COKZ to ensure the FBO comply with general and specific hygiene requirements were largely adequate. However, the audit team noted some deficiencies in relation to the general and specific hygiene requirements in the establishments visited and in relation to the identifiability of ABPs that had not been detected by the CAs.

5.2.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Section II of Annex II to Regulation (EC) No 853/2004 lays down the specific requirements for HACCP-based procedures in slaughterhouses. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4 (3)(a) and (5) of Regulation (EC) No 854/2004).

Audit findings

In response to Recommendations 4 and 8 concerning the assessment of the reliability of own checks, auditing HACCP-based systems and verification of compliance with microbiological criteria, the CCA indicated that all establishments would be audited on the implementation of these issues.

In all establishments visited the official controls had included HACCP-based procedures. The large-scale dairy establishments visited had all established HACCP-based systems which were documented adequately.

The COKZ is also supervising private laboratories involved in sampling of foodstuffs in the framework of own controls. The laboratories are inspected and approved by the COKZ and the register of the approved laboratories is published on the COKZ web page. The laboratories have to fulfil certain quality criteria in relation to staff qualifications, facilities, methods, participation on proficiency testing etc. In 2011, the COKZ inspected 16 such laboratories and carried out documentary checks of 12 accredited private laboratories.

The dairy establishments test each milk truck for inhibitory substances using commercial kits. Should the milk test positive for inhibitory substances, the farmer is penalised heavily and must also pay for the destruction of the milk in the truck.

In 2011, the percentage of truck loads tested positive for antibiotic residues in 2011 was 0.03%. Evidence was available on follow-up actions taken and destruction of the raw milk in case it had tested positive for antibiotic residues

However, the audit team made the following observations:

- In a small-scale dairy establishment visited the FBO had not established a specific HACCP plan for his production but was instead following a generic hygiene code established by the Netherlands Dairy Product Board. However, the provisions of the code had not been adapted to his processing and the code did not include all the prerequisites such as water sampling, cleaning and disinfection, pest control.
- In some of the dairy establishments visited, the procedures given in the HACCP manual were not always followed or an appropriate working instruction was missing (for example, in one establishment visited there was no documented procedure for acceptance of raw material; in another establishment there was no documented procedure of action taken in the case of deviation).
- In two dairies visited the practical testing of raw milk for inhibitory substances deviated from the written procedure.

The audit team made the following observations in relation to controls on potable water:

- The FBOs controls on potable water were not carried out adequately in some of the establishments visited. In the establishments using solely municipal water, the test results available did not cover all parameters given in Council Directive 98/83/EC, especially not pesticides or heavy metals. These shortcomings had been long standing.
- The requirements of the Council Directive 98/83/EC in relation to the frequency of testing were not always respected.
- No evidence was available that the own control schemes covered testing of taps in the production area of three of the seven establishments visited.
- One establishment visited was chlorinating the water received from own boreholes. However, the sampling procedure for this water did not include inactivating of chlorine in

the sample. The same establishment lacked documentary evidence of actions taken in relation to exceeding microbiological parameters in the potable water tested.

Conclusion

The official controls of the CA included the HACCP-based procedures and were adequate in relation to most aspects. However, the official controls and the FBOs control plans and their implementation on potable water were insufficient in relation to some aspects. Furthermore, the CA had in some cases not identified all the deficiencies in relation to the HACCP-based procedures and their implementation.

5.2.3 Microbiological criteria for foodstuffs

Legal requirements

Details on the microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. These cover a range of items with regard to requirements for raw milk and dairy products.

Audit findings

All establishments visited had sampled their products for food hygiene and process hygiene criteria. The results seen were in most cases satisfactory. Evidence was available that actions had been taken by the FBOs in the case of unsatisfactory results. The audit team verified that official sampling had been carried out in the establishments visited.

Conclusion

The FBOs' testing schemes and the official controls to verify compliance with the microbiological criteria as laid down in Regulation (EC) No 2073/2005 were adequate.

5.2.4 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with traceability requirements takes place in all approved establishments.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Regulations (EC) No 1760/2000 and 1825/2000 set out specific labelling requirements for beef meat.

Audit findings

The official controls in dairy establishments cover traceability. However, the auditors do not necessarily do a traceability exercise on-the-spot but rely on the demonstration of the exercise done by the FBO. In the establishment visited the products produced were traceable.

The audit team made the following observations:

- In two dairy establishments visited the traceability was based on production time. In one of the two plants the definition of a lot comprised the production of one week, whereas in the other establishment the lot was defined as the production between two cleaning cycles. In both cases the systems resulted in big raw material lots. In addition, one of the establishments had had a breakdown in the computer system during the production. This meant that some of the data was not available and thus the traceability for that specific lot was not complete.

Conclusion

The official controls covered traceability. In general, traceability systems were in line with Article 18 of Regulation (EC) No 178/2002.

5.2.5 Control of milk production holdings and raw milk upon collection

Legal requirements

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

Audit findings

In response to Recommendation 11 in report 2006-8146 concerning the implementation of official controls on the hygiene of milk production holdings, the CA indicated that the COKZ will assess the systems put in place by the dairy establishment for hygiene controls on dairy farms and will also supervise the correct implementation of these controls.

The dairy establishments are responsible for the hygiene controls on the dairy holdings that deliver milk to them. The dairy companies have established farm quality assurance schemes. Approximately 99% of the Dutch dairy farmers have joined such farm quality schemes. The residual farms are checked by the COKZ staff for the dairy hygiene (in 2011, 90 dairy farms (20 cattle, 20 sheep, 25 goat and 25 horse farms) were controlled directly by the COKZ). Within the farm quality programmes, each dairy farmer is inspected at least once in 2 years. The COKZ has carried out audits over the performance of the dairy farm quality programmes run by the dairy establishments. In 2011, the COKZ visited 64 dairy farms in total in the framework of such audits (of the 80 planned). The audit team received the draft report of these audits. According to the audit report, most farms comply with the requirements of Chapter II, Section IX, Annex II to Regulation (EC) No 853/2004.

The controls on the animal health requirements of Chapter I, Section IX, Annex III to Regulation (EC) No 853/2004 are carried out by PVPs, the certified dairy veterinarians. The certified dairy veterinarians must be registered by the Royal Veterinary Association and have to pass a specific

course. The first course was organised in November 2011. The number of certified dairy veterinarians is currently approximately 650. Since 1 January 2012 dairy farmers have to have a fixed contract with PVPs for the health care of the dairy herds. The farmers have to establish an animal health management plan (comprising veterinary treatments, vaccinations and other preventive programmes) and the certified dairy veterinarians are required to carry out a risk assessment over the dairy farms they visit. The number of annual visits depends on the number and type of deficiencies found and varies between once in two years to four times annually.

The implementation of the controls on the animal health requirements is audited in the framework of the farm quality assurance schemes. In addition, the COKZ plans to carry out direct audits on these controls by accompanying PVPs during 25 of their inspections in 2012. Whilst these controls are currently not directly verified by the COKZ, in future the certified dairy veterinarians will be audited by an independent third party certification body.

In addition, the COKZ staff audit dairy farm milk collection premises. In 2011, there were 30 such premises of which the COKZ audited 10.

The audit team visited two dairy holdings. A register of medical treatments was available and the animals that had been treated were identifiable. Copies of audit reports in relation to the farm quality assurance scheme were available.

The dairy industry has organised the checks on raw milk criteria. All milk is analysed centrally in an accredited industry-owned laboratory. The raw milk is collected from the farms in general every three days. The truck drivers are taking samples from the farm tank each time they collect milk. Samples are send twice monthly to a private laboratory for analysis on SCC, total plate count (TPC). The selection of these samples in done randomly. All samples are analysed in a private laboratory. Each farmer is checked randomly once a month for inhibitory substances.

The truck drivers have been trained for the sampling by the raw milk laboratory and must have also passed a test on the topic. In addition, the COKZ has prepared a manual on raw milk control for the truck drivers (the manual is currently under revision). The audit team verified that the drivers had the manual available and had participated in the training.

The basic rules for the milk payment system are laid down in the Regulation of the Dairy Product Board that is legally binding. The dairy farmers are penalised for exceeding the SCC and TPC limits given in Regulation (EC) No 853/2004.

In 2011, 99.10% of the raw milk delivered to the dairies complied with the TPC limit and 98.95% with the SCC limit as given in Annex III to Regulation (EC) No 853/2004.

Evidence of testing of raw milk samples for SCC, TPC and inhibitory substances was available in the establishments visited receiving raw milk. The results seen were in most cases satisfactory. The results of exceeding the limits for SCC and TPC were communicated to the COKZ.

The audit team visited the laboratory where the raw milk of the Dutch dairies is analysed. The laboratory is ISO/EN 17025 accredited and the list of the accredited methods was available. The laboratory had adequate facilities and equipment and good documentation over its activities. Quality assurance measures were in place and the laboratory participated in proficiency testing rounds. The COKZ carries out administrative audits over the laboratory. The last audit report was received.

The audit team made the following observations:

- The system used in the Netherlands to verify that the health requirements for raw milk and colostrum production, and, in particular, the health status of the animals and the use of veterinary medicinal products are being complied with on milk production holdings is based

on controls carried out by PVPs instead of official controls as required in point 1 of Chapter I, Annex IV to Regulation (EC) No 854/2004.

- The two dairy holdings visited had some shortcomings (the room with the milk tank was not pest-proof, on one farm one of the veterinary medicines used had not been included in the register of veterinary treatments).
- In one dairy visited which was buying the raw milk from another dairy company, no evidence was available on the destiny of the raw milk that had tested positive for antibiotic residues (as this raw milk still belonged to the selling party and the dairy was not informed about where the truck driver went with the load). However, the evidence that the milk had been delivered to a rendering plant could be provided to the audit team the next day.
- In the accredited raw milk laboratory visited the test used to verify the positive test result of a suspect tanker had recently passed its expiry date and some other expired diagnostic tools were noted in one of the fridges.
- In one dairy visited TPC used for issuing warning letters to the farmer was the value of a single testing, not the geometric average.

Conclusion

The system to use PVPs to check the animal health requirements on dairy holdings in not in line with point 1 of Chapter I, Annex IV to Regulation (EC) No 854/2004. The controls had been carried out according to the plan. The system for raw milk quality control was functioning adequately.

5.2.6 Documentation of official controls

Legal requirements

Article 9 of Regulation (EC) No 882/2004 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Audit findings

The COKZ is using two separate electronic databases where documentation over the audits and official samples taken are kept. For older data (for example for 2006), the reports are not available in the database. The two databases are not connected to each other. The audit team received reports of several types of audits for the establishments visited (pre-authorisation audits, regular annual audits and follow-up audits within 4 months). The reports indicated medium shortcomings and deadlines to take corrective actions. Examples of reports of controls carried out by certified third parties in the framework of dairy farm quality controls schemes were available for the audit team.

In relation to the documentation available over the official controls, the audit team noted the following:

- The reports of official controls did not reflect in some cases certain long-standing non-compliances noticed by the audit team.
- Some of the reports were very short and lacked details on what topics had been included.
- The COKZ check-list for dairy establishments comprises controls on water but this point does not include the specific requirements of the Council Directive 98/83/EC for FBOs.

Conclusion

The documentation of the official controls was adequate in relation to most aspects.

6 Overall Conclusions

The CA of the Netherlands have addressed satisfactorily most of the recommendations of the previous report 8146-2006 linked to controls over milk and dairy products.

The system of official controls is well established and in line with most aspects of Regulation (EC) No 882/2004. However, some shortcomings were noted in relation to the implementation of the official controls.

7 Closing Meeting

A closing meeting was held on 14 September with the CCA, the NVWA and the COKZ. 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.

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 ensure that the official controls carried out to verify industrial scale dairy establishments' compliance with the general and specific hygiene requirements and audits on HACCP-based systems are implemented regularly and with appropriate frequency, as required in Article 3.1 of Regulation (EC) No 882/2004.
2.	To ensure that when carrying out official controls, the review of the approval conditions of the establishment is accurate, and that appropriate action is taken when the conditions are not met, as required by Article 31 of Regulation (EC) No 854/2004.
3.	To ensure that the official controls on potable water cover the the requirements of Council Directive 98/83/EC.
4.	To ensure that the animals on milk and colostrum production holdings are subject to official controls to verify that the health requirements for raw milk and colostrum production, and in particular the health status of the animals and the use of veterinary medicinal products are being complied with, as required in point 1 of Chapter I, Annex IV to Regulation (EC) No 854/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6358

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

Legal Reference	Official Journal	Title
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
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
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
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