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Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6874 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

POLAND

FROM 26 NOVEMBER TO 06 DECEMBER 2013

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MILK AND DAIRY PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Poland from 26 November to 6 December 2013. The main objective of the audit was to evaluate the official controls ensuring safety of the production and storage of food of animal origin, in particular milk and dairy products.

The official control system over the production of milk and dairy products in Poland is well structured with adequate implementing legal measures, documented procedures and resources, in line with the requirements of Regulation (EC) No 882/2004. Organisation, prioritisation and documentation of official controls, registration and approval of food business operators were generally adequate, except for approval and controls of milk collection centres.

The official controls implemented were generally satisfactory in dairy establishments regarding general and specific hygiene requirements, the implementation of Regulation (EC) No 2073/2005, labelling and identification marking of dairy products, and animal by-products. Official controls over Hazard Analysis Critical Control Points (HACCP)-based procedures were only partly adequate. Official controls on traceability and the monitoring of the food business operators' checks on raw milk were weak. In addition, the Polish Central Competent Authority (CCA) failed to address a recommendation in a previous FVO report concerning monitoring of raw milk checks.

Official controls in milk production holdings were generally adequate concerning animal health requirements. However, these official controls failed to ensure that certain requirements are fully met, in particular concerning the records of veterinary medicinal treatments, the efficiency of pest control in milk storage areas and animal hygiene and welfare.

Although enforcement measures to ensure that the food business operators remedy deficiencies were generally adequate, the lack of enforcement action in one serious case, somewhat undermines the enforcement system.

A number of recommendations have been made to the Competent Authority (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	Animal By-Product
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
CP	Country Profile Poland DG(SANCO)/2013-6893
CVO	Chief Veterinary Officer
DG(SANCO)	Health & Consumers Directorate General
EC	European Community
EU	European Union
FBO(s)	Food Business Operator(s)
FCI	Food Chain Information
FVO	Food and Veterinary Office
GVI	General Veterinary Inspectorate (*Główny Inspektorat Weterynarii*)
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
MANCP	Multi-Annual National Control Plan
MARD	Ministry of Agriculture and Rural Development (*Ministerstwo Rolnictwa i Rozwoju Wsi)*
NVRI/NRL	National Veterinary Research Institute / National Reference Laboratories
RVI	Regional *(Voivodship)* Veterinary Inspectorates

1 Introduction

The audit took place in Poland from 26 November to 6 December 2013 as part of the planned audit programme of the FVO. The FVO audit team comprised two auditors and one trainee from the FVO.

The FVO audit team was accompanied throughout the audit by a representative from the Central Competent Authority (CCA), the General Veterinary Inspectorate *(Główny Inspektorat Weterynarii* - hereafter: GVI).

The opening meeting was held on 26 November 2013 in Warsaw with representatives from the CCA, from the *Voivodship* (Regional) Veterinary Inspectorates (hereafter: RVIs) and from the National Veterinary Research Institute / National Reference Laboratories (hereafter: NVRI/NRL). 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 with regard to:

- competent authority (CA) organisation and operation,
- official controls over food business operators' compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over the production of raw 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:

Table 1

COMPETENT AUTHORITIES			**Comments**
Competent authorities	Central	3	Opening and closing meetings and a clarification meeting prior to the closing meeting
	Regional and Local		Representatives from the RVIs of Lubelskie and Kujawsko-Pomorskie and from seven District Veterinary Inspectorates were met during the visits to premises in their respective Regions
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Laboratories		3	The NVRI/NRL and two private laboratories of dairy establishments
Dairy establishments		5	
Milk production holdings		3	Supplying milk to the dairy establishments visited
Milk collection centres		2	Supplying milk to the dairy establishments visited

3 Legal Basis

The audit was carried out under the general provisions of European Union (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 Poland and in particular the milk and dairy sectors was carried out from 1 to 12 December 2008, the results of which are described in report DG(SANCO)/2008-7810 – MR Final (hereafter referred to as report 2008-7810). This report is accessible at:

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

The action plan received from the Polish authorities provided satisfactory guarantees in response to the report's recommendation relevant to the milk and dairy sector.

Poland is officially free from bovine tuberculosis (Commission Decision No 2009/342/EC), from bovine brucellosis (Commission Decision No 2009/600/EC) and from ovine and caprine brucellosis (Commission Decision No 2006/169).

According to Eurostat data from 2010, the amount of milk collected by dairies in Poland was circa 9 million tonnes (10.62% of EU-27). According to the information provided by the CCA, in 2012 the milk production in Poland was 12.6 million tonnes.

In the period 2010-2013, nine notifications in the Rapid Alert System for Food and Feed concerning milk and dairy products were recorded, two of which were alerts. The FVO audit team followed up the actions taken by the CAs following a notification concerning butter produced in one of the establishments visited. The information chain had been properly followed-up in a timely manner by all levels of the CAs.

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Article 291.1 of the Treaty on the functioning of the EU requires that the Member States adopt all measures of national law necessary to implement binding Union acts.

Article 7 of Regulation (EC) No 852/2004 stipulates that Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP in accordance with Article 8 of the Regulation.

According to Article 10 of Regulation (EC) No 853/2004 Member States may, without compromising the achievement of the objectives of Regulation (EC) No 853/2004 adopt national measures adapting the requirements laid down in Annex III. The national measures refer to continued use of traditional methods and regions subject to geographical constraints and are subject to notification to the Commission and other Member States. National rules may be maintained or established for prohibiting or restricting the placing on the market of raw milk or raw cream for direct human consumption or to permit the use of raw milk not meeting the criteria for plate count and somatic cell count.

Article 7 of Regulation (EC) No 2074/2005 allows Member States to grant establishments manufacturing foods with traditional characteristics derogations from certain requirements set out in Regulation (EC) No 852/2004.

Audit findings

The national legislation relevant to controls on milk and dairy products comprises the following main acts:

- The Act of 29 January 2004 on Veterinary Inspection
- The Act of 16 December 2005 on products of animal origin
- The Act of 11 March 2004 on the protection of animal health and control of infectious animal diseases
- Ministry of Agriculture and Rural Development (MARD) Regulation of 9 October 2006 on the determination of cases dealt with by administrative decisions by the district veterinarian or the official veterinarian under the authority of the district veterinarian
- MARD Regulation of 26 May 2010 on the amounts of fines for violation of animal products.

National legislation allows for the production of three dairy products (cheese) according to traditional methods, and for derogations for traditional productions for food of animal origin.

There are no national flexibility measures in place for small establishments as described in Article 13(4)(b) of Regulation (EC) No 852/2004 regarding construction, layout and equipment.

An in-depth review of the relevant Polish legislation was not performed. The FVO audit team did not make any finding within the scope of this audit in relation to the implementing measures which could have put into question their adequacy.

5.2 Competent Authorities

5.2.1 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 CAs in Poland responsible for the official controls in the milk and dairy sector are the same as for other foods of animal origin. An overview of how control systems are organised in Poland, based on information supplied by them, is provided in the Country Profile (CP) for Poland and is available at the following link:

http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=PL

5.2.2 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

No findings were identified by the FVO audit team with regard to the co-operation and co-ordination between and within the CAs, in the sector audited.

5.2.3 Training

Legal requirements

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Audit findings

The CCA provided the FVO audit team with a list of training on milk and dairy products, auditing and Hazard Analysis Critical Control Points (HACCP) attended by the Veterinary Inspection staff in the last three years. The FVO audit team noted that the list included 75 training sessions in total, organised between 2010 and 2013 by DG/SANCO (Better Training for Safer Food) and by other training bodies. Staff from all levels of the CAs participated in the training sessions.

The veterinary staff met during the visits in establishments and holdings were knowledgeable regarding the subject of this audit.

5.2.4 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 system for registration and approval of establishments is described in the CP for Poland which is accessible at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm. Report DG(SANCO)/2013-6893 provides further details on approval of establishments. On 16 September 2013 a new CVO instruction (No GIWbz-500-2/2013 of 26 August 2013) on the procedures for approval of establishments entered into force.

The milk production holdings and the dairy establishments visited by the FVO audit team were registered and approved, respectively, in line with CCA guidance and with EU legislation.

Milk collection centres in Poland are approved on the basis of EU and national legislation, and their list is published on the CCA website. The approval documents reviewed by the FVO audit team referred to Article 4(2) of Regulation (EC) No 853/2004, Article 3(1) of Regulation (EC) No 854/2004 and Article 31(2) of Regulation (EC) No 882/2004. Such documents indicated that following the official veterinarian inspection, the milk collection centre fulfils the requirements of Regulations (EC) No 852/2004 and No 853/2004 and of national legislation, and that the food business operator has procedures in place for own checks. In relation to approval of milk collection centres, the FVO audit team made the following observations:

- There is no specific guidance for the approval and for the subsequent official controls of milk collection centres and the districts CAs had different understandings of the applicable requirements. In both districts where the approval documentation was reviewed, the inspections prior to approval were based on the same check-list used for the inspections of general requirements for approved and registered plants. But in one district the official veterinarian filled in only the above mentioned check-list whereas the official veterinarian of another district also filled in the specific check-list for raw milk and dairy products. Several points were ticked as “not applicable”, even if some were applicable, such as those related to the HACCP-based procedures.

- Several requirements of EU legislation and, in particular, of Annex II to Regulation (EC) No 852/2004, mentioned in the approval documents, were not fully met in either a milk collection centre visited, e.g. the ceiling was made of painted timber; the floor had several cracks; the door opened directly to the outside without any protection from pests and absence of a flush lavatory.

- One of the two milk collection centres visited had received an approval in June 2012, although it had been in operation since August 2010.

In another region the FVO audit team reviewed the approval documentation of two "mobile milk collection centres". Such food businesses consist solely of trucks and are approved for the activities of purchase and transportation of raw milk. They differ from other milk transporters (which are not approved) as they purchase the milk, are responsible for performing the relevant tests on raw milk and are obliged to notify the district CAs and the dairy establishments of when the raw milk does not comply with the relevant criteria.

5.2.5 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 frequency of official controls is determined by CVO Instruction No GIWbz 500-2/11 of 1 September 2011, which describes the risk analysis to be performed by the district CAs. The risk analysis takes into account several factors in line with Article 3 of Regulation (EC) No 882/2004 and provides for a score assigned to the establishment, which determines the minimum frequency for official controls. The score determines which of the three risk categories the establishment will fall under, with a minimum frequency of one official control per month for the high risk category, once every six months for medium risk and once per year for low risk. The risk assessment is repeated yearly (with the exception of milk collection centres, for which it is repeated every three years) to take into account the results of the previous year's controls. This instruction applies also to regional CAs to determine the frequency of the verification of the procedures implemented by the district CAs.[1]

All the establishments visited except one were in the low risk category and the set frequency for comprehensive controls was once per year. One establishment had been re-classified as a medium risk following the unfavourable results of the official control performed in September 2013. The set frequency was met in all establishments visited.

Additional thematic controls and *ad-hoc* controls had been carried out based on the CCA instruction or at the request of the CVO.

The frequency of official controls over milk production holdings in the districts visited was based on the available resources rather than on the risk assessment. In one district it was 10% of the farms and had been decreased from 100% since 2012. In another district of the same region the frequency was 30%. In another district in a different region the frequency was 100%. In the holdings visited additional inspections were carried out for other purposes e.g. animal welfare or animal identification and registration.

5.2.6 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

1 In their response to the draft report, the CA noted that in the light of the considerable differences in the number of holdings located in the districts and hence the difficulty in setting a uniform number of inspections to be carried out by all district veterinary offices on such operators, the most recent instruction did not clearly determine the frequency of inspections of milk production holdings.

The National Veterinary Research Institute is the National Reference Laboratory (NRL) for veterinary medicinal products, residues, raw milk hygiene and microbiological criteria for the dairy sector.

Establishments' internal laboratories that want to perform tests on microbiological criteria, in order to be approved by the CA must participate in one proficiency test organised by the NRL. Once they receive the approval, participation of periodic proficiency tests is recommended, but not compulsory. Official and private laboratories approved by the CCA, which must be accredited for the use of testing methods in order to maintain that status, are required to undergo proficiency tests at least once during the four-year accreditation cycle. A representative from the CCA indicated that the relevant national legislation is under review to make this participation compulsory[2].

There are several accredited laboratories, public and private, authorised to perform tests on raw milk to determine the total plate count, somatic cell count and the presence of inhibitors, the presence of residues of veterinary medicinal products, and/or for microbiological criteria in dairy products. The list of authorised laboratories is published on the NVRI/NRL website.

In 2011, the number of official samples of raw milk tested for the presence of residues of veterinary medicinal products was 2 649. There were two positive results, both for tetracycline. In 2012, all of the 2 651 official samples taken were negative.

5.2.7 Procedures for performance of control activities and documentation of official controls

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.

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.

2 In their response to the draft report the CA noted that the Act of 22 November 2013 amending the Act on protecting animal health and combating infectious animal diseases and certain other acts entered into force on 24 January 2014. The above-mentioned Act introduced a new wording for Articles 25a and 25e in the Act of 29 January 2004 on the Veterinary Inspection Services.
Laboratories which have been approved by the CCA to carry out laboratory testing in a particular field for the purposes of official controls are required to participate in proficiency tests conducted by the national reference laboratory with competence in that area. In addition, where the results of laboratory testing carried out (with a view to protecting animal health and ensuring the safety of products of animal origin, animal by-products or derived products or feed) by entities undertaking the activities referred to in the provisions on protecting animal health and combating infectious animal diseases and on products of animal origin or feed are relevant for the purposes of official controls, these tests are also carried out in laboratories entered in the register kept by the CCA. These laboratories, in contrast to those (with approved status) referred to above, are not required to be accredited.
However, laboratories approved as well as those registered by the CCA are subject to proficiency testing in accordance with the testing schedule prepared by the competent national reference laboratory. In the absence of such an NRL, the laboratories concerned should participate at least once every four years in proficiency tests organised by the reference laboratory for the field of testing in question located in another EU Member State or by the Community Reference Laboratory.
The CCA may withdraw a laboratory's approved status or delete it from the register where it fails in two successive proficiency tests to obtain results meeting the criteria defined by the NRL or Community Reference Laboratory which carried out the tests, or where it fails to undergo proficiency testing at all.

Audit findings

The CCA has issued several documented procedures for the performance of official controls, in the form of instructions and check-lists, also covering the area evaluated in this audit, but with the exception of milk collection centres which were not covered.

The FVO audit team noticed that the CCA procedures were generally implemented by the officials. The reporting templates and the comprehensive check-lists for official controls in dairy establishments and milk production holdings were used by the official control staff and were always available in the cases assessed by the FVO audit team. A copy was given to the food business operator and the reports contained the scope, the methods and the results. The district CA issues an administrative decision, together with deadlines, when the food business operator is requested to carry out corrective actions. Evidence of follow-up was also available.

5.2.8 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 MARD Regulation of 26 May 2010 lays down the amounts of fines for violations concerning animal products. This legislation allows the imposition of a fine when, for example, the withdrawal period due to a medicinal treatment is not respected.

The MARD Regulation of 9 October 2006 determines the cases when an administrative decision must be issued by the district CA. Such cases include, for example: the suspension of a farm from supplying milk which does not meet the hygiene criteria; granting permission to use such milk for production of cheese with maturation of at least 60 days; imposition of the corrective measures in case of non-compliances as laid down in Article 54(2) of Regulation (EC) No 882/2004.

Examples of administrative decisions were seen by the FVO audit team, in cases where the food business operators were requested to take actions to remedy deficiencies and, in one establishment, when supplying farms had been suspended because the milk did not meet the hygiene criteria laid down in Chapter I(III) of Section IX, Annex III to Regulation (EC) No 853/2004.

The CAs explained that if the administrative decision issued on the basis of the MARD Regulation of 9 October 2006 is not respected, there is no possibility to impose a fine within a short period of time, but only after a long procedure, which discourages them from starting it.

One example of a financial sanction imposed by the CA and reviewed by the FVO audit team concerned a farm, where several serious hygiene and structural deficiencies had been identified. A fine of 500 PLN was imposed on the basis of the Polish Code of Misdemeanour of 1971. During their inspection the CAs also found an illegal device used to reduce the somatic cell count in the

milk. The farm was not suspended from delivering milk to the establishment and for this fraudulent practice the only measure imposed was a ban on further using it (see also section 5.3.6 of this report).

5.2.9 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

The Polish CAs have a number of procedures in place for the verification and review of official controls and for internal audits. These procedures are described in the Country Profile for Poland.

As regards the milk and dairy sector, internal audits were carried out by auditors from the RVIs, on the official controls related to the supervision of dairy sector establishments, pursuant to requirements set in national and EU rules, and to import requirements of third countries, for 2010 and the first half of 2011. These audits were performed in 56 districts of 15 regions of Poland. The FVO audit team reviewed the results of such audits in two districts of each of the two regions visited, and which also included two establishments visited by the FVO audit team. The internal audit included the district offices and only one dairy establishment in each district but did not include any milk production holding or milk collection centre. In one district, one of the findings of the internal auditors concerned the procedures to withdraw a farm suspension, which had not been correctly followed as the results of the tests for milk hygiene criteria were not yet fully compliant. In the other district the results of the internal audit were generally favourable.

Conclusions on legislation and Competent Authorities

The framework of the official control system for the dairy sector in Poland is generally satisfactory regarding implementing legislation, the CAs' designation, resources, training, documented procedures, organisation, prioritisation and documentation of official controls, registration and approval of food business operators. Nevertheless, weaknesses were identified, in particular in the following areas:

- The lack of guidance on the approval of milk collection centres resulted in inconsistent requirements applied by the district levels of the CAs, which did not ensure that all relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 were met.

- The prioritisation of official controls in dairy holdings was not fully in compliance with the CCA's instructions and with the requirements of Article 3 of Regulation (EC) No 882/2004.

- Although enforcement measures to ensure that the food business operator remedies deficiencies were generally adequate, the lack of enforcement action in the case of a

potentially serious fraud undermines the enforcement systems.

- The limited scope of the internal audits provided only a limited picture.

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

5.3.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the food business operator 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 food business operator 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 food business operators 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 food business operators' compliance with these requirements.

Audit findings

During the most recent official controls carried out in the five dairy establishments visited, the CAs had detected only minor deficiencies, which had been corrected by the food business operators and followed up by the CA. In these establishments the FVO audit team noticed that the general and specific hygiene requirements were generally complied with.

In the two milk collection centres visited, the results of the most recent official controls were satisfactory. However, the FVO audit team noticed certain structural and maintenance deficiencies, such as (not all deficiencies were present in the same establishment): the door opening directly to the road outside without any protection from pests during the milk collection; the roof made of painted timber, cracked floor, part of a wall not easy to clean and disinfect, lack of lavatories that flush.

Conclusion

Official controls in dairy establishments and concerning general and specific hygiene requirements were overall adequate. Official controls in milk collection centres did not ensure that all relevant requirements of Annex II to Regulation (EC) No 852/2004 were met.

5.3.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the food business operator 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

HACCP-based procedures were part of the official controls. All food business operators visited, with the exception of one milk collection centre, had HACCP-based procedures in place. Where these were reviewed by the FVO audit team, the following observations were made:

- In one establishment the critical control point (CCP) for the production of butter had been correctly identified and HACCP-based procedures were satisfactory.

- In another establishment the HACCP-based procedures covered two products which although similar, had different production flows and should have been covered by separate procedures. In addition one of the CCPs (a combination of time and temperature) was not properly controlled.

- In a third establishment, the limits for one of the CCPs (pasteurisation) were the minimum temperature of 73°C and the maximum temperature of 79°C. However, there were no hazards identified if the temperature exceeded 79°C.

- In one milk collection centre there were no HACCP-based procedures[3], whereas in the other milk collection centre visited there was a simplified HACCP based procedure, which did not include all seven principles laid down in Article 5 of Regulation (EC) No 852/2004.

Conclusion

Official controls over HACCP-based procedures were partly adequate, as certain shortcomings in the HACCP-based procedures put in place by food business operators had not been detected.

5.3.3 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, *inter alia*, raw milk and dairy products and other products of animal origin.

Audit findings

3 In their response to the draft report the CA noted that points concerning the HACCP system were not included in the checklist because the milk collection centre was covered by the quality system and procedures of the milk processing and collection establishment. That establishment's procedures provided only for control points (CPs) rather than CCP at the stage of the raw milk collection centre.

Food business operators' testing for microbiological criteria was part of the annual comprehensive official controls carried out by the CAs. In addition, at least one specific control on this topic had been carried out in all establishments visited.

All establishments visited had sampling plans for microbiological tests in place. Where the FVO audit team reviewed these plans, it was noted that these had been correctly implemented by the food business operators and that the CAs had followed the relevant CCA procedures.

Conclusion

Official controls on the implementation of the requirements of Regulation (EC) No 2073/2005 were satisfactory.

5.3.4 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 food business operator 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.

Audit findings

Official controls in the establishments visited included verification of compliance with the legal requirements concerning traceability, labelling and identification marking. The most recent official controls had not reported deficiencies, in particular concerning the traceability systems of the establishments visited by the FVO audit team.

Labelling and identification marking of the products seen were in line with the EU requirements.

In the three establishments where traceability exercises were carried out by the FVO audit team, the following observations were made:

- In one establishment the traceability for whey powder was difficult to follow as the records were sometimes in litres and sometimes in kilogrammes. Therefore it was difficult to correlate the quantities used during the processing steps of concentration.

- In another establishment the traceability for butter was unsatisfactory because the food business operator could not explain the difference in the fat content between the milk delivered and the milk stored in the silo.

- In the third establishment a similar observation concerning inconsistency in the fat content was made but when the FVO audit team highlighted the problem, the food business operator eventually produced an additional document showing that cream had been added to the milk contained in the silo.

Conclusions

Official controls over labelling and identification marking of dairy products were largely adequate.

Official controls on traceability were inadequate.

5.3.5 Controls of milk production holdings

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.

Chapter I of Annex IV to Regulation (EC) No 854/2004 stipulates that animals and milk production holdings are to undergo official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with.

Audit findings

Official controls in milk production holdings to verify the health requirements and the hygiene requirements were carried out according to the CCA procedures. The official controls included, *inter alia*, the verification of the use of medicinal products, animal welfare, the health status of the animals, their identification and registration.

In two out of the three dairy holdings milk production holdings visited the latest official controls carried out had not reported deficiencies. In the third holding the report of an official control carried out on milk hygiene in 2011 indicated some deficiencies related to documentation of water testing, maintenance and cleaning of premises and pest control. Deadlines had been imposed and the follow up inspection performed was favourable.

Premises, overall hygiene, animal identification and welfare were generally adequate in the three holdings visited, albeit with the following exceptions:

- poor hygiene of the animals in one holding;

- insufficient protection from pests in the milk storage area during milk collection in two holdings;

- poor welfare of the animals in one (Point 4 of the Annex to Council Directive 98/58/EC).

Additionally, the records of veterinary medicinal treatments were incomplete in two holdings.

Conclusion

Official controls in milk production holdings were generally in line with the requirements of Article 8 and Annex IV to Regulation (EC) No 854/2004. However, these official controls failed to ensure that certain requirements are fully met, in particular concerning the records of veterinary medicinal treatments, the efficiency of pest control in milk storage areas and the animal hygiene and welfare.

5.3.6 Controls of raw milk upon collection

Legal requirements

Chapter II of Annex IV to Regulation (EC) No 854/2004 indicates that the CAis to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004, concerning plate count, somatic cell count and residues of antibiotic substances.

Audit findings

Recommendation No 6 of report 2008-7810 stated to "further improve the official controls over raw milk quality and assess the reliability of the controls carried out with regard to the criteria for raw milk". In reply to this recommendation the CCA issued a specific instruction to order comprehensive official controls and official sampling to be carried out between March and June 2009.

Monitoring of the food business operators' checks on raw milk hygiene criteria was part of the official controls. Instruction GIWhig - 500-5/06 of 29 December 2006 describes the procedures for monitoring the implementation of the provisions of Regulation (EC) No 853/2004 on raw milk control. The instruction is in line with the provisions laid down in this Regulation. According to this instruction, the food business operator performing the controls on the raw milk criteria is obliged to inform the district CA responsible for the farm, of non-compliant results.

In 2009, in reply to an inquiry from the National Association of Dairy Co-operatives, the CCA stated that the use of devices such as milk separators to reduce the somatic cell count of milk is a fraudulent practice. The letter was copied to the RVIs outlining that such a practice is in breach of national (Article 3(3)(45) of the Law on Food Safety and Nutrition) and EU legislation (Article 8 of Regulation (EC) No 178/2002) and a reminder that there is a penalty of of up to one year imprisonment which could be imposed under Article 97 of the Law on Food Safety and Nutrition.

The CCA informed the RVIs (by letter in November 2012) that during the Standing Committee on the Food Chain and Animal Health on 15 October 2012, Member States reported on the detection of devices such as micro filters and centrifuges. This letter reiterated that such devices are illegal and asked the RVIs to provide information on the number of times such devices were found during the official controls carried out in 2011 and 2012. One RVI replied that such a device had been found at one milk production holding. However, there was no evidence of a penalty being imposed on the farmer other than a fine for poor hygiene (see also section 5.2.8 of this report).

All food business operators of the establishments visited by the FVO audit team performed checks for the presence of residues of antibiotics, somatic cell count and total plate count on the milk from individual farms, with the minimum sampling frequency laid down in Chapter I(III)(3) of Section IX, Annex II to Regulation (EC) No 853/2004. The results reviewed for somatic cell count and/or total plate count were in three out of five establishments too low to be credible although the CA had never found irregularities and did not consider such results as doubtful. In addition, in one of these three establishments the results for total plate count of the milk from individual suppliers were

inconsistent with the results of the tests performed on the bulk milk from the same suppliers during the same period of time.

In a fourth establishment, the FVO audit team reviewed the procedures implemented by the district CAs concerning farms suspended because of the geometric average for somatic cell count on the fourth months exceeded the limits. The suspension was withdrawn on the basis of a very low result. However, this result had dropped in just two days from 476 000/ml to 34 000/ml and the sample had been taken by the farmer.

The quick tests performed in four out of five establishments visited for the presence of antibiotics had never provided any positive, inconclusive or false positive results in the last three years (out of circa 20 000 tests performed). In the fifth establishment the quick tests used had been changed in August 2013 and since then one inconclusive result had been recorded. According to the information provided by the NRL responsible for the approval of quick tests in Poland, the error margin for these tests is around 5%.

Conclusion

Although there is a system in place to monitor the food business operators' checks on raw milk concerning the plate count, the somatic cell count and the presence of antibiotics, its implementation was weak as the CAs did not take into account the reliability of the results. In addition, the Polish CCA failed to address a recommendation in a previous FVO report concerning monitoring of raw milk checks (Article 8 and Annex IV(II) to Regulation (EC) No 854/2004).

5.3.7 Animal by-products

Legal requirements

Article 45 of of Regulation (EC) No 1069/2009 requires that the CAs carry out official controls and supervision on the handling of animal by-products (ABP) falling within the scope of this Regulation.

Regulation (EC) No 853/2004, Annex III, Section IX, Chapter I, point III, paragraph 4 requires that raw milk containing residues of authorised substances cannot be placed on the market. As a consequence it must be treated as ABP and subject to the requirements of Regulation (EC) No 1069/2009.

Audit findings

The official controls carried out by the CAs covered the requirements for ABP.

In the establishments visited there were no records of positive results of milk for antibiotics. The whey obtained from processing milk was used for the production of whey powder for human consumption. The FVO audit team made no observations regarding the identification, separation and disposal of ABP.

In one of the farms visited, the farmer indicated that the milk from animals treated with veterinary medicinal products, including antibiotics, is used to feed young calves.

Conclusion

Official controls on animal by-products were satisfactory.

6 Overall Conclusions

The official control system over the production of milk and dairy products in Poland is well structured with adequate implementing legal measures, documented procedures and resources, in line with the requirements of Regulation (EC) No 882/2004. Organisation, prioritisation and documentation of official controls, registration and approval of food business operators were generally adequate, except for approval and controls of milk collection centres.

The official controls implemented were generally satisfactory in dairy establishments regarding general and specific hygiene requirements, the implementation of Regulation (EC) No 2073/2005, labelling and identification marking of dairy products, and ABP. Official controls over HACCP-based procedures were only partly adequate. Official controls on traceability and the monitoring of the food business operators' checks on raw milk were weak. In addition, the Polish CCA failed to address a recommendation in a previous FVO report concerning monitoring of raw milk checks.

Official controls in milk production holdings were generally adequate concerning animal health requirements. However, these official controls failed to ensure that certain requirements are fully met, in particular concerning the records of veterinary medicinal treatments, the efficiency of pest control in milk storage areas and animal hygiene and welfare.

Although enforcement measures to ensure that the food business operators remedy deficiencies were generally adequate, the lack of enforcement action in one serious case, somewhat undermines the enforcement system.

7 Closing Meeting

A closing meeting was held on 6 December 2013 with the CCA, representatives from the regions and districts visited and from the NRL. At this meeting the FVO 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 FVO audit team. In addition, information on action already taken and planned in order to address particular findings in the establishments visited was provided. The CCA representatives stated that the CVO instruction No 500-5/06 on the official monitoring of the implementation of Regulation (EC) No 853/2004 on the control of raw milk is being amended. The amendments will concern, in particular, the procedures for withdrawing the suspension from delivering milk in the case of exceeded limits of somatic cell count and total plate count, which will be based on official inspection and official sampling; and the monitoring of the results of tests for somatic cell count and total plate count, which in case of very low levels will have to be verified with an official sampling and farm inspection.

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.	The Competent Authority should ensure that establishments such as milk collection centres meet all the relevant requirements of Regulations (EC) No 852/2004 and 853/2004 when these are approved.
2.	The Competent Authority should ensure that adequate guidance is provided to support staff responsible for the official controls in milk collection centres (Article 8(1) of Regulation (EC) No 882/2004).
3.	The Competent Authority should ensure that monitoring of the checks performed by food business operators on raw milk upon collection, as laid down in Article 8 and Annex IV, Chapter II to Regulation (EC) No 854/2004, is effective.
4.	The Competent Authority should ensure that appropriate measures are taken when non-compliances and / or infringements of the feed and food law are identified (Articles 54 and 55 of Regulation (EC) No 882/2004).
5.	The Competent Authority should ensure the effectiveness of official controls in particular on Hazard Analysis Critical Control Point-based procedures (Article 4(3)(a) of Regulation (EC) No 854/2004), on the efficiency of pest controls in milk storage areas and on the animal hygiene on farm (Article 8 of Regulation (EC) No 854/2004) and on animal welfare (Council Directive 98/58/EC).
6.	The Competent Authority should ensure the effectiveness of official controls in establishments regarding traceability of food and of any other substance incorporated into a food so that the food business operators comply with the requirements of Article 18 of Regulation (EC) No 178/2002.
7.	The Competent Authority should ensure the effectiveness of official controls on farms so that all treatments applied to food producing animals are recorded as required in Article 10 of Council Directive 96/23/EC and Annex I, Section III, part 8 (b) to Regulation (EC) No 852/2004.

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=2013-6874

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. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
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. 98/58/EC	OJ L 221, 8.8.1998, p. 23-27	Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC