EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7595 - MR

FINAL REPORT OF AN AUDIT CARRIED OUT IN IRELAND FROM 20 APRIL 2015 TO 30 APRIL 2015 IN ORDER TO EVALUATE THE SYSTEM IN PLACE FOR OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MILK AND MILK 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

This report describes the outcome of a Food and Veterinary Office (FVO) audit carried out from 20 to 30 April 2015 in order to evaluate the official controls related to safety of food of animal origin, in particular milk and milk products in Ireland.

The Irish control system of the dairy sector is well organised: documented procedures (SOPs) are in place to carry out official controls, and are implemented by the local inspectors. Official controls are carried out frequently according to control plans, are risk based and well documented. Reports on the official controls contain the relevant information including deficiencies and shortcomings which are well identified. The follow-up is also documented and carried out regularly. Communication and co-operation between and within the Competent Authorities (CAs) have improved markedly since the last FVO audit on this subject in 2011. In the establishments visited, most of the significant deficiencies had been identified and documented by the CA.

Audits and supervisory visits by the CA are carried out by central and regional levels. The knowledge of the officials met was good and the reports examined highlight the relevant issues.

The official control on general and specific hygiene conditions and Hazard Analysis and Critical Control Points based procedures in the milk processing establishments visited was satisfactory. Some minor shortcomings had not been identified by the CAs.

Ireland is authorised to use the alternative method for calculating the somatic cell count in cow`s milk (Commission Decision 96/360/EC).

Laboratory results are always available and reliable. In the case of non-compliances, the warning letters and, if necessary, suspension was generally carried out on time.

The official control on Tuberculosis was carried out in line with the requirements. However no records were available on the amount, time, method and place of disposal of the raw milk originating from reactor animals at holding level.

The official control system on qualitative traceability was effective, but checks on quantitative traceability were not included.

No potential risk for food safety was identified.

The report makes a number of recommendations to the CA, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AI	Agriculture Inspectorate
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
DAFM	Department of Agriculture, Food and the Marine
DCCD	Dairy Control and Certification Division
DG(SANTE)	Health & Food Safety Directorate General
DSL	Dairy Science Laboratory
EU	European Union
FBO(s)	Food Business Operator(s)
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
MHD	Milk Hygiene Division
MP	Milk Purchaser
SCC	Somatic Cell Count
SVS	State Veterinary Service
SOP(s)	Standard Operating Procedure(s)
TB	Tuberculosis
TBC	Total Bacteria Count
VPHIS	Veterinary Public Health Inspection Service

1 INTRODUCTION

The audit took place in Ireland from 20 to 30 April 2015 as part of the planned work programme of the Food and Veterinary Office (FVO). The FVO audit team comprised three auditors from the FVO.

The FVO audit team was accompanied throughout the audit by a representative from the Central Competent Authority (CCA), the Food Safety Authority of Ireland (FSAI). Representatives from Department of Agriculture, Food and the Marine (DAFM) also accompanied the audit team throughout the entire audit

The opening meeting was held on 20 April 2015 was attended by representatives of the DAFM and the FSAI. 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 AND SCOPE

The main objective of the audit was to evaluate the official controls related to production and storage of milk and milk products and follow-up action taken by the CAs in response to the relevant recommendations made in report DG(SANCO)/2011-6017 MR Final with regard to :

- CA organisation and operation and
- Official controls over food business operators` (FBO) compliance with general and specific rules on the hygiene of food of animal origin.

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

Table 1

COMPETENT AUTHORITIES		**Comments**	
Competent authorities	Central	2	Opening and closing meeting with the representatives of the CCA (FSAI) and of service contract authorities Department of Agriculture, Food and the Marine (DAFM)
	Regional	4	Two regional Agriculture Inspectorates and one regional Veterinary Inspectorate
	Local	6	Two local CAs for the dairy sector and for the veterinary sector
FOOD PRODUCTION / PROCESSING – ACTIVITIES			
Milk processing establishments		7	3 large capacity and 4 small/medium capacity + 2 establishments supplying liquid milk
Milk purchaser		2	
Milk production holdings		2	

Dairy Laboratories	2	

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 (DG (SANCO)/2011-6017) concerning the safety of food of animal origin in Ireland with the scope including milk and milk products was carried out from 17 to 28 October 2011. The action plan received from the Irish authorities provided satisfactory guarantees in response to all of the report's recommendations.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

5.1.1 Legislation

Findings

1. Ireland is authorised to use an alternative method for calculating the somatic cell count (SCC) in cows` milk. This method is described in Commission Decision 96/360/EC. The Decision requests that a report on its implementation be sent to the Commission Services.

2. No report on the implementation of Commission Decision 96/360/EC has been submitted to date by the Irish authorities.

5.1.2 Designation of the competent authority

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.

Findings

3. The FSAI is the CCA with overall responsibility for enforcement of food safety legislation. The responsibility for enforcement for the areas relevant for the scope of this audit is managed through a service contract with the DAFM. The service contract is

available on the FSAI website at:
http://www.fsai.ie/about_us/service_contract_agencies.html.

4. Within the DAFM, the Agriculture Inspectorate (AI), the State Veterinary Service (SVS), and their regional/local offices are responsible for the control of dairy sector. The tasks of the different official bodies are described in the Country Profile (CP) of Ireland available at http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=IE.

Conclusion on Competent Authority

5. Competent Authorities have been designated in relation to the scope of this audit, as required in Article 4 of Regulation (EC) No 882/2004.

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

Legal requirements

Article 8 (paragraphs 3 and 5) of Regulation (EC) No 882/2004 requires efficient and effective co-ordination and co-operation between and within CAs.

Findings

6. The FSAI organises at least twice a year a co-ordination meeting between the main CAs (FSAI, Veterinary Public Health Inspection Service (VPHIS), Dairy Control and Certification Division (DCCD), Milk Hygiene Division (MHD)).

7. There are quarterly and annually service contract liaison meetings between the FSAI and each CA.

8. The FSAI has established different meetings and working groups to ensure consistent enforcement of food legislation and identify gaps and/or overlaps in the system such as a Cross-agency group to implement the Hygiene Package and a Cross-agency group to agree supervision arrangements.

9. In response to a recommendation in the previous report concerning effective co-ordination between the different Units of the same CA responsible for official controls at establishment and holding levels in the case of Tuberculosis (TB) breakdowns, the DAFM established a new procedure for better communication between the relevant divisions. The FVO audit team found that the local/regional inspectors follow the procedures.

Conclusion on Co-operation and co-ordination between and within Competent Authorities

10. There is a communication and co-operation system in place which is co-ordinated by the FSAI. The communication and information exchange has significantly improved between the relevant CAs since the previous audit in 2011.

5.1.4 Registration/approval of Food Business Operators

Legal requirements

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 3 of Regulation (EC) No 854/2004 and Article 31 of Regulation (EC) No 882/2004.

Findings

11. The system for registration and approval of establishments is described in the CP of Ireland chapter 2.2.

12. Milk collection centres and milk purchasers are approved in Ireland. The milk purchasers are often independent legal entities which buy milk from farmers and sell it to processing establishments. They are responsible for the collection of raw milk at milk production holdings and transport it directly to the processing establishments. The milk purchasers are also responsible for the inhibitor control and the quality control including total bacteria count (TBC) and SCC of the raw milk. The milk purchasers calculate the geometric averages, and communicate these results to the farmers and the milk processing establishments.

13. In response to a recommendation in the previous report concerning documented procedures for carrying out official controls in relation to approval of establishments, in particular, for collection centres and milk purchasers' facilities, the CA established a written procedure for the approval and control of the FBOs producing and collecting raw milk (SOP 23). This was implemented at the FBOs visited by the FVO audit team.

14. The MHD issued a detailed procedure for the registration and approval of establishments (SOP 15) including the various categories of milk processing establishments. This procedure had been followed in relation to newly approved establishments.

Conclusion on registration/approval of Food Business Operators

15. There is an effective system in place for registration and approval of establishments including milk purchasers and milk collection centres.

5.1.5 Prioritisation of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004.

Findings

16. The frequency of the official controls in liquid milk plants is based on risk assessment (see in CP of Ireland Chapter 1, Heading: Organisation and implementation of official controls) and is set by the SVS. The minimum frequency is one audit per year, the maximum is two audits plus four unannounced inspections per year. The minimum

frequency of official controls in other dairy establishments is once per year and maximum four times per year set by the AI.

17. The frequency of the official sampling is also risk based. It is between one and four times per year. For new FBOs, the sampling frequency should be at the highest level for at least two calendar years.

18. The hygiene control frequency of milk production holdings is risk based. The risk criteria and number of holdings are agreed on a national basis. Selection of the holdings is done at regional level, based on these criteria.

19. The dairy inspectors have to fill in at least one full section of all checklists during the inspection.
    - Inspection control checklist A: general hygiene requirements (Regulation (EC) No 852/2004)
    - Audit control checklist B: specific hygiene requirements of dairy establishments (Regulation (EC) No 853/2004), traceability (Regulation (EC) No 178/2002) and microbiological controls of FBO (Regulation (EC) No 2073/2005).
    - Inspection/audit checklist C: on offsite storage facilities.
    - HACCP control checklist D.

20. The dairy inspectors have to cover all areas including different checklists (checklist A Sections I, II, III, checklist B Sections I, II, III, and checklist D Section I, II) within an audit cycle. One audit cycle is between 18 months and 3 years depending on the risk category of the establishment.

21. The frequency of the official control was in line with the risk categorisation in all establishments visited.

22. In two large capacity milk processing establishments visited the dairy inspector did not cover all areas within an audit cycle in 2013-2014. This was due to a shortage of staff in this region. New additional staff were recruited at the end of 2014.

Conclusion on prioritisation of official controls

23. There is a risk assessment system in place for prioritisation of official controls including different inspection frequencies for the different risk categories. In some cases the risk assessment is not complete, because a full audit within an audit cycle was not always carried out.

5.1.6 Official sampling and laboratory analyses

Legal requirements

Articles 4, 11 and 12 of Regulation (EC) No 882/2004 set down requirements for official laboratories and analyses.

Findings

24. The Dairy Science Laboratory (DSL) is the National Reference Laboratory in the dairy sector. The DSL organises TBC proficiency controls in 12 milk testing laboratories and SCC proficiency controls in 10 laboratories. Seven of these laboratories are accredited. It is obligatory to participate in these tests. The DSL do not carry out on-the-spot checks in these laboratories but the local dairy inspectors check the working procedures of the laboratories based on a specific checklist.

25. There is no official sampling programme in place to control the TBC and the SCC of the raw milk or to verify the reliability of the results of the private laboratories. The proficiency test schemes and the check lists ensure the uniformity of results from the milk testing laboratories

26. The inhibitor control of raw milk is part of the National Residue Control Programme. The last positive case was found in 2013 (cloxacillin).

27. The FVO audit team visited an official regional microbiological laboratory. The laboratory tested approximately 2 450 samples in 2014. Only one potential food safety risk was detected (*Listeria* in pasteurised milk). The laboratory carried out the test and the confirmation test on time and informed the relevant inspector also on time.

28. There was another recent (13/03/2015) positive *Listeria* case in soft goat cheese made from raw milk. The laboratory also informed the relevant inspector on time and the inspector launched the official procedure.

29. There are different SOPs in place for sampling:
    - DCCD SOP 1 official sampling and reporting procedure relating to the implementation of the Hygiene Package at establishments.
    - DCCD SOP 26 potable water sampling testing and reporting of results for microbiological analyses at establishments.
    - DCCD SOP 13 official sampling arrangements of raw milk for residue testing.

30. The FVO audit team visited an accredited private raw milk quality control laboratory. The laboratory participated in the obligatory proficiency tests with good results. The control method for SCC was accredited. The method for TBC was not included in the scope of accreditation, but the laboratory operated an ISO method for control, and daily calibration records were available.

31. In response to a recommendation in the previous report concerning an adequate supply of potable water to be used, the FSAI issued a guidance document for FBOs (Potable Water Quality for FBOs issue No 1 April 2015.) The recommendations of the guidance were followed by the FBOs in the establishments visited.

Conclusions on official sampling and laboratory analyses

32. The official sampling programmes of the CAs are based on SOPs and these are followed

by the inspectors. The official sampling for SCC and TBC of raw milk is not part of the programmes.

33. There is an efficient and effective laboratory system in place.

34. Action has been taken to ensure compliance with requirements concerning potability of water in milk processing establishments.

5.1.7 Procedures for the performance of control activities and documentation of official controls

Legal requirements

Articles 8 and 9 of Regulation (EC) No 882/2004 set down requirements for the performance and documentation of official controls.

Findings

35. There are well described official procedures in place to carry out official controls in the different milk production holdings and establishments
    - VPHIS SOP/017/2012 and SOP 1 (issue date 11/12 Rev 01) for milk pasteurising establishments
    - DCCD SOP 24 for other milk processing establishments
    - DCCD SOP 23 for raw milk producing and/or collection of raw milk

36. In all establishments visited, the official inspectors knew and followed the relevant SOPs.

37. The official controls were always documented. If any non-compliance was found it was categorised (1-3) and listed in the report. A compliance notice was generally prepared and issued by the local inspector and included a deadline. The non-compliances were followed up by the local officials and the follow-up controls were also documented in establishments visited.

38. In one large capacity establishment visited, there was one category 2 non-compliance. The compliance notice was issued but without a deadline. The follow-up inspection was carried out only four months later.

39. In a small capacity establishment visited, the follow-up of the non-compliances were only documented a few months later than the deadlines.

40. In several establishments visited, the raw milk temperature at the milk production holdings at the time of collection was often higher than 6 ℃, sometimes it was over 10 ℃. Milk collection was usually every second day (sometimes less frequent) and higher temperature generally occurred when collection took place shortly after milking. This is not in line with Section IX, Chapter I, Point II, B, 2a of Regulation (EC) No 853/2004. However, the temperature of the raw milk recorded on delivery to the processing establishments was always under 10 ℃, (in line with legal requirements), therefore, the cold chain was maintained during transport.

Conclusion on procedures for the performance of control activities and documentation of official controls

41. There are documented procedures (SOPs) in place to carry out official controls. Generally these procedures are followed by the inspectors. However, in some cases the follow-up inspections were not carried out on time.

5.1.8 Training

Legal requirements

Article 6 of Regulation (EC) No 882/2004**.**

Findings

42. Several training courses were provided for the officials in the dairy sector since 2011. These included training on new legislation (food additives and food labelling) and on new technologies (thermal processing, high pressure processing, ultrafiltration and nano technology etc.) In this time period 20 officials participated in various Better Training for Safer Food training courses connected to the dairy sector.

43. On-the-spot training was provided to newly recruited staff, while an exchange of technical knowledge between officials is also provided during supervisory activities.

Conclusion on training

44. A system for training of officials and for keeping competences up-to-date is in place, and the knowledge of the officials met was good.

5.1.9 Enforcement measures

Legal requirements

Article 54 of Regulation (EC) No 882/2004.

Findings

45. In one positive *Listeria* case (see chapter 5.1.6) the processing activity of the establishment was suspended until the FBO could provide guarantees that the potential food safety risk was eliminated. The FBO had to take appropriate action, carry out final product and environmental contamination testing and verification control on pasteurisation (phosphatase test). The CA evaluated the corrective actions and when all the test results were acceptable, the CA lifted the suspension.

46. In another positive *Listeria* case (see chapter 5.1.6) the CA has already launched the official procedure. At the time of the audit the corrective actions were not completed, so the processing activity of the establishment was still under suspension.

47. In case of a positive TB test the CA always suspended the TB free status of the milk production holding and carried out additional necessary restrictive measures (updated

Circular ER 06/09 procedures for visiting herds experiencing TB breakdowns in light of the recent changes to the TB eradication scheme dated 17/04/2014).

48. In all cases where antibiotics were found in raw milk, the relevant milk production holdings which were the source of the contamination were suspended pending an investigation (see more in chapter 5.2.6).

Conclusion on enforcement measures

49. Enforcement powers and enforcing tools are available to official control staff. These tools were adequately used by them.

5.1.10 Verification and review of officials control and procedures

Legal requirements

Article 4 of Regulation (EC) No 882/2004.

Findings

50. A detailed description of the system of verification of official control is available in the Country Profile of Ireland (chapter 1).

51. The FSAI has a detailed audit plan for each year. The follow up of FVO recommendations is a key element of their audits.

52. The FSAI carried out an audit on official controls conducted by the Dairy Produce Inspectorate in Small Cheese Producing FBOs in two regions visited by the FVO audit team (in February 2014). The report is available on the website of the FSAI.

53. The FSAI also carried out an audit in February 2014 of a liquid milk establishment in a region visited by the FVO audit team. This audit was followed up by the Superintending Veterinary Inspector in December 2014, and a close out audit was finally carried out by the representative of the VPHIS and the SVI in March 2015 to close all non-compliances identified during the previous audits.

54. The DCCD carried out supervisory controls regularly based on SOP 16 in a region visited.

Conclusion on verification and review of official controls and procedures

55. A well developed and implemented system for verification and review of official controls is in place in the CAs.

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 of Regulation (EC) No 852/2004, Article 3 of Regulation (EC) No 853/2004 and Article 4 of Regulation (EC) No 854/2004.

Findings

56. Official control procedures over FBO compliance with the general and specific hygiene requirements are in place in the different types of milk processing establishments, and were followed by the official staff in the establishments visited by the FVO audit team. With some exceptions, the results of official controls were found to be satisfactory.

57. The FVO audit team noted, that:

- In one establishment, dirty, bad quality, painted wooden pallets were used in the production area where exposed products were packed.
- In two establishments, both the maintenance and the cleaning were not adequate (dirty and rusty equipment).
- In two establishments, inappropriate use of a hose could cause cross- contamination (splashing of cleaning water).
- In one small capacity establishment the outflow from a hand wash basin was not connected directly into the drainage system.
- In a small capacity establishment, major refurbishment and enlargement was ongoing during production; as a result the corrective actions and follow-up of some non-compliances concerning structure and hygiene were delayed.

Conclusion on official controls over food business operators' compliance with hygiene rules at establishment level

58. Notwithstanding that some minor shortcomings had not been identified during official controls, an effective system for control of hygiene conditions in establishments is in place.

5.2.2 Hazard Analysis and Critical Control Points based systems

Legal requirements

Article 5 of Regulation (EC) No 852/2004 and Articles 4 of Regulation (EC) No 854/2004.

Findings

59. Official control procedures for the evaluation of FBOs' Hazard Analysis and Critical Control Points based systems are in place for all the CAs and the official controls were carried out in line with the procedures in the establishments visited. Only minor shortcomings were additionally noted by the FVO audit team.

- In one establishment, the critical limits and monitoring procedure of pasteurisation was not reflected in the procedure used (the critical limit was described as being 72 ℃, but the flow diversion valve operated at 80 ℃) and the real pasteurisation temperature was above 85 ℃. Moreover, the pasteurisation flow was not continuous, leading to frequent activation of the flow diversion valve at a temperature which was not consistent with the procedure described.
- In a small capacity establishment the recorded time of the pasteurisation on the daily inspection sheet was not the real length of the pasteurisation time. The FBO recorded the minimum required time (15 seconds) not the real time of the pasteurisation (112 seconds).
- In a large capacity establishment, based on the FBO explanation, there is always a positive pressure on the processed milk side on each section of the heat exchanger. But there were no records available on the pressure differences. The calibration document of the pasteurization equipment did not mention explicitly the pressure difference between the raw milk and the pasteurised milk part even though it was important for the verification of the CCP (pasteurisation).

Conclusion on Hazard Analysis and Critical Control Points based system

60. Official controls on HACCP systems are generally satisfactory and effective, but some minor shortcomings had not been identified by the CAs.

5.2.3 Microbiological criteria for foodstuffs

Legal requirements

Article 4 of Regulation (EC) No 854/2004. Regulation (EC) No 2073/2005 lays down EU rules with regard to microbiological criteria for foodstuffs.

Finding

61. Official control procedures over FBOs' sampling plans for food safety and process hygiene criteria as required in Regulation (EC) No 2073/2005 are in place and were followed in all establishments visited.

5.2.4 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002, Article 4 of Regulation (EC) No 854/2004, Article 5 of Regulation (EC) No 853/2004 and Article 3 of Directive 2000/13/EC.

Findings

62. Official control procedures over traceability labelling and control of identification marks are in place and were followed in all establishments visited.

63. The CAs carried out qualitative traceability checks, but did not carry out any quantitative controls (i.e. checks of quantities of raw materials received, used in production, remaining in storage, dispatched).

64. The official inspector did not carry out traceability control during the last audit cycle in one establishment visited.

65. The FVO audit team carried out traceability exercises in three establishments. In one case the qualitative traceability was satisfactory. In a second case a simple clerical error was detected. In the third case, the documentation available on-the-spot was incomplete but was subsequently supplied to the FVO audit team. Based on these documents the qualitative traceability was satisfactory.

Conclusions on traceability, labelling and identification marking

66. The official control system on qualitative traceability is effective (though not always carried out).

67. Checks on quantitative traceability are not included in the official control system.

5.2.5 Control of milk production holdings

Legal requirements

Article 8 of Regulation (EC) No 854/2004.

Findings

68. The FVO audit team visited two milk production holdings. The official control frequency was in line with the risk assessment (see in chapter 5.1.5).

69. Records on the treatment of animals were available on both holdings and these were in line with the requirements.

70. Both holdings had been under TB restriction in 2014. Documents were available on both holdings about the date and the results of TB tests, the number and the identification number of the reactor and/or inconclusive reactor animals, dates when the animals were sent for slaughter. Both farmers received official notification of suspension of the TB free status of the herd. One farmer received it one day after the evaluation of skin tests, the other farmer received it one week later, because additional gamma interferon blood tests were sampled and tested, and the results of the two tests (skin and gamma interferon) were communicated at the same time.

71. Documentation on the amount of raw milk collected from reactor animals, storage of this milk, method, location and date of the disposal was not available on either holdings.

72. The temperature of the raw milk at the time of collection was not included in the items being controlled by officials and several times it was higher than the legal requirement (see chapter 5.1.7).

Conclusion on milk production holdings

73. Generally the food safety controls on milk production holdings were implemented.

74. The CA has no documented procedure in place to verify appropriate disposal of milk from TB reactor animals.

5.2.6 Control of raw milk upon collection

Legal requirements

Article 8 of Regulation (EC) No 854/2004.

Findings

75. The FVO audit team visited two milk purchasers (MPs). Both MPs had a complex system in place to test for TBC, SCC and inhibitors in the raw milk purchased from individual milk production holdings.

76. Both MPs had positive inhibitor cases recently. The MPs could trace back to the holdings which were the source of the antibiotic contamination. Both holdings were suspended by the MPs. The suspension was lifted when the farmers could provide negative raw milk samples for antibiotics, but the farmers were under strict supervision for the following 30 days. The CAs were informed but, in one case, this had happened only after 10 days.

77. Both MPs could show several examples when the geometric average for SCC and/or TBC exceeded the limit (corrected by the seasonal factor for SCC). The MPs issued warning letters and after the third warning letter, the milk from the holding was suspended. The suspension was lifted generally after one month or when the geometric average returned to below the limit. The CAs were informed about the warnings, and the suspensions.

78. Both MPs accepted raw milk from milk production holdings, when the temperature of the raw milk at the time of the collection was above 6 ℃ sometimes it was over 10 ℃. This is not in line with the legal requirement (see in chapter 5.1.7.) However, the temperature of the raw milk recorded on delivery was always under 10 ℃, therefore, the cold chain was maintained during transport. In one MP there is a written instruction in place that if the temperature of the milk at collection exceeds the limit, the raw milk can be collected, but the driver must confirm the cooling capability of the bulk tank on the holding.

79. In one processing establishment visited the geometric average for SCC of one supplier exceeded the limit over three consecutive months. The supplier was informed but was not suspended. The CA was not informed.

80. In the case that there is an interruption of at least one month in the supply of milk from a holding (seasonal production), the calculation method for determining the geometric average for SCC differs from that used for TBC:
    - calculation for SCC starts from re-commencement of supply,

- calculation of the TBC average includes the results from the month before the cessation of supply. As consequence the months used in the calculation are not consecutive.[1]

Conclusions on control of raw milk upon collection

81. There is a system in place to control the safety and the quality requirements of the raw milk. Implementation of the system (i.e. suspension of collection when parameters exceed) is the responsibility of the FBOs. However the CA was not always kept fully informed.

82. The calculation of the geometric averages for TBC is not always based on rolling geometric average over a two-month period.

5.2.7 Animal by-products

Legal requirements

Article 5 of Regulation (EC) No 854/2004.

Regulation (EC) No 1069/2009, and in particular Articles 21 and 22 sets out the requirements for collection and transport of animal by products, including requirements for identification, records and the use of commercial documents.

Findings

83. The two MPs visited could provide documentation about the disposal of antibiotics contaminated (category 2) raw milk. However the documentation did not cover all steps of further treatment and disposal.

84. In a milk processing establishment visited, there was a detailed procedure in place for disposal of antibiotic contaminated milk. The procedure was followed by the FBO.

85. On farm disposal of milk from TB reactor animals was not documented. In both cases the milk was spread on land. In one case the farmer stated that the field was not used for grazing, where the milk was disposed. In the other case the grazing was suspended on that particular field for six weeks after the disposal.

Conclusion on animal by-products

86. An effective system for control of animal by-products is in place in milk processing plants but not in milk production holdings.

[1] In their response to the draft report, the CA noted that in relation to TBCs, where supply has ceased for one month, the calculation of the geometric average includes the results from the month before the cessation of supply. The CA's view is that this gives a higher level of consumer protection. If results from consecutive months only were used, the calculation of the geometric average would be delayed for a further month. Accordingly, the competent CA would not propose to amend the method of calculation of the geometric average for TBCs.

6 OVERALL CONCLUSIONS

The Irish control system of the dairy sector is well organised: documented procedures (SOPs) are in place to carry out official controls, and are implemented by the local inspectors. Official controls are carried out frequently according to control plans, are risk based and well documented. Reports on the official controls contain the relevant information including deficiencies and shortcomings which are well identified. The follow-up is also documented and carried out regularly. Communication and co-operation between and within the CAs have improved markedly since the last FVO audit on this subject in 2011. In the establishments visited, most of the significant deficiencies had been identified and documented by the CA.

Audits and supervisory visits by the CA are carried out by central and regional levels. The knowledge of the officials met was good and the reports examined highlight the relevant issues.

The official control on general and specific hygiene conditions and HACCP based procedures in the milk processing establishments visited was satisfactory. Some minor shortcomings had not been identified by the CAs.

Ireland is authorised to use the alternative method for calculating the SCC in cow`s milk (Commission Decision 96/360/EC).

Laboratory results are always available and reliable. In the case of non-compliances, the warning letters and, if necessary, suspension was generally carried out on time.

The official control on TB was carried out in line with the requirements. However no records were available on the amount, time, method and place of disposal of the raw milk originating from reactor animals at holding level.

The official control system on qualitative traceability was effective, but checks on quantitative traceability were not included.

No potential risk for food safety was identified.

7 CLOSING MEETING

A closing meeting was held on 30 April 2015 with the CCA, representatives from the regions and districts visited and from the DSL. 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.

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.

No.	Recommendation
1.	The Competent Authority should ensure that food business operators are to keep and maintain records relating to measures put in place to control hazards in an appropriate manner and period as is required in point III 7, Part A, Annex I to Regulation (EC) No 852/2004 in particular, amount, storage of raw milk, method, location and date of the disposal of raw milk collected from Tuberculosis reactor animals on milk production holdings. *Recommendation based on conclusions No. 74, 86* *Associated findings No 71, 85*
2.	The Competent Authority should monitor and enforce compliance by food business operators with the requirements of Article 18 of Regulation (EC) No 178/2002 in regard to traceability, including the qualitative and quantitative aspects of traceability. *Recommendation based on conclusions No 66, 67* *Associated findings No 63, 64, 65*
3.	The Competent Authority should ensure that the calculation of geometric average of raw milk for total bacteria count is in line with the requirements of point III 3(a), Chapter I Section IX of Regulation (EC) No 853/2004. *Recommendation based on conclusion No 82* *Associated finding No 80*
4.	The Competent Authority should implement an effective system that when raw milk fails to comply with points III 3 and 4, Chapter I Section IX of Regulation (EC) No 853/2004 measures are taken to correct the situation as it is required by point III 5, Chapter I Section IX of Regulation (EC) No 853/2004. *Recommendation based on conclusion No 81* *Associated findings No 79*

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. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Reg. 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)
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. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs