EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7626 - MR

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 09 MARCH 2015 TO 20 MARCH 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.

Executive Summary

The audit took place in Italy from 9 to 20 March 2015 in order to evaluate the official controls related to production and storage of milk and milk products, and the follow-up action taken by the competent authorities (CAs) in response to the relevant recommendations made in the previous audit reports. Three Regions (Abruzzo, Puglia and Piemonte) were visited.

Official controls are carried out frequently according to control plans, are risk based and well documented. However, the establishment reports contain very little relevant information and many deficiencies are overlooked. In addition, there is very little effective follow-up. Communication within local CA units remains poor. In the eight establishments visited, among the deficiencies found by the Food and Veterinary Office audit team, only a few had been identified and documented by the CA.

Audits (Article 4.6 of Regulation (EC) No 882/2004) are carried out by central and Regional levels. The reports of these audits contain findings on non-compliances and systemic problems. Of the seven establishments visited (milk collection centre not included) in three Regions (six provinces) from the point of view of structure, maintenance, equipment, cleanliness and hygiene of operations, - four were satisfactory (with different levels of remarks and deficiencies) and three were unsatisfactory. There was no immediate public health risk. Serious deficiencies in official controls were observed on dairy holdings visited.

Raw milk quality standards (Section IX Annex III to Regulation (EC) No 853/2004): National derogations notified to the Commission for 2008 -2013 for all milk are still in place for sheep and goat milk. Food business operators (FBOs) take samples but these are not always analysed and laboratory performance is not always reliable. The CAs are not always notified of non-compliant results and there is no system in place to ensure notification. (CA does take action when informed). There is no national system for official monitoring of FBO own checks related to raw milk parameters.

Residues: There were procedures in place for inhibitor controls in all establishments visited. However, out-of-date kits were in use in three establishments. The requirement to maintain records of treatment with veterinary medicines on milk production holdings is not enforced.

A number of recommendations have been made to the CA with a view of addressing the deficiencies identified during this audit. At least five of these or very similar recommendations have already been made in the Audit Report DG(SANCO)2010-8502, 2012-6333 and 2013-6875 but have not been properly addressed or implemented.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASL	*Azienda Sanitare Locale* – Local Health Unit (in charge of public health, food safety, animal health and animal welfare)
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
COM	European Commission
DG(SANCO)	Health & Consumers Directorate General currently DG(SANTE)
DG(SANTE)	Directorate-General for Health and Food Safety
EU	European Union
FBO(s)	Food Business Operator(s)
FCI	Food Chain Information
FVO	Food and Veterinary Office
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
SCC	Somatic Cell Count
SINTESIS	*Sistema INTEgrato per gli Scambi, le Importazioni e le Strutture*
TBC	Total Bacterial Count (Plate count at 30 °C)
DGSAN	*Direzione Generale Sicurezza Alimenti e Nutrizione* - General-Directorate for Food Safety and Nutrition

1 INTRODUCTION

The audit took place in Italy from 9 to 20 March 2015 as part of the planned audit programme of the FVO. The FVO audit team comprised two auditors from the FVO.

The FVO audit team was accompanied throughout the audit by a representative from the Central Competent Authority (CCA), the Ministry of Health *(Ministerio del Salute),* and from the Competent Authorities (CAs) of the Regions visited.

The opening meeting was held on 9 March 2015 with the CCA in Rome. 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 the follow-up action taken by the CAs in response to the recommendations made in report DG(SANCO)/2010-8502- MR Final (hereafter referred to as report 2010-8502) 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 addition, some recommendations made in reports DG(SANCO)/2012-6333, DG(SANCO)/2013-6979 and DG(SANCO)/2013-6875 are relevant in the scope of this audit (see section 6 below).

Controls over the production of raw milk and milk 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:

COMPETENT AUTHORITIES			**Comments**
Competent Authorities	Central	1	Opening and closing meetings
	Regional	3	Regions Abruzzo, Puglia and Piemonte
	Local	6	ASL in 6 provinces visited (Asti, Cuneo, Bari, Foggia, l'Auila, Chieti)
FOOD PRODUCTION/PROCESSING/DISTRIBUTION – ACTIVITIES			

Milk processing establishments	7	
Milk collection centres	1	
Milk production holdings	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 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 Italy was carried out from 26 April to 7 May 2010 the results of which are described in report 2010-8502.

Other audits relevant for the scope of the audit are DG(SANCO)/2012-6333, DG(SANCO)/2013-6979 and DG(SANCO)/2013-6875

These reports are accessible at:

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

A table containing full text of the relevant recommendations, with reference to audit reports, as well as evaluation of their implementation, is provided in section 6 of this report.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

5.1.1 Legislation

Findings

Raw milk parameters

1. Italy has been granted derogation from the raw milk parameter requirements laid down in Annex III, Section IX of Regulation (EC) No 853/2004. This derogation was duly notified to the European Commission (COM) and other Member States of the EU by TRIS notification no 2006 0449 (TRIS: Technical Regulations Information System).

2. The derogation applies to Regions with geographic constraints and to the use of traditional methods and relates to a reduction in the frequency of checks for raw milk criteria for bovine, sheep and goat milk. Milk that does not fulfil the criteria is to be used for the production of cheeses with a ripening period of more than 60 days.

Flexibility

3. The flexibility rules (derogations permitted in relevant EU legislation for the flexible application of requirements in small establishments and/or establishments in remote regions) which can be applied are decided at national level and are notified to the COM. However, their application to individual establishments is determined at Regional level and there are variations in how flexibility is applied in practice.

4. In the Region of Abruzzo no flexibility rules are applied.

5. In the Region of Piemonte in one establishment visited, the CA allowed flexibility (reduce the number of sampling units from five to two) on the basis of Article 5, point 3 of Regulation (EC) No 2073/2005. The FBO procedure in place was in line with the flexibility requirements.

6. As indicated in the section "Raw milk parameters" flexibility rules have been applied in this area.

Conclusion on legislation

7. The possibilities and potential benefits of application of flexibility rules are not fully availed of, particularly in some Regions.

5.1.2 Designation of Competent Authorities

Legal requirements

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

Findings

8. An overview of how control systems are organised in Italy, based on information supplied by them, is provided in the Country Profile for Italy and is available at the following link:
http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=IT

9. The CCA relevant for the scope of this audit is the Ministry of Health and in particular, its General-Directorate for Food Safety and Nutrition *(Direzione Generale Sicurezza Alimenti e Nutrizione - DGSAN)*, hereafter referred to as the Ministry.

10. Annual plans for official controls have been developed in all Regions visited, including the Region of Puglia, in which such a plan was absent at the time of the audit DG(SANCO)/2012-6333. Based on these plans, a system for official controls in the establishments, based on risk assessments, has been put in place in the Regions.

11. A system for the verification of the effectiveness of official controls (internal audits) has been put in place at central level and the Regions visited (see section 5.1.10 Verification of Official Controls).

Conclusion on Competent Authorities

12. CAs have been designated and a system for official controls as required in Article 4 of Regulation (EC) No 882/2204, including verification of their effectiveness, as laid down in Article 8(3) of Regulation (EC) No 882/2004, has been put in place in Italy.

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

Legal requirements

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

Findings

13. Organisation of the Competent Authorities has been described in the report 2010-8502 and in the Country Profile, and, in particular, its section 2.2. At central level, the unit relevant for the scope of this audit remains Office III, Hygiene of Products of Animal Origin.

14. A system of internal audits by the Ministry in the Regions has been put in place; see section 5.1.10 (Verification and review of official controls and procedures).

15. Communication difficulties between sections of the ASL responsible for Animal Health (section A), holdings and raw milk (section C) and food establishments (section B) have previously been highlighted in a number of Ministry (CCA) and Regional CAs' audit reports, in particular, in the audit reports of the Ministry to the Regions of Abruzzo and Puglia but also in the audit reports of the Region of Abruzzo to the ASL carried out in October-November 2013. The recommendations made in these reports have not yet been addressed effectively.

16. In one province, the FVO audit team found that non-conformities in raw milk parameters from a particular supplier for three consecutive months, identified by one ASL, were not communicated to the ASL responsible for control at milk production holding level.

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

17. Communication problems between the different sections of the local CA, highlighted in several reports at different levels, have not been properly addressed and the difficulties in communication remain.

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

18. The system for approval of establishments is described in the Country Profile.

19. In the dairy sector, the milk processing establishments as well as milk collection centres, were approved, milk production holdings were registered.

20. Three of the milk processing establishments visited exhibited structural and maintenance deficiencies which meant that they did not fulfil the approval requirements as laid down in Regulations (EC) No 852/2004 and (EC) No 853/2004.

21. The SINTESIS system provides a single list of approved establishments. In addition, it records the various approved activities of individual establishments[1]

22. In one Region an establishment was suspended two years ago on the *Sistema INTEgrato per gli Scambi, le Importazioni e le Strutture* (SINTESIS) list. The CA explained that this was a consequence of the earthquake which took place in Abruzzo in 2009 when damaged establishments were waiting for aid from the authorities to renovate their premises. During the period of suspension, the establishment was visited four times per year to confirm that no activity was taking place. The establishment was delisted on the day the FVO audit team requested to visit it.

23. Another establishment that was suspended in 2013 remains suspended. No criteria on how long an establishment can remain suspended before delisting were available in this Region.

24. In another Region, the CA stated that an establishment is delisted after six months suspension.

[1] Paragraphs 21-24 inclusive have been re-ordered for clarity.

25. One establishment was on the list of heat treatment (liquid milk establishment). However, based on the information provided by the FBO, this establishment has never produced liquid milk.

26. On the web site of the Ministry, there is only one list of approved establishments in Italy, containing all the activities of the establishments concerned:

    http://www.salute.gov.it/portale/temi/transferimento_PROD.jsp

Conclusion on approval of establishments

27. No standardised criteria have been developed in relation to suspended establishments with the result that establishments can remain suspended for an indefinite time. Some minor errors in the lists of establishment activities were noted.

5.1.5 Prioritisation of official controls

28. Official controls are carried out frequently, are risk based and well documented.

29. Decisions on the risk assessment criteria and the frequency of controls are taken at Regional or local level, both in relation to controls in milk processing establishments and milk production holdings.

Conclusion on prioritisation of official controls

30. Systems for risk based prioritisation and determination of frequency of controls are in place in all Regions visited.

5.1.6 Official sampling and laboratory analysis

31. Control plans for official sampling and laboratory analysis are established at Regional level:

    - In one Region, the number of official samples to be taken and the parameters to be checked for milk and milk products, are prescribed.
    - Important criteria are not always included. For example, in one Region testing of cheeses made from unpasteurised milk for the presence of *Listeria* and *E. coli* is not specified.

32. In a second Region, the number of samples to be taken is not specified. The plan requires the CA to verify compliance of the FBO samplings and to take official samples when necessary using the criteria and methods laid down in Regulation (EC) No 2073/2005.

33. Official control plans were not established for checking raw milk criteria on TBC and SCC. Only targeted officials checks were carried out in the case of suspension.

34. The control of inhibitors in raw milk is part of the National Residue Control Plan.

35. The results of official sampling are not used to verify results of raw milk analysis carried out in private accredited laboratories. In one case seen (see section 5.2.6) a conflict between official and FBO analysis from the same milk production holding was not identified or investigated.

36. The CCA informed the FVO audit team that an agreement between the State and the Regions has been reached in order to carry out official controls of laboratories carrying out analyses of FBO own checks. This Agreement, signed on 8 January 2015, lays down guidelines for these controls and is expected to enter into force by the end of 2015.

Conclusions on official sampling and laboratory analyses

37. Control plans for official sampling and laboratory analysis are in place, but exhibit some shortcomings which vary between Regions/localities.

38. Official control plans were not established for checking raw milk criteria on TBC and SCC.

39. Laboratories carrying out examinations for FBO own checks are not yet subject to official controls.

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

40. Different guidelines and checklists are used in different Regions/localities but all were found to be satisfactory.

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

41. Although different procedures apply in different Regions they allow in general the official staff to perform and document the official controls in compliance with Article 8.1 of Regulation (EC) No 882/2004.

5.1.8 Training

42. In one Region where the issue of training was evaluated: following an audit by the Ministry in 2013, at the request of the Regional CA, training in relation to milk and milk products was organised by the Ministry, with the participation of the FVO. There were two training sessions, one in December 2014 and one in January 2015.

43. Findings in relation to official controls in establishments (see para 54) indicate that, while staff who have received training are competent to detect non-compliances, this is not reflected in the standard of official controls performed.

Conclusion on training

44. Comprehensive training has been provided to CA staff performing controls in the dairy sector but it was not always reflected in the standard of official controls performed.

5.1.9 Enforcement measures

45. Based on the Italian national legislation there is a possibility to impose administrative sanctions (penalties, fines, suspensions) in case of non-compliances.

5.1.10 Verification and review of official controls and procedures

46. Internal audits which covered the dairy sector were carried out in 2013-2014 by CAs - (The Ministry to the Regions) and by Regional authorities (the Regions to the ASL) levels.

47. The Ministry carried out an audit to evaluate the official control on milk and milk products in two Regions – one in 2013, the other in 2014.

48. The issue of non-compliant raw milk quality criteria was noted and relevant recommendations were made in all audit reports both at central (The Ministry) and Regional (Abruzzo) levels.

49. One Region did not provide an adequate action plan in response to the recommendations of the internal audit. According to the Ministry, a new audit to this Region is planned for 2015.

50. The report of the other Region contains seven recommendations. The Region has sent back an action plan which was evaluated by the CCA. All but one answer was satisfactory. The answer to one recommendation was considered only partially satisfactory, because the separation of the responsibilities in the milk sector between the two ASLs was unclear.

51. Issues highlighted in the central and Regional level audit reports such as a procedure for the control of raw milk and for communication between different units of the ASL, were in progress.

Conclusion on verification of official controls

52. A system for verification of official controls and procedures and performance of audits as required by Article 4 of Regulation (EC) No 882/2004 is in place and is effective at identifying shortcomings in the official controls. Follow-up of these audits was in progress at the time of the FVO audit and could not be fully evaluated.

5.2 OFFICIAL CONTROLS OVER FOOD BUSINESS OPERATORS' COMPLIANCE WITH HYGIENE RULES AT ESTABLISHMENT LEVEL

5.2.1 General 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

53. In all milk processing establishments visited, official controls took place according to the prescribed frequency, or more often.

54. Official procedures were followed and controls were documented.

55. In most cases, the official reports provided a detailed description of the establishment and the FBO procedures in place. However, the reports seen did not provide an accurate reflection of compliance standards. The majority of non-compliances identified by the FVO audit team had not been recorded in the official reports. (The FVO audit team's findings are provided in paragraph 59 below).

56. Many of the reports did not include findings, conclusions or recommendations.

57. In those cases where recommendations were made, follow-up activities were also documented. However, the corrective actions were often not implemented or were not effective.

58. In one establishment, where the FVO requested the local CA official to perform the inspection, according to their procedures, the official demonstrated a good knowledge of requirements and was able to identify relevant findings and deficiencies. However, the conclusion reached was considered incorrect and not to provide a solid basis for appropriate recommendations.

59. The findings of the FVO audit team in the seven establishments visited are summarised below:
    - Four were considered to be generally in compliance with requirements (some minor deficiencies, usually related to maintenance, hygiene or layout).

- In one establishment, hygiene deficiencies were noted, including condensation water from cooling equipment draining directly into a container of exposed products. Structures in this establishment were not in compliance. However, in the opinion of the FVO audit team, this establishment could be considered eligible for flexibility derogation but such flexibility provisions were not applied in the Region.
- In another establishment, heat treatment records for pasteurisation were not available. This establishment also exhibited significant deficiencies related to cleaning and maintenance (cold rooms generally dirty, rusty structures, condensation, flaking paint in food machines).
- In a third establishment, which had recently undergone upgrading considered satisfactory by the CA, maintenance problems persisted (flaking paint, exposed and damaged insulation, rust, condensation, cracks in walls and floors). The CA stated that these problems had recurred since their previous audit of the establishment, six months previously.

60. In relation to the above, there was no significant difference between the standards in the various Regions visited. None of the deficiencies seen presents an immediate risk for public health.

Conclusion on general hygiene requirements

61. While none of the deficiencies seen represent an immediate risk for public health, the official control system does not ensure consistent compliance with the general hygiene requirements as laid down in 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.

5.2.2 HACCP-based systems

Legal requirements

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

Findings

62. The Hazard Analysis Critical Control Points (HACCP) based system was evaluated in detail in one establishment:

- The process and procedures described in the HACCP documentation did not correspond to those seen in operation in the establishment.
- The HACCP procedure described for the pasteurisation process (temperature parameter) was not in line with legislative requirements.

63. The HACCP documentation had not been checked by the official veterinarian and the above deficiencies had not been identified.

Conclusion on HACCP based systems

64. HACCP based systems are in place but official controls thereon are not sufficiently rigorous.

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.

Findings

65. In one establishment, the CA had correctly applied flexibility possibilities to permit a reduction of the number of final products sampled. The FBO procedures were in line with requirements.

66. In another establishment, the Regional CA had identified, during an audit in 2014, that the FBO was applying obsolete national legislation instead of the requirements of Regulation (EC) No 2073/2005. The CA had taken appropriate action and, since 2015, the FBO was applying the correct standards.

Conclusion on microbiological criteria for foodstuffs

67. Microbiological controls are in compliance with the requirements of Regulation (EC) 2073/2005.

5.2.4 Traceability, labelling and identification marking

Legal requirements

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

Findings

68. The reports of the official controls, seen by the FVO audit team in the establishments visited, did not mention any deficiencies in the traceability system during the last two years.

69. The FVO audit team carried out traceability checks in two establishments:

- In one (a large milk collection centre) the quantities of milk sold to clients could not be easily correlated with the quantities received from individual suppliers (information on suppliers was required by the clients).

- In another, the same batch number was allocated to both pasteurised and unpasteurised milk. This establishment was exporting product to a third country which required that the product be made from pasteurised milk only.

Conclusion on traceability

70. Official controls on traceability are not fully effective.

5.2.5 Control of milk production holdings

Legal requirements

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

Findings

71. Official controls on milk production holdings are carried out by the local CAs (ASLs). Different sections within the ASLs are responsible for different aspects (one sector responsible for hygiene, raw milk quality and zoo-technics; another for animal health).

72. On one of the two milk production holdings visited, the structure of the buildings was poor and impossible to keep clean. An official control report for this holding indicated that "the walls are dirty" and "other species not properly separated". The CA stated that no action had been taken concerning the poor structures because the municipality had determined that the location of the holding was unsuitable and that it was expected that the milk production holding would be relocated.

73. On this first milk production holding, general hygiene was poor, there was insufficient pest protection during milk collection and animal welfare standards were unsatisfactory (animals with overgrown hooves).

74. Structures on the other holding visited were satisfactory.

75. On one of the holdings visited, records of treatment with veterinary medicinal products were not maintained. Treatment records are not subject to official controls.

76. On both holdings visited, the farmers declared that medicines records were kept by their veterinary practitioner who carried out all treatments. Both farmers declared that they did not handle or maintain stocks of veterinary drugs. However, on one holding, veterinary drugs and syringes were present in the milking room.

Conclusion on milk production holdings

77. Official controls in the milk production holdings are not effective. In particular, the requirement to maintain on farm records of treatment with veterinary medicinal products is not enforced.

5.2.6 Controls of raw milk upon collection

Legal requirements

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

Findings

Raw milk quality parameters

78. There is no national or Regional system for official monitoring of FBO own checks related to raw milk parameters as required in Regulation (EC) No 854/2004, Annex IV.

79. In particular, there is no system in place to ensure that FBOs inform the relevant CAs about non-compliant results.
    - In one case, where two FBOs were under the supervision of one official veterinarian, one establishment had an efficient system in place for providing information to all CAs concerned (both the ASL responsible for supervision of the establishment and the ASL responsible for the milk production holding). No such system was in place at the other FBO.
    - One ASL provided evidence of follow-up of cases of non-competences. However, this only occurred when the ASL was notified by the FBO, which was not always the case.

80. The FBOs have put in place systems for the control of incoming raw milk as laid down in Section IX, Annex III to Regulation (EC) No 853/2004. In the establishments visited, samples of raw milk were taken and examined as laid down in the Regulation. However, the results

    - are not always analysed, or/and
    - the results are not credible (see paragraph 81 below) and/or
    - when the results are not satisfactory, the CA is not always notified.

81. While no laboratories were visited during this audit, results were seen which undermine the credibility of the accredited private laboratories:

    - On one of the milk production holdings visited, (selected by the FVO audit team), the FBO informed the CA (ASL) only after five consecutive non-compliant results for TBC. The ASL had submitted samples to an official laboratory; the owner had submitted samples (collected by a producers' association on his behalf) to an

accredited laboratory. The results from the two laboratories were significantly different.

- In one dairy holding a bulk milk sample collected on 8 April 2014 and analysed in this laboratory indicated 133 000 /ml for TBC and 46 000/ml for SCC. On the same holding, an official sample collected a day later and analysed in an official laboratory indicated 357 000/ml for TBC and 469 000 /ml for SCC. No comparative sampling had been carried out to investigate this difference.

82. In one establishment visited, for the control of raw milk quality (TBC and SCC). Samples were taken from each supplier every two months for both TBC and SCC. The samples were sent to two different laboratories. When calculating the geometric average, the FBO selected the lower of the laboratory results.

Inhibitor controls

83. Procedures were in place in all the establishments visited for testing of raw milk for the presence of inhibitory substances. In three of them, the kits used for the control (fast test) were outdated (past their expiry date). In one of them, a communication from the supplier of kits to the FBO was shown to the FVO audit team. It suggested further use of the kit for three months after the expiry date on condition that the user would set up own controls.

84. Very few positive or false positive results have been noted during the last two years (only in two of the establishments visited).

85. The requirement to maintain records of treatment with veterinary medicines on milk production holdings is not enforced.

Conclusions on raw milk controls

86. There is no system in place to monitor the FBOs' checks on raw milk concerning the TBC, the SCC and the presence of antibiotics. The official control was weak as the CAs did not take into account the reliability of the results.

87. Official controls do not verify the reliability of results from accredited laboratories used by the FBOs.

88. A recommendation of a previous FVO audit, concerning monitoring of checks on raw milk (Article 8 and Annex IV (II) to Regulation (EC) No 854/2004) has not been addressed.

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 the collection and transport of animal by-products, including requirements for identification, records and the use of commercial documents.

Findings

89. In one establishment, the legislation relevant for the animal by-products has not been updated in the FBO written procedures. Apart from this, the FVO audit team had no observations related to animal by-products.

6 RECOMMENDATIONS OF THE PREVIOUS AUDITS RELEVANT FOR THE CURRENT AUDIT

Audit report no 2010-8502 from 26 April to 7 May 2010 in order to evaluate the follow-up action taken by the Competent Authorities with regard to official controls related to the Safety of Food of animal origin, in particular meat, milk and their products.	2. To review the lists of approved establishments as to their accuracy and ensure that they correctly reflect the activities of the approved establishment in line with Article 31 of Regulation (EC) No 882/2004	Not fully addressed
As above	3. To ensure that official controls are effective as foreseen in Article 4(2) of Regulation (EC) 882/2004 and to ensure the verification of the effectiveness of official controls as foreseen in Article 8(3) of Regulation.(EC) 882/2004.	Partially addressed but follow-up not effective
As above	4. To resume as soon as possible the implementation of the audit plans and extend the action already initiated in the Regions and of competent authorities at all levels as required by Regulation (EC) No 882/2004.	Not fully addressed in the Regions visited
As above	6. To ensure that official controls are carried out in accordance with	Not fully addressed

	Article 4(2) of Regulation (EC) 854/2004 and that when non-compliances regarding structure, layout, maintenance and, in general, hygiene requirements, as provided by Regulations (EC) No 852/2004 and No 853/2004, are identified, corrective action is taken as required by Article 54 of Regulation (EC) No 882/2004.	
As above	11. To ensure that the CA monitors the check on raw milk carried out in accordance with Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004 as required in Annex IV, Chapter II of Regulation (EC) No 854/2004.	Not addressed
Rapport d'un audit No 2012-6333 effectué en Italie du 18 au 28 juin 2012 afin d'évaluer les contrôles officiels concernant l'abattage et la transformation des viandes fraîches, en particulier la viande fraîche chevaline.	1. De mettre en place dans toutes les régions d'Italie un système de contrôles officiels des établissements basé sur l'évaluation des risques présentés par ces différents établissements, conformément à l'article 3 du règlement EC N° 882/2004.	Addressed in the Regions visited
As above	4. De mettre en place un système d'audit et de vérification des contrôles officiels conformément aux articles 4 et 8 du Règlement (CE) 882/2004 dans toutes les régions d'Italie.	Partially addressed but follow-up not effective
As above	5. D'assurer le respect par les opérateurs de la conformité des établissements avec les exigences en matière d'hygiène conformément à l'article 54 du Règlement (CE)882/2004.	Not fully addressed
As above	6. D'assurer que les procédures pour l'agrément des	Not fully addressed in the Regions visited

	établissements sont conformes aux exigences de l'article 4 du Règlement (EU) 853/2204 et de l'article 3 du Règlement (EU) 854/2004.	
Audit report No 2013-6857 of the audit carried out in Italy from 27 May to 07 June in order to evaluate the official controls on food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005)	6. To ensure that raw milk supplied to dairy establishments fulfils the requirements of Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004 and that official controls on raw milk are carried out in conformity with Annex IV of Regulation (EC) No 854/2004.	Not fully addressed
As above	7. To implement procedures for audit and the verification of effectiveness of official controls in accordance with the requirements of Articles 4 of Regulation (EC) No854/2004 and 8.3 of Regulation (EC) No 882/2004.	Partially addressed but follow-up not effective

7 OVERALL CONCLUSIONS

Official controls are carried out frequently according to control plans, are risk based and well documented. However, the establishment reports contain very little relevant information and many deficiencies are overlooked. In addition, there is very little effective follow-up. Communication within local CA units remains poor. In the eight establishments visited, among the deficiencies found by the FVO audit team, only a few had been identified and documented by the CA.

Audits (Article 4.6 of Regulation (EC) No 882/2004) are carried out by central and Regional levels. The reports of these audits contain findings on non-compliances and systemic problems. Of the seven establishments visited (milk collection centre not included) in three Regions (six provinces) from the point of view of structure, maintenance, equipment, cleanliness and hygiene of operations, - four were satisfactory (with different levels of remarks and deficiencies and three were unsatisfactory. There was no immediate public health risk. Serious deficiencies in official controls were observed on dairy holdings visited.

Raw milk quality standards (Section IX Annex III to Regulation (EC) No 853/2004): National derogations notified to the Commission for 2008 -2013 for all milk are still in place

for sheep and goat milk. FBOs take samples but these are not always analysed and laboratory performance is not always reliable. The CAs are not always notified of non-compliant results and there is no system in place to ensure notification. (CA does take action when informed). There is no national system for official monitoring of FBO own checks related to raw milk parameters.

Residues: There were procedures in place for inhibitor controls in all establishments visited. However, out-of-date kits were in use in three establishments. The requirement to maintain records of treatment with veterinary medicines on milk production holdings is not enforced.

8 CLOSING MEETING

A closing meeting was held on 20 March 2015 with the CCA, the Ministry of Health. 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 did not express disagreement with the findings and conclusions presented by the FVO audit team. The representative of one Region contested the finding on non-reliability of the laboratory carrying out testing for FBO own checks. In addition, information on action already taken and planned in order to address particular findings in the establishments visited was provided by the representatives of the Regions.

9 RECOMMENDATIONS

No.	Recommendation
1.	To develop and implement criteria for the management of suspended establishments (particularly in relation to the duration of suspension) and to ensure that the list of approved establishments is updated as required and provides accurate information on the activities of the establishments, in line with Article 31 of Regulation (EC) No 852/2004. *Recommendation based on conclusion No 27* *Associated findings No 20, 21, 22, 24, 25*
2.	To ensure that official controls are effective as required by Articles 4(2) and 8(3) of Regulation (EC) 882/2004 and that when non-compliances are identified, corrective action is taken as required by Article 54 of Regulation (EC) No 882/2004. Amongst other things, attention should be paid to controls of traceability, in order that food business operators comply with the requirements of Article 18 of Regulation (EC) No 178/2002, and official controls on holdings including recording of treatments as required by Article 10 of Council Directive 96/23/EC and Annex I, Section III, part 8 (b) to

No.	Recommendation
	Regulation (EC) No 852/2004 *Recommendation based on conclusion No 61, 64, 70, 77, 86, 87* *Associated findings No 55, 56, 57, 58, 59, 62, 63, 68, 69, 72, 73, 75, 76, 78, 79, 80, 81, 82, 83, 84, 85*
3.	To ensure efficient and effective co-ordination between and within the Competent Authorities responsible for controls in the dairy sector, as required by Article 4, paragraphs 3 and 5 of Regulation (EC) No 882/2004. *Recommendation based on conclusion No 17* *Associated findings No 15,16*
4.	To develop and implement a system for monitoring food business operator checks on raw milk as specified in Annex IV to Regulation (EC) No 854/2004. In particular, the system should verify that non-compliant results are notified to the relevant Competent Authorities and that appropriate action is taken when the requirements of Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004 are not fulfilled. *Recommendation based on conclusion No 86, 87* *Associated findings No 78, 79, 80, 81, 82*

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=2015-7626

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Reg. 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