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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ITALY
FROM 07 TO 15 OCTOBER 2013
IN ORDER TO EVALUATE THE BOVINE, OVINE AND CAPRINE BRUCELLOSIS
ERADICATION PROGRAMMES

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 audit was carried out as part of the FVO audit programme for 2013.

The objective of the audit was to evaluate the implementation of the bovine brucellosis and ovine and caprine brucellosis eradication programmes, approved by Commission Decision 2012/761/EU and associated animal and public health controls.

In addition to extraordinary measures foreseen for the eradication of brucellosis in the four Southern most affected regions, resources have been reinforced and further measures have been introduced in Calabria. Compulsory electronic identification in this region represent a major improvement in an environment of frequent illegal movements. The level of application and enforcement of the measures in Puglia was significantly lower, in part due to weaknesses in legislation in place at national level.

The complex movements between holdings, involving multiple dealers and fattening herds, of an unknown brucellosis status, represent a risk for the spread of the disease, which is insufficiently controlled, because of the non-application by the official services of the legal requirements for dealers, and the absence of channelling foreseen in the approved eradication plan.

Brucellosis cases are reliably detected at laboratories. Effective measures are taken in holdings when outbreaks are detected, but epidemiological investigations remain rudimentary and incomplete. The useful databases and tools available are not used to their full potential. The definition of epidemiological units in problematic areas was sometimes deficient, having a direct impact on the efficacy of the measures applied.

The specific zoonosis risk represented by the dairy establishments manufacturing products from non-pasteurised milk is insufficiently addressed by official controls. Illegal vaccination of adult buffaloes, with a potential to affect human health through milk, was detected; the current routine diagnostic tests are not adapted to identify such vaccinations.

The actions taken by the CA in the wake of the recommendations from previous FVO audits have not been implemented sufficiently to address most issues.

The report makes recommendations to the Competent Authorities aimed at addressing areas in which further improvements are required.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES</u>	1
3	<u>LEGAL BASIS</u>	1
4	<u>BACKGROUND</u>	1
4.1	<u>PREVIOUS FVO REPORTS</u>	1
4.2	<u>APPROVAL OF THE ERADICATION PROGRAMME</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	2
5.1	<u>COMPETENT AUTHORITIES</u>	2
5.1.1	<u>COMPETENT AUTHORITY STRUCTURE</u>	2
5.1.2	<u>DEVELOPMENT, IMPLEMENTATION, COORDINATION, SUPERVISION, AUDITS OF BRUCELLOSIS ERADICATION</u> ...	3
5.1.3	<u>RESOURCES</u>	3
5.1.4	<u>POWERS AND SANCTIONS</u>	4
5.1.5	<u>LEGISLATION</u>	5
5.2	<u>HOLDING REGISTRATION, ANIMAL IDENTIFICATION & MOVEMENT CONTROLS</u>	6
5.2.1	<u>HOLDING REGISTRATION</u>	6
5.2.2	<u>ANIMAL IDENTIFICATION</u>	7
5.2.3	<u>ANIMAL MOVEMENT CONTROLS</u>	8
5.3	<u>PROGRAMME, SURVEILLANCE AND PREVENTION</u>	9
5.3.1	<u>DISEASE STATISTICS</u>	9
5.3.2	<u>APPROVED PROGRAMME</u>	10
5.3.3	<u>TESTING AND SURVEILLANCE, CLASSIFICATION OF HOLDINGS</u>	11
5.3.4	<u>VACCINATION</u>	13
5.4	<u>IMPLEMENTATION OF THE ERADICATION</u>	14
5.4.1	<u>NOTIFICATION, IDENTIFICATION OF REACTORS, ISOLATION AND SLAUGHTER</u>	14
5.4.2	<u>EPIDEMIOLOGICAL ENQUIRIES</u>	15
5.4.3	<u>ADDITIONAL MOVEMENT CONTROLS, RE-INSTATEMENT OF STATUS</u>	16
5.4.4	<u>DEPOPULATION/REPOPULATION AND COMPENSATION POLICY</u>	16
5.4.5	<u>CLEANSING AND DISINFECTION</u>	17
5.5	<u>LABORATORIES</u>	18
5.6	<u>PUBLIC HEALTH CONTROLS</u>	19
5.6.1	<u>HUMAN CASES</u>	20
5.6.2	<u>CONTROLS ON MILK</u>	20
5.6.3	<u>CONTROLS AT SLAUGHTER</u>	21
	<u>OBSERVATIONS</u>	21
6	<u>OVERALL CONCLUSIONS</u>	22
7	<u>CLOSING MEETING</u>	22
8	<u>RECOMMENDATIONS</u>	22
	<u>ANNEX 1 - LEGAL REFERENCES</u>	24

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BEP	<i>Brucella melitensis</i> Eradication Programme
BMF	<i>Brucella melitensis</i> Free in accordance with Council Directive 91/68/EEC
BMOF	<i>Brucella melitensis</i> Officially Free in accordance with Council Directive 91/68/EEC
CA	Competent Authority
CCA	Central Competent Authority
CFT	Complement Fixation Test
DG(SANCO)	Health and Consumers Directorate General
EU	European Union
FVO	Food and Veterinary Office
ISO	International Standards Organisation
LCA	Local competent authority
MS	Member State
NRL	National Reference Laboratory
OV	Official Veterinarian
RBT	Rose Bengal Test
RCA	Regional Competent Authority

1 INTRODUCTION

This audit took place in Italy from 7 to 15 October 2013 and was undertaken as part of the FVO (Food and Veterinary Office) planned audit programme. The audit team comprised two auditors from the FVO. The team was accompanied throughout the audit by representatives of the Ministry of Health of Italy which is the Central Competent Authority (CCA) within the scope of this audit.

2 OBJECTIVES

The objective of the audit was to evaluate the implementation of the bovine brucellosis and ovine and caprine brucellosis eradication programmes, approved by Commission Decision 2012/761/EU and associated animal and public health controls.

In pursuit of this objective, the following sites were visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	2	
	Regional	2	Calabria, Puglia
holdings		5	2 ovine/caprine holdings, 2 cattle breeding holdings, 1 fattening holding
Dealer's premises		2	
Slaughterhouse		1	
Laboratories		2	
Dairy establishments		1	

3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council 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.
- Article 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.

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

4 BACKGROUND

4.1 PREVIOUS FVO REPORTS

The previous FVO audits on brucellosis in Italy were carried out in June 2009 (bovine brucellosis – DG(SANCO)2009-8258), 2007 (ovine and caprine brucellosis: DG(SANCO)2007-7368); and 2006 (DG(SANCO)8204/2006). The reports of these audits are available on the Health and Consumers

Directorate General website at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

The recommendations of the reports focused on:

- full implementation of the eradication programmes;
- reaching sampling targets, and ensuring that animals excluded from the programme meet conditions of the EU Directive;
- implementation of measures on movement and transhumance;
- implementation of measures to reduce and prevent fraud;
- definition of common criteria for depopulation;
- use of epidemiological enquiries to speed up the eradication process;
- timely response from the testing laboratories;
- enhance controls on holdings delivering raw milk to establishments which are not heat treating it;
- establishing criteria for vaccination, and registration of vaccinated animals.

4.2 APPROVAL OF THE ERADICATION PROGRAMME

The Country programmes for the eradication and monitoring of animal diseases and for the prevention of zoonoses for 2012 and 2013 have been approved by Commission Decisions 2011/807/EU and 2012/761/EU respectively. Commission Decision 2008/425/EC lays down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Union financing

Commission Decision 2012/761/EU lays down the financial contribution to the Brucellosis eradication programmes for 2013. It foresees a maximum contribution of €1.2 million for ovine and caprine brucellosis, and of €3.5 million for bovine brucellosis, in Italy. The co-financing includes costs for vaccination and sampling, testing and compensation to owners for the value of slaughtered animals.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal Requirements

Regulation (EC) No 882/2004 sets out requirements applicable to competent authorities, including co-operation and co-ordination within and between competent authorities, training of staff, the provision of written procedures and the verification of effectiveness of official controls.

Findings

5.1.1 Competent Authority structure

The structure and organisation of the Competent Authorities (CA) are described in the country profile: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=IT

A commissioner “*ad acta*” has been appointed by the national government, to improve the

organisation and delivery of the sanitary services in Calabria. This commissioner reports directly to the Ministry of Health. For the veterinary sector of Calabria, the Commissioner has set up a task force of five administrators, in place until 2016.

A re-organisation of the local competent authorities (LCA) was on-going both in Puglia and Calabria, aimed at having a single managerial structure per province. The other local offices in the provinces were either closed down or attached to the single provincial authority.

5.1.2 Development, implementation, coordination, supervision, audits of brucellosis eradication

While the central level defines the brucellosis control programme for breeding holdings, the regions are responsible for defining the surveillance programmes for fattening holdings. All regions must submit annual reports of their activities to the CA, and the regions which are not officially free from brucellosis must also submit their programmes. However, the CCA is not in charge of validating or controlling the adequacy of the programmes.

A monitoring tool for the completion of the programme is in place (database SANAN). The national reference laboratory monitors the implementation of the programme as reported in the database, on a quarterly basis, and informs the CCA and RCAs¹. The bi-annual coordination and evaluation meetings between regions and the CCA described in the previous FVO reports, no longer take place. The CCA stated that it was more effective to have one-to-one meetings with regions when issues were identified.

The implementation of the programme is performed by the veterinary services of the LCA, which includes also tasks and services for the human health sector. The LCA are free to define their own priorities within their remit. The regional authorities supervise their implementation, but cannot intervene directly (see following chapter).

According to the information available on their website, the CCA had performed audits of the brucellosis programmes in Calabria and Puglia, in 2004 and 2005 respectively. The results of these audits were not available for consultation, and the reports, requested for the preparation of the FVO visit, were not provided.

5.1.3 Resources

In both regions visited, the staff at the regional level had been reinforced:

- In Calabria, a task-force of five veterinary administrators was in charge of reshaping the organisation and delivery of official tasks of the veterinary services in the region. However, this task-force had no administrative assistance, which explained weaknesses in the administrative follow-up of procedures adopted.
- In Puglia, three veterinary administrators were appointed in early 2013, supported by three administrative officers. One of these administrators was in charge of the animal health sector, but had been given the responsibility for brucellosis only from September 2013.

At local level, official veterinarians (OV) are spread across sectors, one of which dealing with

¹ In their reply to the draft report, the CA of Puglia indicated that they have never received these quarterly reports.

animal health. The workforce is supplemented by contracted private veterinarians, recruited by the local director of health services.

- The two regions visited by the audit team had a similar size, similar number of heads of bovine, ovine and caprine animals, with similar breeding patterns. They had a similar number of OVAs in charge of animal health, but Calabria employed three times as many private veterinarians as Puglia (142 versus 42).
- In Calabria, the task-force estimated that the total number of veterinarians working in the animal health sector was sufficient, but with some geographical imbalances, which the region was trying to get corrected (as they have no direct power on this matter). 30 private veterinarians had been contracted for a specific problematic area for brucellosis (with free-ranging grazing animals).
- In Puglia, the head of the veterinary sector of the local office in charge of a specific problematic area for bovine brucellosis indicated to the RCA in 2012 that he would need 11 more veterinarians to implement the 2013 brucellosis eradication programme. No further staff were attributed: the RCA explained that attribution of official posts is of the remit of the CCA, while the attribution of contract staff is decided by the director of the local health services, according to their own priorities. Since 2011, the annual objectives of the directors of local health services in Puglia include one specific veterinary-related objective, amongst their 18 general objectives. Even if the RCA decides to attribute funds to strengthen the veterinary work-force, the director of the local health services may decide to use it for other activities, according to his own priorities.
- Equipment and access to internet was still an issue in both regions. In Calabria, the RCA had insufficient access to internet; in Puglia, local services lack computers and access to internet; a significant investment in IT equipment for the local offices was decided in August 2013.

5.1.4 Powers and sanctions

Recurrent issues have been identified by previous FVO audits on the insufficient actions and sanctions taken by the CA in Italy, in particular when non-compliances are identified for animal identification or illegal movements. The last recommendation, not addressed at the time of the audit, came from FVO audit report 2010-8407 (on bovine tuberculosis).

The RCA in Puglia indicated that before 2012, they had no legal framework to apply administrative sanctions. They also indicated that they feel they still lack adequate legal power to enforce the electronic identification of cattle in the problematic area, despite a new ministerial decree (of 09/08/2012) making it compulsory to enforce it for cattle in free grazing conditions.

- The RCA in Puglia also indicated that the national agency in charge of distribution of direct payments to farmers was not acting on its findings, as payments to the farmers indicated as non cross-compliant by the RCA were not reduced or retained.
- The number of sanctions in relation to non-compliances with animal identification and movement registration, reported in the national database, amounted to 1 (for a holding of 1 animal) in Puglia, and 1 (for a holding of 8 animals) in Calabria.
- The RCA in Calabria gave additional evidence of enforcement and sanction in case of non-

compliance and lack of cooperation for electronic identification of cattle, or for movements to summer grazing. Nine holdings had their official brucellosis status suspended for lack of cooperation from the owners. Such data were unavailable in Puglia.

5.1.5 Legislation

The national legislation for bovine, ovine and caprine brucellosis eradication, applying to all regions, remains as indicated in previous FVO reports:

- for bovine brucellosis: ministerial decree 651 of 27 August 1994 (last amended by decree 429 of 12/08/1997)
- for ovine and caprine brucellosis: ministerial decree 453 of 02 July 1992 (last amended by decree 429 of 12/08/1997).
- The legislative decree 196 of 22 May 1999 transposes into national legislation the provisions of Directive 1964/432/EEC.

The ministerial decree issued in 2006, for extraordinary measures (for tuberculosis and brucellosis) to be applied in four regions (Calabria, Campania, Puglia and Sicilia) elapsed at the end of 2009. A new ministerial decree (of 09 August 2012, hereafter: the 2012 ministerial decree), in force until September 2014, enacts a new set of extraordinary measures for the same four regions.

Observations:

- Legislative decree 196 of 1999 retains the measures foreseen in European legislation, but many differ from those contained in the ministerial decree 651 of 1994. When dispositions differ, the audit team observed that the ones contained in the latter piece of legislation are usually applied in the field.
- The legislative decree 196 of 1999 also foresees the conditions for registration and attribution of approval number of dealers. They are defined under the term “*commerciante*”, a term that was not in use for their registration and approval of their premises, where the term “*stalla di sosta*” was used. This registration as “*stalla di sosta*” was performed in reference to an older piece of legislation (of 1954). The same term of “*stalla di sosta*” was also used in the 2012 ministerial decree.
- A new legislative decree is under preparation, which will harmonise, clarify and update the norms for sanitary measures for brucellosis, tuberculosis and leucosis. This decree will also include a number of annexes, such as a list of approved disinfectants for such diseases. This decree, announced in response to recommendations of previous FVO audits (2010-8407), is still under discussion, and no date for its publication is foreseen.
- The 2102 ministerial decree foresees the derogation from pre-movement test (foreseen in the legislative decree of 1999) for bovine animals, if they come from holdings in which the testing has been complete and registered in the health database for the last three years.

Conclusions

Both regions visited had reinforced their structure and developed their work force at regional level.

The organisational autonomy of the local competent authorities was an impediment to adequate staffing, but was addressed in Calabria. In Puglia, an apparent shortage in staff and equipment resources, with a direct impact on the application of the eradication programme, was identified but not solved.

The elements of CCA supervision and audit of the adaptation of the eradication programme by the regions are limited; this prevents the CCA from identifying regional deviations from the national eradication plan or national legislation.

The enforcement of legislation by the CA was weak in the regions visited: contradictory legislative acts represent an obstacle for enforcement, as is the lack of cooperation from other administrations for the application of administrative sanctions.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION & MOVEMENT CONTROLS

Legal Requirements

Regulation (EC) No 21/2004 requires MS to establish an identification system for ovine and caprine animals which should include individual animal identification, registration of holdings, control of movements and the maintenance of movement registers on holdings. Commission Decision 2006/968/EC provides detailed rules and guidelines for the electronic identification of sheep and goats. Regulation (EC) No 1505/2006 sets out requirements for competent authority checks on the registration and identification of ovine and caprine holdings and animals. In addition, Commission Decision 2008/341/EC, which sets out criteria for the approval of disease eradication programmes, requires that such programmes contain measures on the registration of holdings, the identification of animals and the control of animal movements. Council Directive 91/68/EEC sets out requirements for animal dealers and allows derogations relating to temporary pasturing of animals.

Regulation (EC) No 1760/2000 of the European Parliament and of the Council defines the conditions for identification and registration of bovine animals. They must be individually identified with two ear tags, be issued with an individual passport (with a possible derogation for national movements in a country with a database recognised as fully operational). Animal keepers (except transporters) must keep a movement register of a format approved by the CA on their holding, notify movements within seven days to a computerised database and record them in the passport. The formats of ear tags, passport and holding registers are further detailed in Commission Regulation (EC) No 911/2004. Commission Regulation (EC) No 1082/2003 lays down rules as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals, requiring at least 10% of holdings to be controlled in that framework (unless exception), selected following a risk analysis. Council Directives 64/432/EEC and 91/68/EEC set out requirements for animal dealers.

Findings

5.2.1 Holding registration

The national database, recognised as fully operational, lists the registered holdings according to their activities (breeding, fattening, dealer's premises ("*stalla di sosta*"). Summer grazing areas are also listed.

Following a recognised need to complete and update the database for grazing areas, the 2012 ministerial decree details the conditions of attribution of holding registration number for grazing areas representing an epidemiological unit. The registration is performed by the LCA, upon presentation of an extract from the land register.

Observations:

- the national database contains geographical coordinates of the holdings, usually recorded at the location of the premises. The holdings are not linked to the land register, and therefore the geographical limits of the epidemiological unit are not systematically clearly set.
- Both regions visited reported the registration of further summer grazing fields into the database. In the problematic area in Puglia, communal grazing areas were not registered as such, and therefore movements between such areas and individual holdings were not recorded.
- In Calabria, dealers' premises were registered as such in the database, but not given any approval number, and the premises were not required to comply with any specific condition. The premises visited were not inspected by the CA, and were of unsuitable standards. They could not be cleaned and disinfected, had no appropriate facilities for unloading animals, or isolation facilities (requirements in article 13(2)(c) of Directive 64/432/EEC).
- In Puglia, the dealer's premises visited were of suitable standard. They were approved by the local authorities (municipal authorities), but only according to a presidential decree of 1954. The requirement, introduced by the 2012 ministerial decree, that such premises are separated from breeding or fattening premises was not respected nor enforced by the local CA. Inspections of the premises by the CA were not documented.

5.2.2 *Animal identification*

The 2012 ministerial decree foresees electronic identification (with an endo-ruminal bolus) of all bovine, ovine and caprine animals vaccinated, from infected premises, or subject to common grazing.

Observations:

- The use of risk criteria and choice of the holdings to be controlled for animal identification purpose is left to the local level. In the local office where this was checked, no structured approach was applied. The dealers were not considered as a risk factor. As indicated in section 5.1.4, the amount of non-compliances reported was very low.
- Calabria introduced in 2012 an obligation for electronic identification of all ovine, caprine and bovine animals (with the exception of lambs to be slaughtered before the age of 60 days). The CA acknowledged that this element was a significant improvement in the traceability of animals in the region.
- Puglia had introduced compulsory electronic identification of sheep and goats in 2007, and stated that such identification has been completed since 2009. No overview of the rate of completion of electronic identification of cattle (according to the 2012 ministerial decree) was available from the problematic area, which, according to the RCA, was the only place

where it was applied, but not enforced.

- In the problematic area in Puglia, many cows seen in the common grazing areas had one or no ear-tag. At the premises of a dealer, a group of 8 cattle had never been correctly identified: they all had only one ear tag, and no hole in the other ear which could suggest that they had lost the other one. The LCA did not take any action, as they considered that the dealer had taken adequate action, by ordering and receiving a set of replacement ear-tags for the animals. In Puglia, contrary to Calabria, the RCA could not get information on the number of sets of double replacement ear-tags ordered by the farmers.

5.2.3 *Animal movement controls*

All movements of animals still need to be accompanied by a movement document (“model 4”). This document is prepared by the operator, and completed by an OV if the movement is to another holding. In such cases, the date of individual tests (in case of pre-movement test required) and date of last renewal of holding status must be indicated. The pre-movement test is required for the introduction of bovine animals into a free or officially free holding, and, according to the approved eradication plans, for bovine, ovine and caprine animals sent to common grazing in the four Southern regions.

All animals which are sent to places other than slaughterhouses must come from officially-free or free holdings. However, the eradication programme foresees a derogation for fattening holdings (which are not subject to the brucellosis control, but to regional surveillance plan) to send bovine animals to other fattening holdings. A particular accreditation status must be given to such holdings and the regions must inform each other of the structures involved in this circuit, which must not enter in contact with breeding animals.

The legislative decree 196 of 1999 foresees that dealers keep animals in their premises for a maximum of 30 days. The 2012 ministerial decree includes enforcement measures for this specific measure, including the withdrawal of the dealer's approval in case of repeated non-compliance within a same year.

Movements of animals to common grazing in the four Southern provinces must be pre-notified in the national movement database, and pre-authorized by the LCA of destination. The identity of the animals must be verified within 5 working days after arrival, and confirmed in the database.

Observations:

- Illegal movements remain a common feature in the regions visited. In a sheep holding visited by the audit team, the 180 ewes were reported as having given birth to only 40 lambs over the last year. The national movement database recorded more than 5% of cattle declared lost or stolen in Calabria, and 1.4% in Puglia.
- No information was available on fattening holdings and dedicated channels for movement of animals from fattening holdings to other holdings. Multiple occurrences were seen by the audit team of animals involved in numerous movements through several fattening herds and dealers' premises.
- The rule for the 30 day residency in dealer's premises was not applied nor enforced in the regions visited. In both cases visited, in case the animals remained more than 30 days, the

OV was issuing movement permits, after testing individually the animals over 12 months. In one case, the dealers' premises was declared as officially brucellosis free, with a last date test of three years ago.

- In Calabria, examples of enforcement of the rules for movement for common grazing were presented to the audit team; however, once the animals are in the common fields, the local CA indicated that the check of their identity is not practically feasible.

Conclusions

In a context of frequent illegal movements, traceability has been greatly enhanced in Calabria by the compulsory introduction of electronic identification of all cattle, sheep and goats, going beyond the requirements of national legislation and eradication programme. This is in contrast to the region of Puglia, which only introduced the requirement for bovine electronic identification in one free-ranging area of its territory, and did not enforce it. Completion of registration of summer grazing fields was performed in both regions, but not completed in Puglia.

Dealers premises are identified as such in the national registration database. However, the national legal requirements for their approval, structure, operation and official supervision of dealers, and movement rules from these premises, strengthened recently by specific enforcement rules for the Southern Regions, are not applied nor enforced.

Fattening herds are not subject to the national eradication programme. The channeling system described in the approved eradication programme for fattening herds is not in place, representing a real risk as movement patterns of cattle frequently involve numerous fattening herds and dealers.

5.3 PROGRAMME, SURVEILLANCE AND PREVENTION

Legal Requirements

Council Decision 2009/470/EC provides for a Union financial contribution towards the eradication of certain diseases including bovine and ovine and caprine brucellosis, and establishes elements that eradication programmes should include. Commission Decision 2008/341/EC sets out detailed criteria for the approval of co-financed eradication programmes.

Council Directives 64/432/EEC and 91/68/EC, set out criteria for the classification of Member States, regions and holdings according to brucellosis status, for bovine brucellosis, and ovine and caprine brucellosis respectively. They also set out the conditions for vaccination, the approved tests to be used for classification of herds, for control at movement of animals (required for bovine animals), in case of suspicion of to maintain or regain a free or officially-free status (the first status being in case of vaccinated animals in the herd).

Directive 78/52/EEC sets criteria for national plans for the accelerated eradication of brucellosis in cattle, with specific provisions in relation to isolation and slaughter of infected animals, cleaning and disinfection, and strict movement controls between herds of different health status.

Findings

5.3.1 Disease statistics

The Southern Regions of Italy are the ones with the highest prevalence of bovine, ovine and caprine brucellosis. Herd and individual prevalence of bovine, and ovine and caprine brucellosis, over the last few years in these regions is as follows:

	Sicilia	Puglia	Calabria	Campania	Basilicata
2008	6.1%	2.0%	5.8%	1.1%	3.2%
2010	5.6%	1.4%	3.5%	1.0%	3.0%
2011	4.8%	1.6%	3.0%	1.3%	1.1%
2012	2.8%	2.2%	1.7%	1.1%	1.1%

Table 1a: herd prevalence of bovine brucellosis in the Southern Regions of Italy

	Sicilia	Puglia	Calabria	Campania	Basilicata
2008	1.4%	0.3%	2.4%	0.6%	0.7%
2010	1.1%	0.4%	1.2%	0.4%	0.6%
2011	0.8%	0.5%	0.9%	0.4%	0.2%
2012	0.4%	0.8%	0.8%	0.4%	0.1%

Table 1b: individual prevalence of bovine brucellosis in the Southern Regions of Italy

	Sicilia	Puglia	Calabria	Campania	Basilicata
2008	12.0%	2.8%	2.8%	1.3%	0.2%
2009	13.1%	1.9%	1.9%	0.9%	0.1%
2010	9.2%	1.6%	1.6%	1.1%	0.2%
2011	7.4%	1.2%	1.2%	1.1%	0.2%
2012	5.6%	0.4%	0.4%	0.9%	0.1%

Table 2a: flock prevalence of ovine/caprino brucellosis in the Southern Regions of Italy

	Sicilia	Puglia	Calabria	Campania	Basilicata
2008	4.1%	1.9%	1.4%	0.6%	0.1%
2009	4.1%	1.0%	0.9%	0.4%	0.1%
2010	2.7%	0.3%	0.7%	1.0%	0.1%
2011	2.7%	0.5%	0.6%	0.6%	0.0%
2012	2.2%	0.4%	0.1%	0.8%	0.0%

Table 2b: individual prevalence of ovine/caprino brucellosis in the Southern Regions of Italy

Observations:

- Sicilia remains by far the most affected region for both types of brucellosis. The situation has improved over the last few years, but prevalence of ovine and caprine brucellosis remains higher there in 2012 than it was in any other region in 2008.
- The situation for ovine and caprine brucellosis is improving in Calabria and Puglia, with reduction of both flock and individual prevalence, but not in Campania.
- The situation of bovine brucellosis is worsening in Puglia, but improving in Calabria. It remains stable in Campania.
- In Calabria and in Puglia, bovine brucellosis was of particular concern in one specific area for each region, where free-grazing and/or summer/communal grazing is a common

practice. In Puglia, the herd prevalence in the local territory of concern was above 14%.

5.3.2 *Approved programme:*

Both eradication programmes are to be applied on the whole territory of Italy, but co-financing is only requested for non-officially free regions or provinces. The officially-free regions and provinces adopt specific control and surveillance programmes, the one for ovine and caprine brucellosis being adopted with the agreement of the CCA and the NRL. For bovine animals, the national eradication programme targets only breeding herds; fattening herds are subject to regional surveillance plans. The approved programmes foresee additional measures to be applied in the four Southern most affected regions.

To give effect to specific measures foreseen in the programmes for the four most affected regions, the 2012 ministerial decree adopted measures including:

- electronic identification of animals subject to summer or free-range grazing,
- individual registration of all sheep and goats electronically identified in the national database;
- Compulsory use of the national sanitary database in case of outbreaks, and insertion of epidemiological investigations into the sanitary database;
- notification of positive cases to the keepers within 2 days, and slaughter within 15 days of notification;
- suspension of the holding status in case of lack of cooperation of the owner, or overdue testing;
- enforcement of the separation of dealers premises from any fattening or breeding holdings, and of the obligation to move animals within 30 days;
- update of holding codes for mountain and free-razing sites, and authorisation and control system for movements to these areas.

In addition to the national programme, the Region of Calabria adopted a regional eradication plan in 2011, including additional measures, such as compulsory electronic identification (bolus) of all bovine, ovine and caprine animals (except lambs to be slaughtered before 60 days), organisation of reporting from the local authorities and supervision from the RCA, identification of risk areas, attribution of powers to the regional task-force (power to substitute the director of veterinary services of a local authority).

Observations:

- The CCA receives reports of the execution of surveillance from all regions, and also the regional control programmes of the non officially-free regions;
- The regions are not requested to submit their surveillance plans for fattening herds to the CCA; none of the four Southern regions states what their regional plan for surveillance in fattening holdings is.

5.3.3 *Testing and surveillance, classification of holdings*

According to national legislation, bovine animals over 12 months from all breeding herds must be tested twice a year (unless prevalence is below 1% at provincial level), and a representative portion

of animals over 6 months from all breeding flocks must be tested once a year for brucellosis. Bovine animals over 12 months moving to breeding herds must be tested within 30 days prior to movement.

All abortions, the cause of which is not ascertained must be declared to the CA. In such cases, epidemiological enquiry must be performed and samples collected for official analysis. The eradication programmes also foresee an intensification of the surveillance at slaughterhouse level.

The rate of herd testing in the last few years has been, according to the CCA, as indicated in the tables below for the Southern Regions:

BV	Sicilia	Puglia	Calabria	Campania	Basilicata
2010	100%	100%	100%	99%	100%
2011	96%	100%	100%	97%	95%
2012	99%	100%	100%	99%	100%

Table 4a: rate of testing of eligible herds for bovine brucellosis

BV	Sicilia	Puglia	Calabria	Campania	Basilicata
2010	96%	95%	82%	71%	97%
2011	96%	93%	83%	71%	95%
2012	96%	93%	79%	72%	98%

Table 4b: rate of testing of all registered herds for bovine brucellosis

OV/CP	Sicilia	Puglia	Calabria	Campania	Basilicata
2011	100%	100%	100%	100%	100%
2012	98%	100%	95%	97%	99%

Table 5a: rate of testing of eligible flocks for ovine/caprine brucellosis

OV/CP	Sicilia	Puglia	Calabria	Campania	Basilicata
2011	99%	100%	99%	100%	100%
2012	97%	100%	93%	95%	99%

Table 5b: rate of testing of all flocks for ovine/caprine brucellosis

Observations:

- Neither the CCA nor the regions visited monitored the frequency of (twice) annual testing in bovine herds in regions or provinces with a prevalence above 1%. In Puglia, the RCA indicated to the LCA that they could reduce the frequency of testing to once a year if the prevalence was below 1% in their territory, instead of applying the threshold at Provincial level;
- The rate of advancement of testing is reported and can be monitored in a national dedicated database (SANAN). This was not operational for Puglia, as information is not fully reported into the database (no information was available on how much is reported into the database from the region). In this region, the RCA uses spread sheet or a “regional database” to extract information twice a year. The national database was recently reorganised in order to extract data and reports relevant to the local organisation. In practice, it meant in Puglia that data could be obtained at the provincial level, but no longer at the lower operational (sub-province) local level, depriving this latter level from a useful monitoring tool.
- The presence of animals at the holdings was checked against the information contained in the national database in the regions visited; at this occasion, the information was often

updated with declaration of loss or stolen animals.

- The herds considered as non-eligible for testing include herds with no animals, Neither the CCA nor the regions visited monitored the selection criteria used to declare herds as being non-eligible for testing.
- Between 1,000 and 1,300 abortions were reported annually in 2011 and 2012 to the CA. Between 85% and 90% of them were reported from Veneto, Lombardia, and Emilia Romagna, which account for 50% of the national cattle population.
- No abortion was officially reported to Calabria during these two years. A local official veterinarian stated that he would only investigate cases with multiple abortions within a short period.
- The CA in Puglia did not report any notification of abortion in 2012; during the same period, the regional laboratory had investigated 33 cases, on request of owners or private veterinarians. The laboratory staff stated that they would notify the CA only in case of positive result. The total number of abortions investigated by the official laboratories in Italy was not available.
- The veterinary services of the regions visited were not involved or informed by the human health services of the epidemiological investigations carried out in case of human brucellosis. A project for increased collaboration on zoonosis between veterinary and human health services was under development in Calabria.
- The 2012 ministerial decree introduced the exemption of pre-movement test before sending animals to summer grazing; this exemption (not in line with EU legislation) was not used in the regions visited. Pre-movement tests for cattle over 12 months moving to other holdings were performed in all cases reviewed by the audit team.
- The qualification of herds as brucellosis or officially brucellosis-free was not however directly linked to the testing/vaccination history of the herd and all its eligible animals. In Puglia, herds which experienced an outbreak were incorrectly classified by the CA as “brucellosis free” after having 2 consecutive tests 21 to 28 days apart; In Calabria, the CA attributed in 2013 an “officially brucellosis-free” status to a dealers premises, where animals had been last tested five years before.
- The 2012 ministerial decree does not foresee the requirement of pre-movement tests for sheep and goats, contrary to what was in the 2006 decree (and what is stated in the 2013 approved eradication programme). Such measure was not indicated either in the regional eradication plans submitted by the regions visited to the CCA. The laboratory staff of Puglia indicated that such tests were still performed in their region, on the basis of a regional eradication plan adopted in 2000.

5.3.4 Vaccination

Since 2012, no vaccination of sheep and goats is foreseen in the eradication plan: the vaccination activities that were performed in Sicily have been discontinued. Vaccination against bovine brucellosis is performed on buffaloes, on holdings located in a single province of Campania. The sole vaccine registered is a RB51 vaccine, imported exclusively by a pharmaceutical laboratory for

the CA, from Spain.

Year	Nb of vaccinated holdings	Nb of vaccinated animals
2008	156	3,644
2009	209	5,529
2010	138	4,609
2011	81	3,048
2012	60	2,458

Table 3: vaccination of buffaloes in Campania

Observations:

- The RCA from Campania indicated that some herds were vaccinated with a Buck19 vaccine. The CCA was to investigate these vaccinations but no further information was given to the audit team.
- Illegal vaccination of adult buffaloes in Campania was identified in May 2013, and investigated by an enforcement corps from the Ministry of Agriculture, with the support of the NRL. The NRL indicated the routine CFT used could not detect such occurrences. Sanitary measures had been taken for the milk (destruction of milk for 6 months, as it has been shown that milk could contain residual bacterial presence), then pasteurisation, until the holding gets back a “free” status, attributed by the CA following 2 negative tests with a CFT performed with a specific vaccine antigen.

Conclusions

The routine testing of herds and flocks is monitored. Its completion is generally satisfactory, but a level of uncertainty is introduced by the absence of clear criteria used (and control) to declare some herds as non-eligible for testing, and by the absence of monitoring of the effective bi-annual testing of bovine herds in the relevant territorial units. Passive surveillance was insufficient and the requirement to report abortions was not enforced.

Documentation of full herd and flock testing was adequate, but the assurance of effective complete testing was hampered by the significant numbers of animals reported as lost or stolen.

The pre-movement test of cattle over 12 months was consistently performed for movements from officially free holdings to other holdings or registered summer grazing areas, but the status of the holdings, given or modified by the local authorities, was not always in line with EU and national legislation.

The illegal use of vaccine in adult buffaloes in Campania discovered incidentally, with a potential detrimental effect on human health, revealed a weakness in the official control system. The protocol followed by the CA to re-establish the brucellosis free status of these herds was not in line with EU legislation.

5.4 IMPLEMENTATION OF THE ERADICATION

5.4.1 *Notification, identification of reactors, isolation and slaughter*

In the four Southern most affected regions, the CA must notify the owner within two working days of positive results, and identify the reactors (electronic bolus, in addition to permanent mark). The owner must isolate them and have them slaughtered within 15 days. The transport is performed under official control (special movement permit, pre-notification of the slaughterhouse of destination, lorry sealed for a direct transport to the slaughterhouse).

Observations:

- The delays for notification and slaughter were not monitored in the regions visited;
- The audit team was informed that the owners usually avail of the services of a dealer, who purchases the animal to be slaughtered. The difficulty to obtain a good price under such a short time pressure was an incentive for some owners to delay the slaughter of the animals, even if the CA has the possibility to withhold the compensation in case of delayed slaughter. The audit team asked for but did not receive information on the consistent application of this measure.

5.4.2 *Epidemiological enquiries*

A national format is available for epidemiological enquiries in case of outbreak. The information must be entered into the national sanitary database (SIMAN) and this obligation has been inserted into the 2012 ministerial decree.

Observations:

- No guidelines were available on the way to perform, analyse and use the epidemiological enquiries;
- The official veterinarian is not required to conclude on the possible ways of introduction of the disease, or make any comment on the possibility to effectively apply the measures (such as isolation of infected animals, cleaning and disinfection operations, isolation of the herd from other herds). The owner is required to counter-sign the epidemiological enquiry, and an OV indicated the difficulty to report suspicion of illegal activities under such conditions.
- The epidemiological form may be downloaded from the sanitary database, with pre-filled information on the movement history, presence of animals, and testing and status history. In the regions visited, this option was not used, a blank template was used instead. The information collected was not entered into the sanitary database, or entered as a scan copy of the hand-written enquiry.
- No written procedure was in place on the definition and follow-up of epidemiology linked holdings. The national database extracts by default information on all movements that occurred within the last 3 month before declaration of the outbreak. This time frame had no particular basis, and was the same used for all diseases.
- In a case reviewed, animals were moved from a holding shortly before it was declared as an

outbreak. The CA did not perform any follow-up as the place of destination was a fattening holding, supposed to send animals only to slaughterhouses. However, two of these animals had been sent to other holdings in other regions.

- Regional epidemiological expertise is foreseen to be available for all regions, at the regional laboratories. However, neither Calabria nor Puglia avails of a dedicated regional epidemiological expert. On the request of the CCA, the NRL used in June 2013 the information available in the national databases to produce a very relevant epidemiological report for the problematic area of Puglia, identifying several critical issues, like incorrect classification of herds, complex and multiple movements of animals through dealers and herds.
- The three national databases (SIMAN; SANAN and national movement database) are linked but not integrated: in order to find information and extract data, experts of the NRL needed to move from one database to another, changing their registration profile.
- The format of the epidemiological enquiry did not request elements to be reported about the presence or risk associated to dogs.

5.4.3 Additional movement controls, re-instatement of status

When the owner is informed of restriction on his herd or flock, he is also informed on the movement restrictions for his animals. The herd/flock cannot be repopulated before it has passed two clear tests, the first one at least 42 days after the elimination of the positive animals, the second one performed 4 to 6 weeks after the first one.

The national measures (decree 651 of 1994) also include the testing of dogs present in infected holdings, and, in case of positive results, their isolation for more than three months and/or their treatment.

Observations:

- Any movement other than to slaughterhouse need to be certified by an official veterinarian. In addition, the CA in Puglia was holding the passports of bovines from holdings under restriction.
- In the field, the re-testing performed is not the one described in the eradication programme, as the two re-test can be performed within 6 weeks after elimination of the infected animals. However, the officially-free status is not to be restored until a further clear test is performed, 4 to 8 months later.
- The EU requirement (transposed in the legislative decree 196 of 1999 but not in the ministerial decree 651 of 1994), that final check in infected herds are be performed at least 21 days after the last pregnant cow has calved, before restoring the officially-free status, is not applied;
- In the problematic area of Puglia, the LCA considered that the individual holdings did not represent epidemiological entities, as the animals were moving easily and without notification to communal areas; yet, movement restrictions were only applied to a unique owner in case of outbreak; no link between individualisation of restrictions and proper

individualisation of the holding (fences in good conditions,...) was applied.

- The CA in Puglia stated that dogs would only be tested in case of significant outbreak. At the outbreak visited, where 11 out of 59 animals were found positive, the dogs had not been tested.

5.4.4 Depopulation/repopulation and compensation policy

The 2012 ministerial decree gives power to the LCA to order depopulation in the four Southern regions (without needing a validation from the local municipal authorities). They can be assisted by the regional laboratory in their evaluation of the interest of depopulation.

The level of compensation is established according to a national grid published every year, initially representing the national average of market prices. In addition to the compensation, the owners receive the selling price of the infected animals sent to slaughter.

Observations:

- No guidelines have been issued on depopulation;
- The CCA explained that the risk of having a level of compensation so high that it would be deterrent to efforts against the disease was mitigated for cattle as farmers obtained low prices when selling infected animals, and the national level for compensation for this species was now lower than the actual value of the animals.

5.4.5 Cleansing and disinfection

Cleansing and disinfection must be performed in the presence of an OV, who issues a certificate. Some regions use external teams, or have technicians in charge of disinfection.

Observations:

- Cleansing and disinfection is not performed in extensive holdings, nor is the requirement to keep the pasture free from animals for 60 days applied. On the contrary, the animal owners wish to keep animals on the grazing fields to maintain their rights to use public grazing areas.
- A list of disinfectants and guidelines for treatment and disinfection of manure and slurry will be included as annexes to the legislation to be adopted in the matter.

Conclusions

Clear instructions are in place for formal movement restrictions and testing scheme for recovery of the status of holdings experiencing a brucellosis outbreak, and were applied in the cases reviewed. These are largely in line with EU requirements, or even go further, with the exception of the last testing of herds not being done after all the pregnant cows at the time of the outbreak have calved.

The absence of definition of the epidemiological unit for herds availing of common grazing areas meant that insufficient restrictions were applied, representing a significant factor for the persistence of the disease in such areas.

The lack of guidelines and instructions on the activities related to epidemiological investigations and the absence of records of some measures applied to avoid re-infection of the holding (isolation, cleaning and disinfection, pastures), represent a major impediment for their implementation or evaluation, and in the end for the eradication of the disease.

Insufficient expert epidemiological support was seen in the regions visited. In addition, these regions did not avail of the national software tool developed to facilitate epidemiological investigations and analyses. The lack of such expertise and of national guidelines for depopulation hampers the consistent and efficient use of this measure.

The compensation of animals according to a national average price, added to the effective sale of the animals for slaughter, raises questions on the effective incentive for avoiding introduction of the disease in flocks or herds raised extensively.

5.5 LABORATORIES

Legal Requirements

General requirements applicable to laboratories are set down in Regulation (EC) No 882/2004: Article 4 requires competent authorities to have, or to have access to, adequate laboratory capacity; Article 11 establishes requirements for sampling and analysis; Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls and requires that such laboratories be accredited. Requirements on the laboratory tests to be used within the framework of an eradication programme are specified in the Annex to Commission Decision 2008/341/EC which in turn refers to Annex C to Council Directives 64/432/EEC and 91/68/EEC. According to Article 6A of Directive 64/432/EEC, each Member States must designate a national reference laboratory (NRL) for brucellosis, coordinating the standards and methods; its tasks and responsibilities are set in point 4 of Annex C to the Directive.

Findings

The use and interpretation of tests for brucellosis are set in national legislation (ministerial decrees 453 of 1992, and 651 of 1994, for ovine and caprine, and bovine brucellosis respectively). Rose Bengal test (RBT) and complement fixation test (CFT) are used as screening and confirmation test respectively. A national norm established that results must be issued within 7 days of submission of samples.

In addition, officially free regions may use milk ELISA tests. Bacterial isolation is performed exclusively for epidemiological purpose, the confirmation of infection being done from the positive serological confirmation test. Brucellin tests have been used in few occasions (suspect cases in officially free regions, investigation of illegal vaccination in Campania).

The antigens are controlled by the NRL, which also produces the national standard, controlled by the EU-RL before release. The ELISA test is performed with commercial kits.

Diagnosis of brucellosis is performed in a network of public laboratories, the organisation of which is controlled by the regions. The NRL developed and validated standard procedures for brucellosis tests, and distributed them to the network of laboratories. 74 laboratories perform RBT, and 62 CFT. Local laboratories performing RBT only send the samples for the CFT confirmation test to another

laboratory in the same region.

Annual national proficiency tests are organised by the NRL, which provides also samples for the national proficiency testing. The NRL participates regularly to the proficiency tests organised by the EU-RL.

Observations:

- The NRL indicated that all laboratories involved in brucellosis diagnosis are accredited according to ISO 17025 by the national accreditation body, with the methods used included in the scope of accreditation.
- The NRL has no statutory role over the various laboratories in the country; however, it performed, together with the CCA, an inspection of poorly performing laboratories in 2011;
- Quality control and release forms were documented for the batches of antigen. The control of sterility reported on the release form of one batch did not meet the minimum duration required by international standards (OIE manual); the NRL indicated that it was an error of transcription.
- Batches of ELISA kits are not controlled at the NRL (although required by Directive 64/432/EEC), but the NRL stated that they were relying on batch validations performed from other NRLs within the EU.
- The NRL also produced specific RB51 antigen for a specific CFT aimed at identifying illegal vaccination, in the frame of the investigation on-going in Campania.
- RBT is systematically used instead of serum agglutination test, including in case of re-test of suspect bovine animals, which is not in line with point II, 3A of Annex A to Directive 64/432/EEC. However, the NRL is confident that the sensitivity of RBT is superior to the one of SAT, as reported in an EFSA study².
- In Calabria, milk ring tests were performed on samples taken from dairy establishments. This method, not included in the scope of accreditation, was not controlled nor validated by the NRL, which would not recommend it.
- In Puglia, the regional laboratory found that 95% of the test results were issued within 7 days of submission of samples. However, these delays were not monitored.

Conclusions

The restriction to a limited number of tests and the uniform method, clear interpretation rules, accreditation of all laboratories and their participation to national proficiency testing, promote the consistent performance and reliability of diagnostic tests across the country for the eradication programme. The use of RBT, instead of sero-agglutination test, including for discarding suspect animals, is not exactly in line with EU legislation, but scientifically justified.

On the other hand, the use of a non validated test for dairy plant controls in Calabria raises doubt on its value for official controls.

² <http://www.efsa.europa.eu/en/efsajournal/doc/432.pdf>

The NRL performs its tasks and responsibilities as foreseen by EU legislation, except for the validation of ELISA kit batches. The routine diagnostic tools, in line with EU legislation, are not adapted to detect fraudulent vaccination of adult animals.

5.6 PUBLIC HEALTH CONTROLS

Legal Requirements

Section IX of Annex III to Regulation (EC) No 853/2004 lays down hygiene rules for raw milk and dairy products including a requirement that raw milk must be obtained from BMOF or BMF flocks. However, raw milk for human consumption may be obtained from animals of a lower health status provided that the animals have not reacted positively to a brucellosis test or have been vaccinated and that the milk is heat treated such that it yields a negative Alkaline Phosphatase test result (or is used for the production of cheese with a maturation period of at least two months for sheep and goat milk).

In relation to slaughter, Regulation (EC) No 853/2004 requires Food Chain Information (FCI) to be received prior to acceptance of animals at a slaughterhouse. *Inter alia*, FCI must include the health status of the animals and their holding of provenance and results of testing relevant to the protection of public health, including testing in the framework of the control and monitoring of zoonoses. Regulation (EC) No 854/2004 (Articles 4 & 5 and Annex I, Section I, Chapter II, A) requires the official veterinarian (OV) to check and analyse FCI.

Regulation (EC) No 854/2004 (Annex I, Section II, Chapter III, Point 7) requires the OV to impose conditions under which animals are to be dealt with under a specific scheme for the eradication or control of a specific disease. Annex I, Section IV, Chapter IX, F of this Regulation details precautions to be taken in relation to specific hazards: for brucellosis it requires that animals, that have reacted positively or inconclusively to a brucellosis test, be slaughtered separately, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse. It further requires that, in relation to such animals, the udder, genital tract and blood must be declared unfit for human consumption.

Findings:

5.6.1 Human cases

The CCA provided information on human cases of brucellosis³. The last published data on human brucellosis published by the human health services are from 2009⁴. According to these, the four most affected regions are Sicily, Calabria, Puglia and Campania (with 85, 27, 19 and 13 cases respectively). The human cases are located in the areas where specific problems of bovine brucellosis are also encountered.

The 2012 report on the integrated control plan indicates a further reduction of human incidence, from 0.29 cases for 100,000 population in 2009 to 0.11 and 0.02 in 2011 and 2012 respectively⁵.

3 http://www.izs.it/IZS/Engine/RAServeFile.php/f/pdf_vari_grafica_/formazione/2012/Seminario_brucellosi/3aBrucellosiumana2009-Italia.pdf

4 http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=812&area=Malattie%20infettive&menu=vuoto

5 <http://www.salute.gov.it/relazioneAnnuale2012/paginaAttivitaRA2012.jsp?sezione=capitolo1&capitolo=trasversali1&id=1245>

5.6.2 *Controls on milk*

The CCA indicated that the State-Region conference adopted guidelines on official controls on holdings selling raw milk, and on milk destined to heat treatment. These guidelines were to be transposed into regional legislation, and the CCA will perform sectorial audits on the topic.

The planning and implementation of the official controls is delegated to the LCAs.

Observations:

- Information on milk restriction was systematically given to the owners of herds or flocks declared infected, together with the notification of infection and restriction.
- In the regions visited, a distinct area of the LCA was in charge of public health official controls in dairy holdings. The risk assessment method to establish the frequency of visits to the holdings included the historical brucellosis status of the holdings, but there was no plan to check specifically the holdings before the infected animals were sent to slaughter or during the period of restriction.
- In Calabria, where the audit team checked it, a risk-assessment was also performed to define the frequency of official controls in milk-processing establishments. The manufacture of dairy products from non pasteurised milk was included as one risk factor, but weighed against many other factors. The presence and processing of pasteurised and non-pasteurised milk in the same establishment in the same time frame was not considered as an additional risk.
- The check-list used for the control of milk processing establishments did not include any specific check on the official brucellosis status of the providers, or on the channelling of milk in case of dual-processing establishments;
- A dual-processing establishment was visited: the only official supervision report available dated from 3 years ago. No list of providers was available; scarce and outdated information was available about the official status of some providers; no incoming register was available. The plant presented obvious shortcomings in term of hygiene and flow. Despite prior notice, the operator was not available; the channelling of milk was impossible to verify. The RCA planned a further comprehensive visit the following day, but was denied entry by the operator.

5.6.3 *Controls at slaughter*

Reactors sent for slaughter are preferentially sent to a slaughterhouse in the province or region of origin. Slaughterhouses get specific pre-notification, and official control is performed on the arrival of the animals (movement document signed by an official veterinarian and presence of seals). For other animals, the food chain information, including the status of the holding of origin regarding brucellosis, is included with the movement document.

Observations:

- Adequate documentation related to the controls at slaughterhouse was available at the slaughterhouse visited, including follow-up on identification inconsistency. Reactor animals

were slaughtered at the end of the day. No system for recuperation of endo-ruminal boluses was set up.

- At the slaughterhouse level, the choice of disinfectants for the lorries transporting animals (including brucellosis infected animals) is left to the operator. At the slaughterhouse visited, the operator indicated that he used a specific detergent for lorries transporting positive animals. No written procedure could corroborate this statement. The detergent did not display any composition or expiry date.

Conclusions

Subject to confirmation, the decrease of human incidence is a reassuring element regarding the overall risk control system.

However, the procedure of weighing different risk factors against each other to establish the frequency of controls of dairy establishments, does not ensure that the ones with the highest risk of spreading brucellosis to humans through the production of unpasteurised milk products are subject to tighter controls. The official controls of such establishments and of their providers are insufficient to ensure the respect of the legal provisions regarding the milk from non-brucellosis free herds or flocks.

6 OVERALL CONCLUSIONS

The objective of the audit was to evaluate the implementation of the bovine brucellosis and ovine and caprine brucellosis eradication programmes, approved by Commission Decision 2012/761/EU and associated animal and public health controls.

In addition to extraordinary measures foreseen for the eradication of brucellosis in the four Southern most affected regions, resources have been reinforced and further measures have been introduced in Calabria. Compulsory electronic identification in this region represent a major improvement in an environment of frequent illegal movements. The level of application and enforcement of the measures in Puglia was significantly lower, in part due to weaknesses in legislation in place at national level.

The complex movements between holdings, involving multiple dealers and fattening herds, of an unknown brucellosis status, represent a risk for the spread of the disease, which is insufficiently controlled, because of the non-application by the official services of the legal requirements for dealers, and the absence of channelling foreseen in the approved eradication plan.

Brucellosis cases are reliably detected at laboratories. Effective measures are taken in holdings when outbreaks are detected, but epidemiological investigations remain rudimentary and incomplete. The useful databases and tools available are not used to their full potential. The definition of epidemiological units in problematic areas was sometimes deficient, having a direct impact on the efficacy of the measures applied.

The specific zoonosis risk represented by the dairy establishments manufacturing products from non-pasteurised milk is insufficiently addressed by official controls. Illegal vaccination of adult buffaloes, with a potential to affect human health through milk, was detected; the current routine

diagnostic tests are not adapted to identify such vaccinations.

The actions taken by the CA in the wake of the recommendations from previous FVO audits have not been implemented sufficiently to address most issues.

7 CLOSING MEETING

A closing meeting was held on 15 October with the CCA and the RCAs of the regions visited. At this meeting, the FVO audit team presented the main findings and preliminary conclusions of the audit.

The representative of the CA acknowledged the findings and conclusions presented. They indicated that they intended to present a report regarding the illegal vaccination case in buffaloes to the Commission, once the judicial case is closed.

8 RECOMMENDATIONS

The Competent Authorities should provide the Commission services with details of actions taken and planned including a timetable for completion within twenty five working days of receipt of the report to address the following recommendations:

N°.	Recommendation
1.	To ensure that the Competent Authorities have access to a sufficient number of suitably qualified and experienced staff to perform control duties in the regions and in the areas with high brucellosis prevalence (including for effective and efficient epidemiological expert support).Article 4 (2) (c) of Regulation (EC) No 882/2004.
2.	To ensure that adequate and enforceable legal basis is in place, transposing in an unambiguous way the dispositions of Directives 64/432/EEC and 91/68/EEC.
3.	To approve and supervise dealers and dealers' premises in line with Article 13 of Directive 64/432/EEC and Article 13 of Directive 91/68/EEC. To ensure that the enforcement measures foreseen by the national legislation are applied.
4.	To ensure that all regional brucellosis programmes and their implementation comply with the EU rules regarding the herds and flocks to be tested, the frequency of testing, the respect of delays for notification and slaughter of positive animals. Point II, (2) of Annex A to Directive 64/432/EEC, and Chapter I, I(B) and II of Annex A to Directive 91/68/EEC, article 7 of Directive 78/52/EEC.
5.	To ensure that epidemiological inquiries, described in the approved eradication programmes, requested in the ministerial decrees 453 of 1992 and 651 of 1994 (article 11(a)) and in the 2012 ministerial decree (article 10) are carried out in a consistent and effective way, and their results analysed and used to speed up the eradication process.

N°.	Recommendation
	Article 11(1) of Decision 2009/470/EC.
6.	To ensure that the regional channelling system for fattening herds described in the approved bovine brucellosis eradication programme, is effectively applied, and that movement rules comply with provisions of Directive 64/432/EEC and article 11 of Directive 78/52/EEC. Article 11(1) of Decision 2009/470/EC.
7.	To ensure that all summer fields and communal grazing fields are registered, and that movements to these places are registered, authorised only to brucellosis-free herds and flocks, and performed following a pre-movement test as required by the EU legislation or national legislation cited in the approved eradication programme. Article 11(1) of Decision 2009/470/EC.
8.	To consider developing guidelines for depopulation in order to ensure a consistent and effective use of this measure.
9.	To consider reviewing whether the compensation levels are appropriate to encourage farmers to adopt measures to reduce the future risk of infections.
10.	To enforce EU and national rules for identification, registration and movement of animals, by clarifying the legal basis, verifying the adequacy of the risk analysis performed at local level to plan the controls, and applying proportionate and dissuasive sanctions when relevant. Regulations (EC) No 1082/2003 and No 1505/2006; articles 8 and 55 of Regulation (EC) No 882/2004.
11.	To ensure that adequate controls are placed on Food Business Operators processing milk without pasteurisation and in particular that the provisions of Section IX, Chapter I, I, points (3) and (4) of Annex III to Regulation (EC) No 853/2004 are applied.

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=2013-6979

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 77/391/EEC	OJ L 145, 13.6.1977, p. 44-47	Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle
Dir. 78/52/EEC	OJ L 15, 19.1.1978, p. 34-41	Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle
Dir. 91/68/EEC	OJ L 46, 19.2.1991, p. 19-36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals
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. 911/2004	OJ L 163, 30.4.2004, p. 65-70	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
Reg. 1082/2003	OJ L 156, 25.6.2003, p. 9-12	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals

Legal Reference	Official Journal	Title
Reg. 21/2004	OJ L 5, 9.1.2004, p. 8-17	Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC
Reg. 1505/2006	OJ L 280, 12.10.2006, p. 3-6	Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals
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
Dec. 93/52/EEC	OJ L 13, 21.1.1993, p. 14-15	93/52/EEC: Commission Decision of 21 December 1992 recording the compliance by certain Member States or regions with the requirements relating to brucellosis (<i>B. melitensis</i>) and according them the status of a Member State or region officially free of the disease
Dec. 2002/598/EC	OJ L 194, 23.7.2002, p. 45-46	2002/598/EC: Commission Decision of 15 July 2002 approving vaccines against bovine brucellosis within the framework of Council Directive 64/432/EEC

Legal Reference	Official Journal	Title
Dec. 2003/467/EC	OJ L 156, 25.6.2003, p. 74-78	2003/467/EC: Commission Decision of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds
Dec. 2006/968/EC	OJ L 401, 30.12.2006, p. 41-45	2006/968/EC: Commission Decision of 15 December 2006 implementing Council Regulation (EC) No 21/2004 as regards guidelines and procedures for the electronic identification of ovine and caprine animals
Dec. 2008/341/EC	OJ L 115, 29.4.2008, p. 44-46	2008/341/EC: Commission Decision of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
Dec. 2008/425/EC	OJ L 159, 18.6.2008, p. 1-45	2008/425/EC: Commission Decision of 25 April 2008 laying down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing
Dec. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2011/807/EU	OJ L 322, 6.12.2011, p. 11-22	2011/807/EU: Commission Implementing Decision of 30 November 2011 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2012 and following years

Legal Reference	Official Journal	Title
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013