



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL  
Directorate F - Food and Veterinary Office

Ares(2011)848089

DG(SANCO) 2010-8407 - MR FINAL

FINAL REPORT OF A SPECIFIC AUDIT  
CARRIED OUT IN  
ITALY  
FROM 06 TO 17 DECEMBER 2010  
IN ORDER TO EVALUATE THE OPERATION OF THE BOVINE TUBERCULOSIS  
ERADICATION PROGRAMME  
IN THE CONTEXT OF A GENERAL AUDIT

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

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Italy, which took place between date 6 to 17 December 2010, as part of the as part of the general audit of Italy carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.*

*The specific audit evaluated the implementation of national measures, aimed at the control of the bovine tuberculosis eradication programme.*

*There has been an increase in the prevalence of bovine TB recorded in the semi autonomous region of Val D'Aosta, reaching a peak in 2008. A variety of measures were introduced by way of a "special plan" (some measures supplementing those foreseen in the approved eradication programmes) to control the disease and the incidence of TB is now falling again. However, farming practices in this alpine region (transhumance, fairs & "cow fights") mean that there are many animal movements and possibilities for contact between animals, increasing the risk of disease spread. Ongoing support from the regional government is seen as a critical issue.*

*In the autonomous region of Sicily, there has been a gradual decline in herd bovine TB prevalence – however, the rate remains high compared with other regions. The reasons are well known to the CA, have been reported in previous FVO missions and were noted again during the current mission – poor animal identification, delays in testing/removal of reactors and infected animals, "lost" animals, transhumance (i.e. mixing of animals), illegal movements and reluctance on the part of farmers to depopulate herds with long standing problems. Paradoxically, targeted CA inspections lead initially to an apparent dramatic increase in bovine TB prevalence within the province selected and data collected to-date; indicate there will be a small overall increase in herd prevalence in 2010. The CA lack a clear strategy to overcome the difficulties described.*

*It was concluded that the semi autonomous region of Val D'Aosta has broadly implemented the approved bovine TB eradication programmes for 2009 & 2010. The autonomous region of Sicily has implemented their programme to a much lesser extent, largely due to fundamental difficulties in applying basic legislation on animal identification and movement controls foreseen in EU legislation. However, for Italy as a whole, the number of regions/provinces recognised as officially free (mainly in Northern & central Italy), continues to increase.*

*The report makes a number of recommendations to the Italian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.*

# Table of Contents

<b>1</b>	<b>INTRODUCTION</b>	<b>1</b>
<b>2</b>	<b>OBJECTIVES OF THE MISSION</b>	<b>1</b>
<b>3</b>	<b>LEGAL BASIS FOR THE MISSION</b>	<b>2</b>
<b>4</b>	<b>BACKGROUND</b>	<b>2</b>
4.1	CONTRIBUTION TO THE GENERAL AUDIT	2
4.2	SUMMARY OF PREVIOUS FVO MISSION RESULTS	2
<b>5</b>	<b>FINDINGS AND CONCLUSIONS RELATED TO IMPLEMENTATION OF REGULATION (EC) no 882/2004</b>	<b>3</b>
5.1	COMPETENT AUTHORITIES	3
5.1.1	DESIGNATION OF COMPETENT AUTHORITIES	3
5.1.2	CO-OPERATION BETWEEN COMPETENT AUTHORITIES	3
5.1.3	CO-OPERATION WITHIN COMPETENT AUTHORITIES	4
5.1.4	DELEGATION OF SPECIFIC TASKS RELATED TO OFFICIAL CONTROLS	4
5.1.5	CONTINGENCY PLANNING	4
5.2	RESOURCES FOR PERFORMANCE OF CONTROLS	5
5.2.1	LEGAL BASIS FOR CONTROLS	5
5.2.2	STAFFING PROVISION AND FACILITIES	5
5.2.3	STAFF QUALIFICATIONS AND TRAINING	6
5.3	ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS	6
5.3.1	REGISTRATION / APPROVAL OF FOOD BUSINESS OPERATORS	6
5.3.2	PRIORITISATION OF OFFICIAL CONTROLS	6
5.3.3	CONTROL ACTIVITIES, METHODS AND TECHNIQUES	7
5.3.4	SAMPLING AND LABORATORY ANALYSIS	8
5.3.5	PROCEDURES FOR PERFORMANCE AND REPORTING OF CONTROL ACTIVITIES	8
5.3.6	TRANSPARENCY AND CONFIDENTIALITY	9
5.4	ENFORCEMENT MEASURES	9
5.4.1	MEASURES IN THE CASE OF NON-COMPLIANCE	9
5.4.2	SANCTIONS	10
5.5	VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES	10
5.5.1	VERIFICATION PROCEDURES	10
5.5.2	AUDIT	11
5.6	MULTI ANNUAL NATIONAL CONTROL PLAN	11
<b>6</b>	<b>SECTOR SPECIFIC FINDINGS AND CONCLUSIONS</b>	<b>12</b>
6.1	BACKGROUND	12
6.2	EPIDEMIOLOGICAL SITUATION	12
6.3	HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL	14
6.4	IMPLEMENTATION OF THE BOVINE TUBERCULOSIS ERADICATION PROGRAMME	16
6.4.1	CLASSIFICATION OF HERDS	16
6.4.2	TESTING REGIME	16
6.4.3	ADDITIONAL MOVEMENT CONTROLS, ISOLATION, MARKING AND TRANSPORT OF REACTOR CATTLE	18
6.4.4	SUPPLEMENTARY TESTS	19
6.4.5	EPIDEMIOLOGICAL INVESTIGATIONS	19
6.4.6	HERD DEPOPULATION	20
6.4.7	COMPENSATION	21
6.4.8	CLEANING AND DISINFECTION PROCEDURES AT HOLDINGS, TRANSPORT VEHICLES AND MARKETS	21
6.4.9	LABORATORIES	22
6.5	FOOD SAFETY CONTROLS	23
6.6	FOLLOW UP OF THE RECOMMENDATIONS OF MISSION DG(SANCO)/9091-2003	24

<b>7</b>	<b><u>OVERALL CONCLUSION</u></b> .....	<b>25</b>
<b>8</b>	<b><u>CLOSING MEETING</u></b> .....	<b>25</b>
<b>9</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>25</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>27</b>

**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
AUSL/ASP	Local Health Units <i>(Aziende Unità Sanitarie Locali/Provinciale)</i>
CA	Competent Authority
CCA	Central Competent Authority
DGAHVM	Directorate General for Animal Health and Veterinary Medicine
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
GA	General Audit
ISO	International Organisation for Standardization
ISS	National Health Institute <i>(Istituto Superiore di Sanità)</i>
IZS	Experimental Zooprophyllaxis Institute <i>(Istituti Zooprofilattici Sperimentali)</i>
MANCP	Single Integrated Multi-Annual National Control Plan
MH	Ministry of Health
MS	Member State
NAS	Carabinieri Health Protection Unit <i>(Comando Carabinieri per la Tutela della Salute - Nuclei Antisofisticazione e Sanità dei Carabinieri)</i>
NDB	National (bovine) Data Base
NRL	National Reference Laboratory
OTF	Officially Tuberculosis Free
OV	Official Veterinarian
SA	Specific Audit
SANAN	Animal health internet database
SID	Single Intra Dermal test
SOP	Standard Operating Procedure
TB	Tuberculosis

## 1 INTRODUCTION

The Specific Audit formed part of the FVO's planned mission programme. It took place in Italy 6 to 17 December 2010. The audit team comprised 2 inspector(s) from the Food and Veterinary Office (FVO) an observer from the Health and Consumers Directorate-General of the European Commission (DG SANCO) in Brussels. Representatives from the central competent authority (CCA) accompanied the audit team for the duration of the audit. An opening meeting was held on 6 December 2010 with the CCA. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team and the control systems were described by the authorities.

## 2 OBJECTIVES OF THE MISSION

The main objective of the specific audit is to verify that official controls are carried out in accordance with the multi-annual national control plan (MANCP) referred to in Article 41 of Regulation (EC) No 882/2004 and in compliance with Community law. The mission team evaluated the implementation of the bovine tuberculosis (TB) eradication programmes approved for Community co-financing. Particular interest was paid to:

- the progress made with the approved bovine TB eradication programmes 2009 and 2010 (Commission Decisions 2008/897/EC and 2009/883/EC);
- the performance of the competent authorities in their role of supervising and coordinating the above-mentioned programmes;
- the implementation of the Annexes A and B to Council Directive 64/432/EEC;
- the actions taken in response to the previous FVO mission on the bovine TB eradication programme (DG(SANCO)/9091/2003);

In addition, the mission team evaluated the progress in relation to animal health issues contained in Part 3.1 (Animal health) of the 2009 Country Profile of Italy, in relation to mission number 9091/2003 (transposition of Directive 64/432/EEC).

The table below lists sites visited and meetings held in order to achieve that objective:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES (CA)	Central	1	Semi autonomous region of Val D'Aosta and the autonomous region of Sicily
	Regional	2	
LABORATORIES (NRL)		1	The Experimental Zooprohylaxis Institute (IZS) of Brescia – the National Reference Laboratory/Centre (NRL) for Tuberculosis ( <i>M. Bovis</i> )
LABORATORIES		2	The IZS of Piedmont, Liguria and Val D'Aosta and teh National Institute of Public Health (ISS)
CATTLE MARKET		1	For veal calves < 6 weeks of age
FARMS		4	Dairy and fattening herds
ESTABLISHMENTS		5	Dairy plants (3) and Slaughterhouses (2)
DEALER'S PREMISES		2	Referred to as “ <i>Stalla di sosta</i> ”

### **3 LEGAL BASIS FOR THE MISSION**

The mission was carried out under the general provisions of Community 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;

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

### **4 BACKGROUND**

#### **4.1 CONTRIBUTION TO THE GENERAL AUDIT**

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the MANCPs referred to in Article 41 and in compliance with Community law.

This Specific Audit (SA) was carried out as a component of a General Audit (GA) to Italy. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

#### **4.2 SUMMARY OF PREVIOUS FVO MISSION RESULTS**

Official controls on the bovine TB eradication programme were last inspected by the FVO in March 2003 (DG(SANCO)/2003-9091-MR Final). This report (henceforth referred to as 2003-9091) has been published on the website of the Directorate General for Health and Consumers: [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

Report 2003-9091 noted that good progress was being made with eradication of bovine tuberculosis in the northern and central regions, with two northern regions (Bolzano and Trento) already being Officially TB Free (OTF) at that time. Problems persisted in the southern regions, and there was no clear oversight of the situation at regional or local level and epidemiological studies were inadequate to provide information on the source of infection. No effective system had been put in place to co-ordinate and audit activities at regional level. During this mission Piemonte and Calabria were visited.

## 5 FINDINGS AND CONCLUSIONS RELATED TO IMPLEMENTATION OF REGULATION (EC) NO 882/2004

### 5.1 COMPETENT AUTHORITIES

#### 5.1.1 Designation of Competent Authorities

#### Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

#### Findings

- The structure, organisation and designation of competences of the CAs are described in detail in the MANCP of Italy, accessible on the CA website: <http://www.ministerosalute.it/sicurezzaAlimentare/piani> and in FVO report DG(SANCO)/8105/2009 Country Profile for Italy: [http://ec.europa.eu/food/fvo/country\\_profiles\\_en.cfm](http://ec.europa.eu/food/fvo/country_profiles_en.cfm).
- Within the Ministry of Health (MH), Office II and III of the Directorate General for Animal Health and Veterinary Medicine (DGAHVM) are responsible for drawing up national eradication programmes, which must then be implemented by the regional authorities.
- Controls are carried out at local level by veterinarians working in "area A" of the Local Health Units (AUSL).
- In the autonomous region of Sicily (hereinafter referred to as Sicily) there are 9 provincial health care units (ASPs), responsible for 59 districts. In the semi autonomous region of Val D'Aosta (hereinafter referred to as Val D'Aosta) has only 1 AUSL and 16 animal health "veterinary zones". The AUSL/ASPs have considerable autonomy in relation to the allocation and management of resources.

#### 5.1.2 Co-operation between Competent Authorities

#### Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between competent authorities.

#### Findings

- The CCA co-ordinates the regional authorities through regular bi-annual meetings. Information on epidemiological data and technical reports are forwarded by the AUSL to the Regions and by the Regions to the CCA twice a year. Issues arising may be discussed at a standing technical committee comprising representatives from central and regional level.
- Regional authorities are responsible for the implementation of the bovine TB eradication programme. While the Regions are administratively controlled by the CCA, it does not have the authority to modify regional policies.



- The bovine TB eradication programmes applied in the regions comprise a number of different approaches/procedures which in most cases, are checked by the MH and the NRL (IZS) of Brescia.

### *5.1.3 Co-operation within Competent Authorities*

#### **Legal Requirements**

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

#### **Findings**

- On the basis of annual information provided by the regions, the CCA may make further enquiries and take measures when there are problems with the implementation of an eradication programme.
- Where fraud is suspected, an investigation can be instigated by NAS, a special branch of the Carabinieri which operates under the supervision and direction of MH. NAS worked in close co-operation with the AUSL in Val D'Aosta in 2008 to investigate the illegal use of treatments that suppress the skin reaction to the official intra-dermal skin test for bovine TB.

### *5.1.4 Delegation of specific tasks related to official controls*

#### **Legal Requirements**

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

#### **Findings**

- There is no delegation of official control tasks to control bodies.

### *5.1.5 Contingency planning*

#### **Legal Requirements**

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

#### **Findings**

Not applicable to this specific audit

## Conclusions on Competent Authorities

The CAs have been clearly designated for official controls on animal health and there is a mechanism to monitor the implementation and results arising from the different regional eradication programmes. However, the CCA has limited opportunity for direct intervention at the regional/local level<sup>1</sup>.

### 5.2 RESOURCES FOR PERFORMANCE OF CONTROLS

#### 5.2.1 *Legal basis for controls*

#### Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

#### Findings

- Public officials have powers of entry and inspection by virtue of Law 689/1981 (Article 13). Staff performing official controls at all levels have the status of civil servant and judicial police under Article 357 of the penal code and also under Law 441/1963, Articles 17 and 22<sup>2</sup>. In addition, inspectors may request assistance from the police (Article 3 of Law 283/1962).
- Private veterinarians on temporary contracts "*Veterinari Convenzionati*" can undertake routine testing but are not considered judicial police and for example, cannot sign official certificates. Their role and scope of activities is currently under negotiation at regional level<sup>3</sup>.
- The audit team was provided with information on the controls and investigations carried out by NAS in Val D'Aosta on request from the MH. NAS officials have the title of health inspector and the authority of judicial police. This allowed them to inspect farms, examine documents and require additional testing (to verify results obtained in the bovine TB eradication programme).

#### 5.2.2 *Staffing provision and facilities*

#### Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are

- 1 In their response to the draft report the Competent Authority noted that, nevertheless, the Ministry of Health is able to support eradication of animal diseases at regional level through its officials. Examples were provided for the autonomous regions of Val D'Aosta and Sicily.
- 2 In their response to the draft report the Competent Authority provided a detailed description (with full legal basis) of the designation and the role of judicial police.
- 3 In their response to the draft report the Competent Authority acknowledged that a question has arisen with regard to the status of such staff which should be resolved by the regional CA or Prefect.

free of any conflict of interest.

## Findings

- Statistics are available in the country profile on the staff numbers. However, the position regarding external/contract staff (and the hours/week performed by them) has yet to be clarified.
- As regards conflict of interest, it is covered by the Professional Code (*Codice Deontologico*), to which every veterinarian must make reference in the execution of his/her duties. Compliance with the professional code is checked by the organisation "*Ordine dei Medici Veterinari*" that has the power to undertake disciplinary measures against officials who violate the code, including suspension of duties.
- The MANCP does not provide an overview of the laboratory facilities available. However, some detail is provided in relation to testing for bovine TB in section 6.4 below.

### 5.2.3 *Staff qualifications and training*

## Legal Requirements

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

## Findings

- In the regions visited, training was organised at least annually at a regional/provincial level (participants list and details of the course material were available).
- The CCA does not co-ordinate/evaluate regional training programmes or identify training needs. The regional CA is independent and bases their programme on specific territorial priorities. For example, in 2010 the CA in Sicily provided training on their "extraordinary plan" for brucellosis and west Nile fever.

## Conclusions on Resources for Performance of Controls

The CAs at all levels had adequate legal powers, access to carry out official controls and staff had received training relevant to priorities identified at regional level.

## 5.3 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS

### 5.3.1 *Registration / approval of food business operators*

## Legal Requirements

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

## Findings

Not applicable to this specific audit

### 5.3.2 *Prioritisation of official controls*

#### **Legal Requirements**

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

#### **Findings:**

- Presidential Decree 189/2006 established the National Secretariat for risk assessment in the food chain, which supports the work of the Strategic Steering Committee for risk assessment and the National Committee for Food Safety. The role of the secretariat is to undertake preliminary investigation and to coordinate the risk assessment processes. For example, the region of Lombardia has been identified a high risk area for bovine diseases due to the high cattle density.
- In the animal health sector, eradication and surveillance programmes drawn up at the central level, establish priorities, risks, and frequency of the controls. These plans are generally defined at national level, however, Regional Authorities can set up specific local plans.
- The two national legal instruments applicable to the bovine TB eradication programme (Ministerial Decree 592 of 1995 & Decree Law 196 of 1999) do not explicitly discriminate between levels of risk. Regional authorities may apply elements of either legislation, in some cases imposing more stringent control measures than required by European Union (EU) legislation<sup>4</sup>.
- The CCA stated that they were to clarify the risk basis for bovine TB testing of herds in officially free regions.
- In the autonomous region of Sicily, a fixed percentage of farms (5%) are visited each year on a random basis (i.e. not risk based). However, other visits are arranged in response to problems identified through the animal health database – SANAN.

### 5.3.3 *Control activities, methods and techniques*

#### **Legal Requirements**

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

#### **Findings**

- 
- 4 In their response to the draft report the Competent Authority provided a more detailed description of the application of these two national legal instruments. They also provided details of the proposed application of Decree Law 196 of 1999 (which has more restrictive standards) from 2011. In particular, for the regions of Calabria, Campagna, Puglia, and Sicily the Ministerial Order of 14-11-2006 is to be renewed and for Val D'Aosta, the gamma interferon test is also to be used for re-acquisition of health status and the maintenance of the health status in the following year.

- Each year, the relevant regional veterinary services draw up an annual regional integrated control programme, which constitutes the legal framework for the inspection/control activities undertaken by their staff. These activities (inspection, verification, monitoring/surveillance and analysis) are carried out following written procedures prepared at regional level, using standard evaluation and inspection forms.
- The CA in Val D'Aosta was certified ISO (International Organisation for Standardization) 9001 for their official controls in 2008. Detailed standard operating procedures (SOPs) have been elaborated covering all aspects of the bovine TB eradication programme.
- The CA monitor their annual work plan closely using data held at local level or by reference to data held on a regional or national databases (e.g. in the case of Sicily, the animal health database – SANAN).

#### *5.3.4 Sampling and Laboratory analysis*

### **Legal Requirements**

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

### **Findings**

- Laboratory services for animal health are provided by a network of public laboratories at regional level. Analyses of food of animal origin and animal health are carried out by the IZS. There are 10 IZS, 6 of which can undertake all diagnostic work associated with bovine TB (i.e. up to the point of official confirmation).
- The accreditation of all IZS and the ISS is carried out by ACCREDIA – the “National Organisation for Accreditation of Certification and Inspection Bodies and of Laboratories”. The IZS are subject to control and supervision by the Regions and co-ordination by the DVPHNFS.
- Brescia IZS is the designated NRL for bovine TB and the ISS is responsible for checking the quality of PPD used in intra-dermal skin testing.

#### *5.3.5 Procedures for performance and reporting of control activities*

### **Legal Requirements**

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

Article 9 of the above Regulation requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied,

the results obtained and any action to be taken by the business operator concerned.

## **Findings**

- Legislative Decree No 112 of 31 March 1998 (Article 115) provides the State, with sole competence for adopting guidelines and standards to be followed by the Regions. Guidelines are adopted through the "State-Region Conference". The "Guidelines for official control in accordance with Regulations (EC) No. 882/2004 and No 854/2004" (DGSAN/3/6238/P) were adopted on 31 May 2007.
- In all regions form 2/33 is used by the Official Veterinarian (OV) to record and report the outcome of farm visits made under the bovine TB eradication programme. The information is sent to the AUSL and the relevant database is updated. Where there is a problem (e.g. inconclusive or positive intra-dermal skin test result), a copy of the form is forwarded to the IZS. Subsequent actions taken by the food business operator (FBO) and CA are described in Chapter 6 below.
- Information on epidemiological data and technical reports are forwarded by the AUSL to the Regions and by the Regions to the CCA twice a year.

### *5.3.6 Transparency and confidentiality*

## **Legal Requirements**

Article 7 of Regulation (EC) No 882/2004 requires that competent authorities carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

## **Findings**

- Disclosure of confidential information is an offence under Article 326 of the criminal code.
- The CCA publishes information on the bovine TB eradication programme on their website. The last data presented is for 1997.

## **Conclusions on Organisation and Implementation of Official Controls**

The controls were carried out in the two regions in accordance with annual plans and generally following documented procedures and reporting requirements laid down by the CCA. The CCA information provided to the public is now out-of-date.

## **5.4 ENFORCEMENT MEASURES**

### *5.4.1 Measures in the case of non-compliance*

## **Legal Requirements**

Article 54 of Regulation (EC) No 882/2004 requires a competent authority which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

## **Findings**

- These measures are described in the Annual Report on the implementation of the MANCP for 2007, chapter 4 "Action taken by the Competent Authorities following controls and improvement targets".

### *5.4.2 Sanctions*

## **Legal Requirements**

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

## **Findings**

- Most infringements are covered by administrative sanctions (the basic law being Law 689/1981). It allows fines to be levied within prescribed limits, based on the seriousness of the offence and the ability of offender to pay. A number of Legislative Decrees lay down sanctions for specific sectors (see Country Profile for further detail - link in section 5.1.1).
- In Sicily, it was noted that sanctions (other than warning letters) were rarely applied for the failure to identify animals correctly/on time. The CA indicated that the range of fines foreseen under Legislative Decree 58/2004, were disproportionate and excessive, given that in most cases, the infringements were by subsistence farmers with low incomes.
- Despite fines based on the seriousness of the offence, the CA continue to report high levels of illegal movements and cattle rustling.

## **Conclusions on Enforcement Measures**

The penalties laid down in national legislation have not been effective and dissuasive in all regions, particularly in relation to the proper identification of animals and illegal movement/theft. There is evidence that in some cases the range of penalties available is too high.

## **5.5 VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES**

### *5.5.1 Verification procedures*

## **Legal Requirements**

Article 4 of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

## **Findings**

- Legislative Decree No 502 of 30 December 1992 (Articles 2 and 8) requires the Region to supervise the AUSLs and requires that both levels have control and monitoring arrangements.
- In Sicily, the regional director made the two verification visits in 2010 at provincial and district level (The veterinary services lost their independence in 2008 and were included in the Department of Public Health and Epidemiology in 2009). His post replaces 4 staff members who dealt with animal health issues at regional level). Due to the resources available, most verification is undertaken indirectly by monitoring AUSL (and individual OV) activity in "real time" on the SANAN (animal health) database and the distribution of a quarterly report showing performance.

### *5.5.2 Audit*

## **Legal Requirements**

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

## **Findings**

- To-date there have been 11 audits in 8 regions (30 local authorities visited). Two audits dealt with milk and milk products. These audits didn't cover aspects of TB/disease control in cattle but were focused on food hygiene and food safety matters. However, epidemiological data concerning TB and Brucellosis status of holdings conferring milk to milk plants were taken into account in the planning of the specific audits.
- The most recent animal health audit took place in the autonomous province of Trento following a number of bovine TB cases (the province has been officially bovine TB free since 2003). The CCA is to forward a copy of the report (once available).

## **Conclusions on Verification Procedures**

The CCA has recently implemented an audit system at regional level.

## **5.6 MULTI ANNUAL NATIONAL CONTROL PLAN**

### **Legal Requirements**



Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated MANCP. According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

## **Findings**

- The structures are described in detail. However, changes have taken place since the publication of the MANCP (e.g. the organisation of the accreditation bodies) and no reference is made to the National Reference Centre for bovine TB in Brescia (i.e. part III to be completed).
- The MANCP states that the regions are responsible for drawing and implementing a bovine TB eradication programme. The CCA is to collate these plans and provide central oversight. However, no information is provided on the operational aspects (e.g. planning or policy/strategy).
- The audit system described in Part III is now being implemented.

## **Conclusions on Multi-Annual National Control Plan**

The plan is essentially descriptive and does not provide any significant operational information, or establish strategic objectives. Part 3 of the MANCP (Management tools) is not yet written and it remains to be seen to what extent this may fill some of the gaps.

## **6 SECTOR SPECIFIC FINDINGS AND CONCLUSIONS**

### **6.1 BACKGROUND**

The Italian cattle population consists of approximately 165,200 herds with 6,090,700 animals. The majority of the population is in the North, the South-West and Sicily. Most of the officially TB free (OTF) regions are in the North.

There are large variations in testing intervals, depending on the regional policies and TB prevalence. Most regions test all bovine animals (cattle and buffalo) >6 weeks old every year. However, the region of Friuli-Venezia-Giulia undertakes surveillance at slaughter-houses, while other regions test a proportion of the cattle population each year.

According to the Ministry Ordinance of 2006, in four Regions with particular problems with eradication of tuberculosis and brucellosis (i.e. Calabria, Campania, Puglia and Sicilia), all positive animals must be identified with electronic boluses and/or special ear tags. Furthermore, tissue samples are taken from these animals (for genetic testing) to identify positive animals upon arrival at the slaughterhouse. The same order requires tuberculin reactors to be slaughtered within 15 days of notification. Other provisions are discussed in the relevant sections below.

As identified in report 9091-2003, there is incomplete transposition of Council Directive 64/432/EEC (see section 6.6 on follow-up). Furthermore, regions can adopt their own legislation

while applying elements from either Ministerial Decree 592/95 or Decree Law 196/1999. The Ministry of Health (MH) is seeking to change their legislation on TB, so that it will cover the entire territory, while taking account of different regional (or within region) bovine TB risk levels.

## 6.2 EPIDEMIOLOGICAL SITUATION

In Italy measures against bovine TB were enforced for the first time in 1954, with compulsory slaughter of cattle with clinical disease. Eradication was on a voluntary basis from 1964 and since 1977, the Community has made financial measures available to support Member States (MS) in their eradication programmes. In Italy, these programmes have been compulsory in every breeding herd with the exception of separate specialised fattening herds. Since 1995, more strict measures have been applied (typically in the South of Italy) through the application of Ministerial Decree 592/1995 and subsequently, the Ministry Ordinance of 2006, with special provisions for the 4 regions where bovine TB is endemic (Sicily, Calabria, Campania and Puglia).

More recently, there has been an increase in the prevalence of bovine TB recorded in Val D'Aosta, reaching a peak in 2008<sup>5</sup>. That year, NAS undertook an investigation in collaboration with the Regional Veterinary Services (CA) to investigate the fraudulent use of treatments to conceal the presence of this disease. A variety of measures were introduced by way of a "special plan" (some measures supplementing those foreseen in the approved eradication programmes) to control the disease, and the incidence of TB is now falling again. However, farming practices in this alpine region (transhumance, fairs & "cow fights") mean that there are many animal movements and possibilities for contact between animals, increasing the risk of disease spread<sup>6</sup>. Ongoing support from the regional government (given the influential farm lobby & their resistance to some test requirements in the "special plan") is seen as a critical issue.

In the autonomous region of Sicily, there has been a gradual decline in herd bovine TB prevalence – however, the rate remains high compared with other regions. The reasons are well known to the CA, have been reported in previous FVO missions and were noted again during the current mission – poor animal identification, delays in testing/removal of reactors and infected animals, "lost" animals, transhumance (i.e. mixing of animals), illegal movements and reluctance on the part of farmers to depopulate herds. Paradoxically, targeted CA inspections lead initially to an apparent dramatic increase in bovine TB prevalence within the province selected and data collected to-date; indicate there will be a small overall increase in herd prevalence in 2010.

However, there is a national trend of decreasing disease prevalence and for Italy as a whole, the number of regions/provinces recognised as officially free (mainly in Northern & central Italy), continues to increase. Where the disease is still present or endemic, bovine tuberculosis infection is associated with classical risk factors both (directly or indirectly) related to cattle movements.

The M. Bovis situation in humans is not known. The Ministry can obtain data but there is no regular data flow between the public health and veterinary services.

Table 1: Development of the bovine TB herd prevalence 2006 – 2009

---

5 In their response to the draft report the Competent Authority noted that the peak in 2008 was foreseeable, since it took place in the middle of concentrated eradication activity, with extensive use of the gamma interferon test.

6 In their response to the draft report the Competent Authority noted that these movements constitute a known risk, which is continuously monitored, and are part of custom, practice and long-standing tradition, as well as being an important part of the regional economy and a source of income. With regard to transhumance in Val D'Aosta, such movements will continue to be registered in the regional database, including animals, locations and dates, while for other movements, such as fairs and fights, the various associations are already required in 2011 to register the presence of animals electronically within 7 days in the regional database in order to keep a record of them.

EVOLUTION OF BOVINE TB HERD PREVALENCE (%) - CATTLE				
Region	2006	2007	2008	2009
Abruzzo	0.25	0.09	0.04	0.21
Basilicata	0.52	0.09	0.04	0.21
Calabria	0.47	0.48	0.91	0.72
Campania	0.37	0.43	0.37	0.44
Lazio	0.3	0.37	0.42	0.31
Liguria		0.88	1.55	0
Lombardia		0.14	0.19	0.05
Marche	0.09	0.28	0.3	0
Molise	0.1	0.55	0.04	0.08
Piemonte	0.25	0.29	0.23	0.08
Puglia	0.46	0.5	0.62	1.89
Sardegna	0.08	0.58	0.88	0.28
Sicilia	7.18	5.34	4.1	3.71
Toscana	0.07	0	0.13	0
Umbria		0.23	0	0.2
Val D'Aosta		2.91	3.3	1.6
EVOLUTION OF BOVINE TB HERD PREVALENCE (%) - BUFFALO				
Campania	0.45	0.72	0.8	2.27
Lazio	0.36	0	0.34	0.3

### 6.3 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL

#### Legal Requirements

Council Regulation (EC) No 1760/2000 lays down the requirements for cattle identification, the computerised database, cattle passports and holding registers and its Article 2 defines a holding as any establishment, construction or, in the case of an open air farm, any place where animals are held, kept or handled.

Article 2 of Council Directive 64/432/EEC defines a herd as an animal or group of animals kept on a holding as an epidemiological unit and, if more than one herd is kept on a holding, each of these herds shall form a distinct unit and shall have the same health status.

Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 lays down additional requirements as regards ear tags, passports and holding registers.

Commission Decision 2001/672/EC of 20 August 2001 requires the MS to register pastures

located in mountain areas for cattle grazing during summer, to control cattle movements to and from the pastures and to record details of each movement in the national database for bovine animals within 7 days.

Point 4 (b) of Article 2 of Commission Regulation (EC) No 1082/2003 requires the CA to select the holdings to be checked on the basis of a risk analysis which shall take into account public and animal health considerations, and in particular the existence of previous outbreaks of animal disease.

## **Findings**

### National database and holding registration

- A national database (NDB) is in place for bovines maintained by the Teramo IZS, which is also the National Reference Centre for epidemiology. The autonomous region of Val D'Aosta has a regional database and data is transferred (in batches) to the National database. AUSL have access to their regional database (where present) and the national database.
- The NDB has been recognised as fully operational by Commission Decision 2006/132/EC. However, in one instance the audit team noted that the NDB had not been updated since 2006 in respect of a farm in Val D'Aosta<sup>7</sup>.
- The regional and NDB list registered pastures (i.e. summer grazing areas used for transhumance).
- Some farms visited did not keep a farm register (they relied on data held on the regional/national database<sup>8</sup>). In some cases, the database had not been updated to include all animals present on the farm making it difficult for the OV to determine which animals were > 6 weeks old and required a single intra-dermal test (SID) for bovine TB<sup>9</sup>.
- Premises registered as a dealer's premises (*stalla di sosta*), may keep animals more than one month and be co-located with other operations (e.g. fattening holdings and in the case of Sicily, a slaughter house). The register inspected in Val D'Aosta did not have full information on the origin/destination of animals or transporter details<sup>10</sup>.

### Movement controls

- In principle, transported cattle must be accompanied by a passport and movement certificate (model 4) containing information on the holding of origin and destination, individual animal

---

7 In their response to the draft report the Competent Authority noted that this holding had ceased activity and many cases like this occur because reports do not always reach the regional database. Notification from such holdings will be requested in Val D'Aosta to keep information updated.

8 In their response to the draft report the Competent Authority noted that under Regional Law 17/1993 the register is maintained by the Livestock Services Office in electronic form, and the farmer must provide timely notification of movements.

9 In their response to the draft report the Competent Authority stated that they are arranging for the database to be updated on an ongoing basis so that up-to-date 2/33 forms can be printed and the official veterinarian (OV) can perform a routine check of passports on the farm before the intra-dermal tuberculosis test, comparing them with the animals present.

10 In their response to the draft report the Competent Authority stated that the RCA of Val D'Aosta will request an up-to-date form from the Ministry and in the meantime, instruct the USL to record this information.

identification number, their health status and transport details. This form must be countersigned by an OV for movements from farms under restriction.

- In Val D'Aosta, for all movements (including animals attending fairs, "cow fights" and exhibitions), the model 4 certificate is used<sup>11</sup>.
- The audit team noted other instances in Sicily of movements without a model 4 certificate.
- In Sicily, the CA acknowledged that there were many illegal movements, and this was reflected, for example, in the low birth rates recorded in Messina and the high number of "missing" animals.

#### Animal identification

- Most animals seen during the visit to Val D'Aosta were identified by ear tags or a combination of ear tag/s and a rumen bolus (only readable in the region of origin).
- In Val D'Aosta, regional legislation permits the use of a single ear tag with a rumen bolus (as seen by the audit team).
- In Sicily, the audit team noted significant numbers of unidentified animals at farm level and a delay in administering rumen boluses in infected herds.

#### **Conclusions**

Improvements have been made to the system of holding registration, bovine identification and movement control. However, there is considerable variation between regions and weaknesses remain in all three areas which hamper the implementation of the eradication programme.

### **6.4 IMPLEMENTATION OF THE BOVINE TUBERCULOSIS ERADICATION PROGRAMME**

#### *6.4.1 Classification of herds*

##### ***Legal requirements***

Chapters I and II of Annex A to Council Directive 64/432/EEC lay down the provisions for combating bovine TB, and Article 2 of Council Directive 78/52/EEC defines the different TB status of the herds.

##### ***Findings***

- The approved eradication programme for 2010 requires the classification of herds in accordance with minimum Union requirements. As first reported in 9091-2003, in some cases Italian legislation is more strict (e.g. in relation to the suspension and restoration of OTF status of herds).

---

<sup>11</sup> In their response to the draft report the Competent Authority noted that as of 2011 the organiser is requested to register the presence of the animal electronically and to submit this information to the regional database within 7 days in order to keep a record of such movements.

- There are a variety of eradication programmes plans at regional level (5-6 significant variations), which in most cases are reviewed by the CCA with the assistance of the NRL for bovine TB (the IZS of Brescia).
- Classification of herds (bovine and buffalo) is performed by the OVs, on the basis of interpretation of the intra-dermal skin tests with PPD and, when stipulated by the regional programme – the complementary gamma interferon test is also used.

### ***Conclusions***

Classification of herds is broadly carried out as foreseen in EU legislation. However, the classification of some fattening herds requires clarification (see section 6.4.2 below).

#### *6.4.2 Testing regime*

### ***Legal requirements***

Council Directive 78/52/EEC lays down the minimum criteria for eradication plans in order for them to be eligible for a financial contribution by the Community. Point 1 of Article 3 thereof requires Member States (MS) to increase the proportion of the national cattle population which is subject to eradication and preventive measures so that most or all such cattle may be placed or kept under monitoring controls as soon as possible.

Annex A, B and C of Council Directive 64/432/EEC lays down the requirements for TB testing.

In order to enable the TB-free status of a herd to be retained officially, point 2 (c) of Chapter I of Annex A of Council Directive 64/432/EEC allows MS or part of the MS to alter the frequency of routine TB testing to two years and to exclude male animals for fattening from TB testing, provided that all the bovine herds in this area are subject to an official programme to combat TB;

- the average of the percentages of bovine herds confirmed as infected with TB is not more than 1 % of all herds within this area during the most recent annual supervisory periods;
- the bovine animals excluded from TB testing come from officially TB-free herds and
- The CA guarantees that these male animals for fattening within an isolated epidemiological unit will not be used for breeding and will go directly for slaughter.

Directive 78/52/EEC requires the MS to ensure that officially supervised intradermal tuberculin testing is carried out on all animals over six weeks old at least every six months in T1 and T2 herds until such time as they become T3 herds. Point 1 of Articles 6 and 14 of Council Directive 78/52/EEC requires the CA to ensure that, where a herd contains an animal suspected of having bovine TB, official investigations are carried out as soon as possible to confirm or rule out the presence of the disease.

### ***Findings***

- The official eradication programme is applied on the entire national territory, except in

regions officially free (where surveillance measures are required). Additional measures (e.g. intensified slaughterhouse surveillance, movement restrictions, additional identification measures and slaughter within 15 days of official confirmation) are foreseen under Ministerial Ordinance of 2006 in Calabria, Campania, Puglia and Sicily. In Sicily, it was noted that there may be delays in issuing the official confirmation that an animal is TB positive.

- Fattening holdings are identified in the NDB and may be classified OTF on the basis of the health status of incoming animals (as these holdings are exempt from routine TB testing). A few limited cases were noted by the audit team of animals from these holdings being sold for reproduction.
- In Val D'Aosta, the audit team observed a herd test based on a printout from the regional database made in September 2010. As a result, not all animal over 6 weeks old were identified. The CA subsequently informed the audit team that they had returned to the farm to complete the testing<sup>12</sup>.
- The single intradermal tuberculin (SID) skin test method described in Annex B 2.2 to Council Directive 64/432/EEC is used in Italy, and the result read using calibrated equipment.
- In Sicily, the audit team noted that repeat tests and follow up (due to inconclusive or positive results) were often delayed during the summer months and animals (including reactors) released without authorisation from the OV onto extensive pastures with adjoining herds.

### ***Conclusions***

Clear requirements are laid down for routine testing and enhanced measures in four regions with bovine particular TB problems. However, tests may be organised on the basis of incomplete information or may be delayed due to specific local circumstances.

#### *6.4.3 Additional movement controls, isolation, marking and transport of reactor cattle*

### ***Legal requirements***

Article 12 of Council Directive 78/52/EEC requires all movements of cattle into and within herds covered by an eradication plan to be subject to official monitoring.

Point 1 (c) of Chapter I of Annex A of Council Directive 64/432/EEC sets out the conditions for pre- or post-movement TB testing.

Articles 6 and 14 of Council Directive 78/52/EEC require reactor animals to be isolated and marked and require authorisation by the CA before cattle are moved out of the holdings for the purpose of slaughter.

### ***Findings***

---

<sup>12</sup> In their response to the draft report the Competent Authority noted that the Val d'Aosta RCA will instruct OVs to go to the farm either with up-to-date form 2/33 or to make individual passport checks and compare them with the animals present.

- The audit team noted that in farms with a confirmed case of TB, the cattle passports are seized and held by the CA. Passports are released for individual authorised movements.
- Movements of animals from farms under restriction (for any SID test with results > 4mm) can only take place with a "model 4" certificate countersigned by the OV with details of any supplementary identification (see section 6.4.4) for reactor/positive animals.
- Reactor animals are further identified by the application of a ruminal bolus and in the case of Val D'Aosta, a brand "M" is applied.
- Movement of bovine animals from infected herds are not blocked in the NDB, as reported by the CA in mission report 9091-2003<sup>13</sup>.
- Transhumance is generally restricted to animals for OTF farms. In limited cases, transhumance can take place for animals in other farms that are subject to two clear SID tests (42 day interval) and movement to an isolated pasture. In Sicily, the CA noted that bovine diseases (such as brucellosis and TB) were observed along traditional transhumance routes.
- In Val D'Aosta, the CA record many movements between OTF herds. A significant number of positive cases arise in such herds, linked to animals originating in other OTF herds<sup>14</sup> (i.e. where no additional movement restriction apply).
- During a farm visit by the audit team in Sicily, it was noted that reactor animals were not separated from other animals.

### ***Conclusions***

Additional movement controls are in place for animals from infected herds and non OTF herds. However, bovine TB cases are arising due to normal movement activity. Reactor cattle are not always isolated.

#### *6.4.4 Supplementary tests*

### ***Legal requirements***

Point 3 of Annex B to Council Directive 64/432/EEC sets out the conditions for supplementary testing (gamma-interferon test) in order to enable the detection of the maximum number of TB infected and diseased animals in a herd or a region.

### ***Findings***

- To detect the maximum number of infected animals in a herd, the CCA has authorised the use of the gamma-interferon test. This test is not used in Sicily and there is resistance from industry to its introduction.

---

13 In their response to the draft report the Competent Authority noted that for the RCA of regards Val d'Aosta, the block was created in the regional database and the procedure allowed for the passport to be withdrawn by the competent veterinarian.

14 In their response to the draft report the Competent Authority noted that Since 2010, all positive results have arisen from slaughterhouse reports.



- In Val D'Aosta, the gamma-interferon test was made obligatory in 2007 on farms that had their OTF status suspended or revoked (including those with an epidemiological link) under the regional "special plan to fight TB". The widespread use of this test reached a peak during the NAS enquiry in 2008. In 2009, the CCA issued guidance that this test was to be restricted to farms where their OTF status had been revoked.
- A regional decision in Val D'Aosta allows the OTF herd status to be withdrawn on the basis of PCR results<sup>15</sup> (see also section 6.4.9 on laboratories). This molecular diagnostic technique is available at all IZS.

### ***Conclusions***

The CA can apply supplementary tests to improve the efficiency of their eradication programme. The approach adopted varies significantly between regions.

#### *6.4.5 Epidemiological investigations*

### ***Legal requirements***

Point 3A (b) of Chapter I of Annex A to Council Directive 64/432/EEC requires the CA to carry out epidemiological examinations following the suspension of the officially TB-free herd status.

Point 3B (d) of Chapter I on Annex A to Council Directive 64/432/EEC requires the CA to trace and check any herd considered to be epidemiologically related to the index herd.

### ***Findings***

- Epidemiological investigations are carried out at holdings in which cattle are infected or suspected to be infected with TB, based on guidelines issued by the CCA and a standard enquiry form.
- Detailed epidemiological studies in Val D'Aosta demonstrate that in 2008 and 9, bovine TB outbreaks were caused by purchase, numerous movements (including transhumance) and prior infection with approximately 33% of cases with no obvious cause.
- In Sicily the audit team visited one farm with ongoing bovine TB problems where the last epidemiological enquiry took place 10 years ago. The OV concerned checked movements in the farm register but did not check the regional database. The CA indicated that some farmers were not co-operative and this situation was exacerbated by poor organisation within some ASP leading to delayed follow up and investigation of outbreaks.
- Spoligotyping (a genetic fingerprinting technique), is performed by the CA in order to distinguish between different strains of *M. bovis*, enabling patterns of origin, transmission and spread to be described.

---

<sup>15</sup> In their response to the draft report the Competent Authority noted that this only occurred during a "decontamination campaign". Under normal circumstances microbiology is deemed to be the 'gold standard' in accordance with the instructions from Brescia NRC for *M. bovis*.

- At present, wildlife vectors are not considered to have an impact on the TB situation despite numbers equalling domestic animals. They may be an issue as herd TB prevalence falls. Goats may represent a reservoir in some cases.

### ***Conclusions***

The quality and timing of the epidemiological studies varies widely between regions. In Val D'Aosta, the studies are adequate to provide information on the source of infection in most cases, while in Sicily they are less systematic.

#### *6.4.6 Herd depopulation*

### ***Legal requirements***

Point 4 of Article 3 of Council Directive 78/52/EEC requires measures to combat enzootic diseases to be systematically applied.

### Findings

- There are no national guidelines on herd depopulation. However, the issue is addressed in the Ministerial Ordinance of 2006 and the CA is considering developing this text into guidelines.
- The NRL seeks to maintain the current system whereby herd depopulation decisions are taken on a case by case basis by a technical group comprising members from the IZS, CA and AUSL.
- In Val D'Aosta, an example was provided for herd depopulation in 2009. However, in Sicily the audit team visited a farm with long standing TB problems (under restriction for 10 years), which the CA wished to depopulate. This was not possible without the agreement of the owner.

### ***Conclusions***

In the absence of national guidance on herd depopulation and with the requirement for agreement from the farmer, this option is used infrequently.

#### *6.4.7 Compensation*

### ***Legal requirements***

Point 2 of Article 3 of Council Directive 78/52/EEC requires breeders to be appropriately compensated for animals slaughtered on the instructions of the OV.

### Findings

- There is a clearly defined compensation system and payments are made subject to certification from the relevant slaughterhouse to demonstrate that animal have been slaughtered within the correct time. A ministerial decree lays down a fixed compensation for culled animals and the value of the meat is included in the compensation calculation.

- The compensation is not paid if the animal dies, is emergency culled, slaughtered > 30 days after notification, or was bought without the correct certification.
- The Ministerial Order of 2006 in four Southern regions, requires a shorter period between notification and slaughter (15 days).
- The farmer referred to in section 6.4.6 above, stated that the compensation was not adequate to allow him to re-stock his farm. He maintained that local slaughterhouses drop the meat prices for animals slaughtered following depopulation<sup>16</sup>.

### ***Conclusions***

While there is a clear mechanism to slaughter animals and receive compensation, in some instances the amounts are not adequate to encourage depopulation.

#### *6.4.8 Cleaning and disinfection procedures at holdings, transport vehicles and markets*

### ***Legal requirements***

Points 1 of Article 8 and of Article 16 of Council Directive 78/52/EEC require instruction given by the CA to be followed during cleaning and disinfection of infected holdings after slaughter of the infected cattle.

Points 3 of Article 8 and of Article 16 of Council Directive 78/52/EEC require the means of transport to be cleaned and disinfected after transport of reactor animals, and the disinfectant used for the disinfection of infected premises, transport vehicles, etc and its concentration, to be authorised by the CA.

### **Findings**

- Where checked, cleaning and disinfection of infected farms was completed within 7 days by the farmer and the process repeated by the CA with the issue of a certificate.
- The CA ensures that vehicles used to transport TB reactor animals to the slaughterhouse are properly cleaned and disinfected by the FBO before leaving the slaughterhouse and issue a certificate on completion (model 11).
- In the slaughterhouses visited, the CA had provided no written guidelines to the FBO on cleaning and disinfection of the establishment after the slaughter of reactor cattle<sup>17</sup>.
- While there is an official list of CCA approved disinfectants, no information is provided by on the concentration or dilution for use<sup>18</sup>.

---

16 In their response to the draft report the Competent Authority noted that in Val D'Aosta, slaughter of such animals is compulsory, they are not fattened and finished and the price is determined by the market, allowing the farmer the opportunity to choose the slaughterhouse and negotiate the price.

17 In their response to the draft report the Competent Authority noted that disinfection of the premises (by the FBO) is supervised and certified by the OV. It is the responsibility of the FBO to carry out disinfection taking into account the risk associated with the type of slaughter carried out.

18 In their response to the draft report the Competent Authority noted that the Val D'Aosta RCA will instruct the

- In the veal collection centre visited, cleaning and disinfection was not overseen by the OV and there were no recent reports available documenting this issue<sup>19</sup>.
- There was no treatment of farm manure with disinfectant on the infected premises visited as manure was stored for at least 5 months.

### ***Conclusions***

The procedures and controls over the cleaning and disinfection of farms and transport vehicles are satisfactory. However, written guidance is lacking in slaughterhouses, particularly in relation to the concentration of disinfectant to be used.

#### *6.4.9 Laboratories*

### ***Legal requirements***

Article 12 of Regulation (EC) No 882/2004 requires the CA to designate, assess and accredit laboratories that carry out the analysis of samples taken during official controls. Article 18 of Regulation (EC) No 2076/2005 provides for derogation from this requirement until 31 December 2009 if certain conditions are met.

### ***Findings***

- The laboratory network, accreditation and designation of the NRL is described in section 5.3.4 above. In brief, TB diagnosis is split between ante-mortem tests (gamma-interferon) and post mortem tests.
- For post-mortem tests by the IZS, an integrated protocol is used whereby all results (i.e. Bacteriology, histopathology and molecular biology) are reported together. In the IZS visited in Turin, molecular biology includes Polymerase Chain Reaction (PCR) direct from tissue, genotyping and molecular characterisation (Direct Variable Repeat (DVR) spoligotyping and Variable Number Tandem Repeats (VNTR) typing).
- Bacterial culture remains the gold standard and molecular biology will be restricted to PCR from tissue research only (even if positive for "TB complex"), if *M. bovis* is not cultured within 60 days.
- Some difference in interpretation possible between AUSL and the IZS on the meaning of a PCR positive combined with negative culture. CA is seeking guidance from the EU-Reference Laboratory on updating their legislation, as Ministerial Decree 592 gives little guidance on molecular microbiology.
- Accreditation does not cover some elements of molecular biology and PPD testing.

---

veterinary service to provide written instructions for use of authorised disinfectants in the slaughterhouse, with particular reference to cleaning and disinfecting methods following the slaughter of TB-positive animals, disinfection of transport equipment and relevant certification by the OV. The application of these instructions, are to be interpreted by the FBO, following a suitable risk assessment.

<sup>19</sup> In their response to the draft report the Competent Authority noted that the Val D'Aosta RCA has instructed the OV to perform periodic checks of disinfection procedures.

## ***Conclusions***

Official laboratory services are available and where checked, were found to be of a high standard. Some clarification is needed with regard to the interpretation of conflicting PCR and bacterial culture results.

### **6.5 FOOD SAFETY CONTROLS**

#### **Legal Requirements**

Point 12 of Chapter IV of Annex III to Regulation (EC) No 853/2004 lays down the physical conditions for carrying out *post mortem* inspection.

Chapter I of Section IV of Annex I to Regulation (EC) No 854/2004 lays down the requirements for *post mortem* examination.

Point E.2 of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004 requires that all meat from animals with localised TB lesions in a number of organs or a number of areas of the carcass, is to be declared unfit for human consumption.

Point I (3) of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 permits dairy establishments to use milk from restricted herds (but not from reactor cows) subject to authorisation by the CA.

Point 1, 3 (a) of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 permits dairy establishments to use milk from restricted herds (but not from reactor cows) after having undergone a heat treatment such as to show a negative reaction to the alkaline phosphatase test.

#### **Findings**

##### Slaughterhouse

- *Ante mortem* and *post mortem* inspection were carried out by OV's. Slaughter of reactors is permitted subject to the prior agreement of the OV responsible for the slaughterhouse in order to ensure that they are slaughtered separately and that appropriate samples are collected. When lesions are suspected to be due to TB during normal slaughter, samples for laboratory examination are taken and the OV notifies the relevant veterinary service.
- The routine *post mortem* inspection of bovine carcasses in the slaughterhouses includes the incision of the lymph nodes, and visual inspection of the lungs and kidneys. Adequate facilities were not available for the visual inspection of offal, and the palpation of gastric and mesenteric lymph nodes in the slaughterhouse visited in Val D'Aosta. In one slaughterhouse the OV had to make multiple incisions to locate the sub-maxillary, retropharyngeal and parotid lymph nodes, raising doubts about the frequency of this examination.

##### Dairy establishments

- In Italy, there are many products produced from milk which is not subject to pasteurisation

(e.g. unpasteurised Fontine cheese is the main dairy product made in Val D'Aosta).

- Establishments that process milk collected from primary producers are subject to regular supervision by OV's. However, the checks performed did not identify the fact that in some cases, the lists of herds supplying milk for processing was not comprehensive or the herd number was missing.
- In Val D'Aosta, for herds where the OTF status has been withdrawn or suspended, the OV immediately informs the milk processing establishments that it supplies. In Sicily, this is the responsibility of the farmer which in practice, may lead to significant delays before the dairy is notified officially. The CA acknowledged that co-operation should be improved between the animal and public health services.
- A dairy farmer visited in Sicily, was not aware of what do with milk from reactor animals. Reference was made to two churns (one for milk from "infected" animals), both of which were collected by the dairy establishment tanker and mixed, as according to the transporter, all milk was to be pasteurised.
- In the dairy visited in Sicily, the FBO quality assurance manager and the milk transporter provided conflicting versions of how milk from farms with reactor cattle was collected (the collection records showed that one collection run/day is performed collecting from both OTF farms and farms with a suspended status, rather than individual return journeys to farms under restriction).

## Conclusions

While the Italian legal requirements with regard to the treatment of milk and meat from infected herds were found to be in compliance (see also report 9091-2003), there were missing elements in the post mortem facilities/checks and in the dairy sector, there were weaknesses in the identification of supplying farms, delays in the official notification of dairy establishments about the change of supplying herd status and in some instances a failure to reliably segregate and heat treat milk.

## 6.6 FOLLOW UP OF THE RECOMMENDATIONS OF MISSION DG(SANCO)/9091-2003

### Findings

The report for the previous mission identified some shortcomings. The following table lists the outstanding recommendation of the last mission on bovine TB in 2003 and indicates how this has been addressed by the CCA.

Mission report reference	Follow up during mission DG(SANCO)/2010-8407
DG(SANCO)/9091-2003	
(12970) To complete transposition of all the provisions of Council Directive 64/432/EEC, as amended.	The CCA have two overlapping legal instruments (Ministerial Decree 592/95 and Legislative Decree 196/99). While in some cases, this legislation imposes more stringent measures than EU legislation, it does not fully

	<p>transpose Council Directive 64/432/EC as amended, particularly in relation to Directive 2008/73/EC, and Decisions 2008/984/EC and 2009/976.</p> <p>The CCA has been working on a draft Ministerial Decree since 2006. In addition to transposing Directive 2008/73/EC, this Decree seeks to give more powers to the NRL, implement provisions on transhumance, require the use of the animal health database SANAN, establish common criteria for herd depopulation, and manage bovine TB (and other diseases) in 4 regions (Calabria, Campagna, Puglia and Sicily) covered at present by special measures foreseen under Ministerial ordinance of 14 November 2006. However, there is no clear date for adoption.</p> <p>Assessment: In progress</p>
--	--

## **7 OVERALL CONCLUSION**

The autonomous region of Valle D'Aosta has broadly implemented the approved bovine TB eradication programmes for 2009 & 2010. The autonomous region of Sicily has implemented their programme to a much lesser extent, largely due to fundamental difficulties in applying basic legislation on animal identification and movement controls foreseen in EU legislation. However, for Italy as a whole, the number of regions/provinces recognised as officially free (mainly in Northern & central Italy), continues to increase.

## **8 CLOSING MEETING**

A closing meeting was held on 17 December 2010 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement and stated that they await the draft report before commenting in full.

## **9 RECOMMENDATIONS**

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this specific audit report.

N°.	Recommendation
1.	Complete transposition of all the provisions of Council Directive 64/432/EEC (as amended), as already requested in FVO report 9091-2003.
2.	Ensure that official controls are consistently carried out on a risk basis (particularly in relation to random farm visits, and surveillance in OTF regions) as required by Article 3 of Regulation (EC) No 882/2004 and up to date information on the bovine TB situation should be provided to the public as required by Article 7.
3.	Ensure that appropriate actions are taken and applicable sanctions are implemented when non-compliances are identified as required by Articles 54 and 55 of Regulation (EC) No 882/2004, in particular in relation to the identification of bovine animals and illegal movements (including the sale of breeding animals from untested fattening herds).
4.	Ensure that a (complete) single integrated MANCP is put in place for the period 2011-2014 as required by Article 41 of Regulation (EC) No 882/2004.
5.	Clarify the conditions necessary for registration of dealers premises (stalla di sosta) and ensure that all relevant data is recorded as required by Article 13 of Council Directive 64/432/EEC.
6.	Carry out appropriate epidemiological investigations as foreseen in point 3 A (b) of Annex A to Council Directive 64/432/EEC.
7.	Ensure that the herds may retain their officially tuberculosis free status only if all animals (from 6 weeks old) on the holding are subject to routine tuberculin testing at yearly intervals, as required by point I (2)(c) of Annex A to Directive 64/432/EEC. In this respect the CA should also ensure that the NDB can supply updated information when requested, as foreseen in Article 14, 3. C(3) of the same Directive.
8.	Ensure that reactor cattle are isolated, marked and all movements out of the holding are authorised by the CA as foreseen by Article 6 and 14 of Directive 78/52/EEC.
9.	Ensure that requirements in Article 14 of Directive 78/52/EEC regarding manure and slurry, and Article 15 of the same Directive on the concentration of disinfectant to be used are applied.
10.	Ensure that PM examinations are consistently carried out in accordance with Annex I, Section IV, Chapter I of Regulation (EC) No 854/2004, in particular with the provisions of point (B)(1) and (6) of this Chapter.

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



[http://ec.europa.eu/food/fvo/ap/ap\\_it\\_2010-8407.pdf](http://ec.europa.eu/food/fvo/ap/ap_it_2010-8407.pdf)

## 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
Reg. 494/98	OJ L 60, 28.2.1998, p. 78-79	Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine 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. 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
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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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. 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
Dec. 90/638/EEC	OJ L 347, 12.12.1990, p. 27-29	90/638/EEC: Council Decision of 27 November 1990 laying down Community criteria for the eradication and monitoring of certain animal diseases
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. 2004/292/EC	OJ L 94, 31.3.2004, p. 63-64	2004/292/EC: Commission Decision of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC
Dec. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
		following years
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years
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. 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