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Health and food audits and analysis

DG(SANTE) 2015-7571 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
GREECE
FROM 12 OCTOBER 2015 TO 16 OCTOBER 2015
IN ORDER TO
EVALUATE THE ERADICATION PROGRAMME FOR SHEEP AND GOAT BRUCELLOSIS

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 an audit carried out by the Food and Veterinary office in Greece from 12 to 16 October 2015.

The objectives of the audit were:

- *to determine whether eradication measures are in compliance with planned arrangements, implemented effectively and suitable in achieving objectives; and*
- *to evaluate whether prior epidemiological information, knowledge and experience in implementation of the Programme, have been used effectively in setting objectives and targets of the next year Programme.*

The Programme measures such as vaccination and sampling are not implemented to the extent planned. There are significant differences between regions. Under-implementation of vaccination significantly affects its effectiveness in reducing the disease prevalence. Measures on positive holdings are generally implemented according to the Programme, but their effectiveness is compromised by a failure to test all eligible animals in infected herds and insufficient controls of movements of animals from such herds. This may result in prolonged duration and spread of infection. The suitability of the current Programme is hampered by a significant mismatch between the Programme targets and human resources available for its implementation. The Central competent authority had made efforts to overcome the problem of staff resources, e.g. the involvement of private veterinarians but solutions are not operational yet.

Monitoring and review of the progress of the Programme has improved. However, there has been no adjustment of the Programme objectives and targets in order to take into account the available resources. The lack of analysis of existing data on risk factors for introduction and spread of B. melitensis and in particular of the impact of non-vaccinated male animals, prevented adjustment of the Programme measures to the epidemiological situation.

The control of sheep and goat brucellosis is compromised by absence of reporting and analysis of abortions. This results in a lack of detection or late detection of positive holdings, which is often triggered by the investigation of cases in humans. The fact that 65% of human cases are associated with consumption of unpasteurised dairy products and the same proportion of cases come from farming and non-farming communities, indicate that the zoonotic risk is insufficiently controlled in infected dairy herds.

Additional constraints that hamper the elimination of infection in infected herds arise from vaccination of adult animals. This limits the use of serological tests. However, around 50% of animals are vaccinated at the age of 3 to 6 month, meaning they are eligible for serological testing when older than 18 months. However, they are not tested in positive herds. Effective actions are required as regards updating the national herd database and in particular registration of very small holdings to ensure that planning and evaluations are based on reliable data.

Considering the current level of achievements of the Programme objectives and targets on one hand, and available human resources on the other, the Programme and its implementation needs major adjustments to deliver its intended results.

The report makes 6 recommendations to the competent authorities aimed at addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BMOF	*B.melitensis* officially free status established according to the criteria set in Annex A, Chapter 1(I)(A) of Council Directive 91/68/EC
Programme	Programme for eradication of *B. melitensis* in sheep and goats population in Greece for 2015, approved by "Grant Decision approving national programmes and associated funding" of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077)
CCA	Central Competent Authority
CCME	Committee for the coordination, monitoring and evaluation of *Brucellosis* control and eradication programme
DAAVFC	Directorate of Agricultural, Animal, Veterinary & Fishery Controls
DZAHD	Department of Zoonoses of the Animal Health Directorate
EDB	Electronic Database
EU	European Union
MIAR	Ministry of Interior and Administrative Reconstruction
MRDF	Ministry of Rural Development and Food
NHD	National Herd Database
NRL	National Reference Laboratory
OV	Official veterinarians
PV	Private veterinarians
PVD	Veterinary Directorate in Periphery (Region)
RU	Regional Unit
RVD	Veterinary Department in RU, (65 RVD, each cover one or more RU)

1 INTRODUCTION

This audit took place in Greece from 12 to 16 October 2015 and was undertaken as part of the planned audit programme by DG Health and Food Safety. The audit team comprised 2 auditors from DG Health and Food Safety. The team was accompanied throughout the audit by representatives of the Department of Zoonoses of the Animal Health Directorate (DZAHD) which is the central competent authority (CCA) for the scope of this audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit are:

- to determine whether eradication measures are in compliance with planned arrangements, implemented effectively and suitable in achieving the objectives.
- to evaluate whether prior epidemiological information, knowledge and experience in implementation of the Programme, have effectively been used in setting objectives and targets of the subsequent years Programme.

The implementation of the activities that the CCA initiated based on our recommendations during the previous audit dealing with control and eradication of sheep and goats brucellosis (*B.melitensis*) (Mission Report: DG(SANCO)/2008-7793 – MR Final [1]) has also been verified.

In pursuit of the objectives, the following sites were visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	1	1
	Regional	3	Veterinary directorates and veterinary departments
Laboratories		1	
Sheep/goat holdings		4	
Private veterinarians		3	

3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council 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 37 of Regulation (EC) No 652/2014 of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal

[1] http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=2031

welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC;

- Article 11(1) of the Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals; and
- Article 13(1) of the Council Decision 90/242/EEC of 21 May 1990 introducing Community financial measures for the eradication of brucellosis in sheep and goats.

Annex I comprises a full list of EU legislation providing the audit criteria for this audit. The annex refers, where relevant, to the last amended version.

4 BACKGROUND

PREVIOUS DG HEALTH AND FOOD SAFETY REPORTS

DG Health and Food Safety carried out an audit on the same subject in 2008 (DG(SANCO)/2008-7793). The audit report included six recommendations related to the implementation of the tuberculosis and brucellosis eradication programmes, as follows: (i) insufficient resources to implement the programmes and related official controls; (ii) coordination between the central and local authorities; (iii) testing of all eligible herds at an appropriate frequency; (iv) application of EU compliant testing schemes; (v) implementation of the vaccination effectiveness study and (vi) introduction of the accreditation procedures in the national reference laboratory (NRL). The CCA provided DG Health and Food Safety with information on actions undertaken to ensure improvement. Before this audit, none of the above mentioned DG Health and Food Safety recommendations had been closed but improvement had been noted as regards resources and accreditation of NRL.

4.2 APPROVAL OF THE ERADICATION PROGRAMME

The Programme for eradication of *B. melitensis* in sheep and goats population in Greece (from now on the Programme) for 2015 is approved by "Grant Decision approving national programmes and associated funding" of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077).

4.3 PROGRESS OF CONTROL AND ERADICATION OF BRUCELLOSIS OVER TIME

Control of *B.melitensis* in Greece started in 1975. Over the past 40 years, Greece has applied different approaches to reduce the burden of the diseases in animals and humans. These included vaccination of either all young female sheep and goats replacements or young female replacements and adult females.

From 1992 to 1998, test and slaughter policy was in place in the whole country. In 1998/1999 the vaccination of young breeding females was reintroduced in the attempt to address increasing number of cases in humans and animals. Currently, in mainland and on the islands

Thasos, Leros, Lesvos and Evia (so called vaccination zone (vaccination zone)), the Programme establishes vaccination (with Rev-1 vaccine) of young breeding females and adult females to reduce the disease prevalence. On other islands (so called eradication zone (eradication zone)) the Programme foresees testing of all animals older than 6 months and slaughter of those found to be positive.

Over the past 12 years (except in 2009/2010) the Programme has been approved by the European Commission. For many years the implementation of the Programme was significantly below targets. The low implementation rate and limited progress (measured as reduction of disease prevalence) resulted in significant rejection of co-financing by the European Commission, in particular over the past years.

Although the disease continues to pose a significant burden in animal population, the number of human cases has decreased. While the annual incidences between 1995 and 2005 range between 5.5 to 2.1 cases per 100 000 inhabitants, over the last 10 years the annual incidence in humans has decreased from 3.4 to 1.0 cases per 100 000 inhabitants.

5 FINDINGS AND CONCLUSIONS

COMPETENT AUTHORITIES (SETTING OBJECTIVES, PLANNING)

Legal requirements

Grant Decision approving national programmes and associated funding, of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077), Point 4.2 of the Programme.

Findings

1. The DZAHD of the Directorate General of Sustainable Animal Production and Veterinary Medicine (former Directorate General of Veterinary Services) in the Ministry of Rural Development and Food (MRDF, former Ministry of Reconstruction of Production, Environment and Energy), is the CCA responsible for drawing up and implementing the Programme. This is mentioned in Point 4.2 of the approved Programme for 2015. A major change is the dissolution of the previous Directorate of Veterinary Audit and Controls which was a part of the former General Veterinary Directorate. Audits over the implementation of the Programme are now executed by the new Directorate of Agricultural, Animal, Veterinary & Fishery Controls (DAAVFC), which is under the responsibility of the Deputy Minister of the MRDF.

2. The Programme was formulated and communicated through the Ministerial Decision Ref 4888/130873 (OG No 3545 31.12.2012). This Ministerial Decision was drafted in consultation with local veterinary services, scientific institutions, farmers and other stakeholders. It sets the objectives that the Programme should achieve by the end of 2015. The objective for the eradication zone was to reduce the prevalence of brucellosis among herds to 4% or lower. For the vaccination zone the objective was to achieve a vaccination coverage of 95% (at animal level). The objective in the Programme approved for 2015 is to reduce by 50% the prevalence of brucellosis in the country

compared to the prevalence in 2012 (which was 8.7%). There is communication and coordination in setting the annual Programme targets between the central and local level.

3. In Regional units (RU), Veterinary Departments (RVDs) set an annual plan of implementation of the Programme at a RU level. A RU plan generally details the number of animals to be vaccinated and sampled per month. RVDs deliver the majority of veterinary work within the framework of the Programme and they can control the work done by private veterinarians (PV).

4. In Peripheries (Regions), Veterinary Directorates (PVD) are given the duty to coordinate, supervise and evaluate the implementation of the Programme at the periphery level (Article 3 of the Ministerial Decision Ref 4888/130873). Administratively, PVD and RVD belong to the same Region and the same Ministry (Ministry of interior and administrative reconstruction (MIAR), but there is no hierarchy between them. According to the CCA, PVD supervises and coordinates the work of RVD. However, in the two RUs visited, the audit team observed that PVDs take a part in communication and to some extent evaluation of implementation of the Programme activities at a periphery level, but enforcement actions were missing. The CCA pointed out that the implementation of corrective or enforcement actions or deployment of staff and other resources relevant for the implementation of the Programme, is subject to agreement between the MRDF and MIAR. According to the CCA, this adds to the complexity and reduction of efficiency of the administration which affects both implementation of the Programme and related enforcement actions.

5. In order to improve the coordination and communication regarding the Programme, the CCA simultaneously communicate and provide relevant information to both PVDs and RVDs. Similarly, RVDs send information to both periphery and the CCA. In addition the CCA has established a "*Contact point*" for the Programme in each RU. They coordinate the implementation of the Programme at the RU level. They also act as a local point for the Programme related communication, coordination and reporting (monthly, 6-monthly, annual report on implementation of the Programme).

6. According to the analysis of resources carried out in 2012, Greece needs 625 teams (one veterinarian and one assistant per team) working 60 full days, for full implementation of the approved Programme. In many RU, existing staff is far below the number indicated in the analysis. For example, in one RU visited, the audit team was informed that the available staff represent about one third of the estimated needs.

7. The Programme activities are carried out by both official veterinarians (OVs) working in RVDs and PVs (PVs have been involved in the implementation of the Programme since 2013). For the implementation of the 2014 Programme, around 390 OVs in RVDs were involved less than 60 days. They were also carrying out other official tasks (in areas of animal health and welfare, food safety, etc). The number of PVs taking a part in the implementation of the Programme increased from 91 in 2013 to 204 in 2015.

8. In 2014 and 2015 there was some progress establishing the so called "*farm veterinarian*" (e.g. PV holding a contract with a farm and who is authorised and paid by the government to implement the Programme and other programmes for surveillance, control and eradication of animal diseases). This includes the adoption of relevant legal framework (Decision on farm veterinarians (No 816/156798, OG No 3385/2014)) and establishment of publically available register of farm veterinarians. At the time of the audit, there were 437 farm veterinarians registered (out of 450 estimated to ensure full implementation of the Programme). On the other hand, the instrument of using farm veterinarians has not yet been effective due to legal deficiencies (gaps) in the regulated contract. The CCA explained that the Decision on farm veterinarians has to be amended in order to solve these deficiencies.

9. In order to harmonise the implementation of the Programme, CCA developed the "Manual of instruction for implementation of the brucellosis control and eradication programme for sheep and goats (Manual of Instruction, 4th Version, 2013)". It contains comprehensive procedures, instructions and information necessary for consistent implementation (e.g. vaccination and precautionary principles for vaccinators and assistants, sampling, interpretation of diagnostic tests) and documentation on implemented measures (e.g. vaccination and sampling records, templates of official decisions ordering implementation of measures in infected herds (Official Decisions)).

10. The Programme is communicated to farmers mainly via OVs and PVs. The CCA also produces leaflets and television commercials to promote the implementation of the Programme and to inform farmers: e.g. that they are not allowed to sell the milk unless all eligible animals have been vaccinated. Evidences of communication were shown to the audit team.

11. The CCA is aware that farmers participation and interest as well as public and private co-responsibility for implementation of the Programme is crucial for future progress. In some RUs visited, the OV indicated the challenge of keeping farmers involved and informed. Also, the CCA mentioned that the level of acceptance and commitment to the Programme is different when comparing commercial and non-commercial farmers. This is partly explained by the requirements for placing on the market of milk (such as attestation of vaccination of animals), which is relevant for commercial farmers.

12. The DZAHD is empowered to provide advice on how to improve reporting procedures as well as to implement corrective actions in case of non-compliances or non-response regarding the reporting of the implementation of the Programme measures.

13. The Committee for the coordination, monitoring and evaluation of *Brucellosis* control and eradication programme (CCME) continues to assist the DZAHD as regards planning and evaluation of the Programme.

14. Audits and evaluation of the effectiveness of the Programme is done by the DAAVFC.

Conclusions on Competent Authorities (Setting objectives, planning)

15. The role of the CCA and local authorities is clear and recognised among stakeholders. The existing arrangements when setting the targets and objectives allow for wide understanding of the Programme. The current system does not allow for effective supervision and enforcement of implementation of the Programme measures, which hinders the quality and continuous improvement. Although the issue is well recognised, the CCA still has no solution for improvement.

16. Objectives and targets set for 2015 do not match with available resources for the implementation of the Programme in many RUs, which hampers the progress in eradication of the disease.

17. The appointment of single programme coordinators has improved the interaction, communication and exchange of information between the central and regional authorities. Continuous awareness campaigns contribute to farmers' participation and interest, but they are not sufficient to create ownership and engagement for the Programme throughout the farming community.

5.2 SYSTEM FOR IDENTIFICATION AND REGISTRATION OF ANIMALS

Legal Requirements

Grant Decision approving national programmes and associated funding, of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077), Point 4.4.3 and 4.4.5 of the Programme; Articles 2, 4, 7, 8 and 11 of Regulation (EC) No 21/2004.

Findings

5.2.1 Holding registration and coverage with the Programme

18. The definition of a herd (holding) used for the Programme is in line with Article 2 of Regulation (EC) No 21/2004. In the national herd database (NHD), the lowest standardised description of the geographical location of a holding is the central point of the municipality.

19. In October 2015, there were 123,384 sheep and goat herds registered as operative in the NHD. These operative herds had 15,641,496 sheep and goats (10,966,495 sheep and 4,675,001 goats). At the same time 3,168 herds were registered as inoperative (having ceased their operation).

20. The audit team observed discrepancies between the number of operative herds in the NHD and those included in the operational Programme for 2015. The total number of herds included in the operational Programme for 2015 account for about 66% of the total number of operative herds in the NHD. Animals from fattening herds were excluded from this calculation by the audit team. Similarly, the number of herds

considered in the planning and monitoring of implementation of the Programme in the vaccination zone in 2015, is 30% lower than the number of herds included in the approved Programme for 2015. The number of herds included in the operational Programme for 2015 is also 30% lower than the one in 2014.

Year	**Table 1.** Number of herds in the operational Programme in 2014 and 2015					
	Vaccination Zone		**Eradication zone**		**Total**	
	Number of herds	Number of animals	Number of herds	Number of animals	Number of herds	Number of animals
2014	87 973	11 550 218	27 437	4 138 404	115 410	15 688 622
2015	61 475	9 398 446	19 460	3 937 795	80 935	13 336 241

21. The audit team also observed discrepancy in data at the RUs visited. In one, 5,461 operative herds were registered in the NHD at the time of the DG Health and Food Safety audit but only 3,652 herds were considered in the Programme for 2015. The number of herds where males were tested in 2014 was higher than the number of herds included in the 2015 Programme (3,810 compared to 3,652, respectively). In another RU, the audit team was informed that about 500 herds were not considered in the Programme. The regional authority explained that the objective was to keep the annual targets realistic and matched with available resources.

22. The CCA estimated that, on average, 24% of the herds registered as operative in the NHD are inoperative in reality. These inoperative herds create problems for planning and evaluation of the results. For that reason, the CCA decided that herds registered as operative in the NHD, which did not provide inventory of animals, did not order ear tags and did not register movements over the previous 2 years were considered as inoperative and not included in the Programme for 2015. In 2014 for example, 67% of registered holdings provided the annual inventory of sheep and goats to the NHR. These holdings kept 87% of the animals in the NHR. According to the CCA, instructions were provided to the regional CA (No 621/51809/17.04.2014) aiming to address the issue of inoperative holdings. However, the audit team was not provided with evidence that the CA verifies on-the-spot that herds not included in the Programme and still registered as operative in the NDB, indeed do not keep sheep and goats.

23. There are sheep and goats herds (holdings) that are not registered in the NHD, which is not in line with Article 7 of Regulation (EC) No 21/2004. In one RU visited, the audit team was informed that small herds, keeping 5 to 10 animals, were not registered. These represented 10% of herds in that RU (around 150 to 200 herds). No action was implemented by the RVD to address this issue.

24. On all holdings visited, holding registers were available on the spot. The holding registers mainly contained information relevant for traceability of animals, but on three out of four holdings visited, they did not have date of identification of animals recorded,

which is not in line with Point B(2)(b) of Annex of Regulation (EC) No 21/2004. In one RU visited, the OV carrying out on-farm checks indicated that, during official visits, farmers are advised to enter the date of identification in the holding register. Holding registers checked by the audit team contained the date of on the spot checks and signature of the OV. In some instances their update was delayed.

25. The NHD does not allow recording animal health information (e.g. health status of a herd, movement restrictions), which is not in compliance with Point D(1)(g) of Annex of Regulation (EC) No 21/2004.

5.2.2 Animal identification

26. Since 2012, vaccinated sheep and goats are identified with two ear tags (conventional if vaccinated at age up to 6 months, otherwise one conventional and one electronic) bearing a unique-individual number.

27. In March 2015, the CCA issued a new manual on sheep and goat identification. It aims to further clarify and consolidate and inform farmers on their obligations as regards identification and registration of movements of sheep and goats, annual of inventory of animals and keeping an up-to-date holding register.

28. The CCA performs on-the-spot checks over the sheep and goat identification and registration as required by the Article 2 of Regulation (EC) No 1505/2006. This includes checks of accuracy of annual inventory animals in a herd, animal identification and checks of the herd register. The reports for 2012 and 2013 indicate that non-compliances were detected at 11% of holdings each year. Penalties were imposed on 14% and 3% of holdings with non-compliances in 2012 and 2013, respectively.

29. In one region visited, the OV used an electronic reader for ear tags to collect information on vaccinated/sampled animals. The Electronic database, in testing phase, does not allow automatic uploading of individual information on vaccinated/sampled animals and officials have to enter it manually.

5.2.3 Animal movement controls

30. Every movement of sheep and goats needs a movement document (filled and signed by the keeper) and a health certificate (issued by the relevant RVD). On holdings visited, the audit team observed that the general practice was to register information on animal movements into the holding register (all holdings visited except one, where the holding register did not contain the movement of positive animals sent to slaughter).

31. According to the national rules all movements of sheep and goats should be registered into the holding register and in the NHD. Registration of movements into the NHD is done by the OV. This requirement was not equally understood nor implemented in all RUs visited. In one RU, the official indicated that only movements to transhumance were registered into the NHD. In another RU, the staff showed good knowledge of the

rules on registration of animal movements but the OV indicated that those rules were not fully followed due to shortage of staff.

32. In 2014, according to the data provided by the CCA, 4,319 sheep and goat movements (271,913 animals) were registered in the NHD. Outgoing movements were registered only in 31 RUs (less than 50% of total RUs). Incoming movements of sheep and goats were registered in the NHD in 50 RUs.

33. All data on vaccinated animals are kept in paper form, at RVDs. OVs have access to information on whether animals to be moved to transhumance are vaccinated or not. Only when animals move to transhumance out of the RU of origin there is an obligation to get the attestation that they come from a vaccinated herd, and those movements have to be registered in the NHD. The OV at the municipality of destination approves the arrival of animals as mentioned in Point 4.4.5 of the approved Programme.

Conclusions on system for identification and registration of animals

34. The system for identification of sheep and goats provide for keeping adequate records on individual animals vaccinated or sampled and ensures traceability of animals covered by the Programme. However, the number of unregistered herds and animals, whose movements are not recorded nor controlled and whose health status is unknown, hamper the usefulness of the measures taken in registered and controlled herds.

35. The amount of herds and animals excluded from the Programme, without any on-the-spot verification, compromise seriously the reliability of the data used for planning, monitoring and evaluation of the effectiveness of the Programme measures.

36. The controls for animals going on transhumance provide additional guarantee of management of risk of spread of infection over long distances. However, the absence of registration of all movements to common pastures, in particular within a RU, compromises the traceability and prevents the evaluation of the possible impact of such movements (and mixing of animals from different herds) on the spread of infection among herds.

37. The use of electronic identifiers for vaccinated and sampled animals and the availability of appropriate readers of ear-tag numbers, is a promising step forward to simplify and reduce the work load of staff involved in the Programme activities and to decrease human error.

5.3 IMPLEMENTATION OF THE CONTROL AND ERADICATION MEASURES

In the vaccination zone (comprising of 48 RVD) selective vaccination (see Point 41) is used to control the disease. In the eradication zone (comprising of 17 RVD) vaccination is prohibited and only test and slaughter policy to eliminate the disease applies. The implementation of the Programme activities in 2014 and 2015 (January to August) is summarised in Table 2 and Table 3.

Table 2. Implementation of the Programme in the vaccination zone in 2014 and 2015					
Year	**Number of vaccinated herds (%[2])**	**Number of animals vaccinated (%[3])**	**Number of herds where sampling took place (%[4])**	**% of positive herds out of tested**	**Number of animals sampled (%[4])**
2014	23 518 (27%)	1 036 500 (39%)	19 216 (22%)	6.2%	114 270 (20%)
2015*	24 661 (40%)	901 859 (41.7%[2])	17 707 (29%)	2.7%	96 314 (24%)

Table 3. Implementation of the Programme in the eradication zone in 2014 and 2015			
Year	**Number of herds where sampling took place (%[4])**	**% of positive herds out of tested**	**Number of animals sampled (%[4])**
2014	1 802 (7%)	1.2%	162 353 (3.9%)
2015*	1 003 (5%)	0.4%	77 177 (2%)

*) January to August

2) Percentage of total herds in the operational Programme

3) Percentage of expected in the operational Programme

4) Percentage of expected in the operational Programme (around 395 000 male animals, based on calculation of % of male animals in the population registered in the NHD)

5) The implementation rate is calculated based on sheep and goats population considered in the Programme. If herd data from the approved Programme for 2015 are used, the implementation rate at herd level would be 33.9%).

Legal Requirements

Grant Decision approving national programmes and associated funding, of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077), Points 4.4.1, 4.4.6 to 4.4.10 of the approved Programme, Annex A and C to Council Directive 91/68/EC and Council Decision 90/242/EC.

Findings

5.3.1 Notification of abortions

38. In 2015, there were no abortions notified in the country. Considering the size of the sheep and goat population, a rate of abortions of around 0.1% (farmers met during the audit indicated a rate of 1% as normal) and if rate of notification is only 10%, it should have been at least 1000 notifying farms subject to investigation of suspicion of brucellosis annually.

39. According to a PV met in one RU, farmers frequently complain about abortions in sheep and goats, but they are reluctant to notify abortions due to associated cost of testing that should be borne by the farmer. The CCA explained that due to constraints on resources little progress has been made in terms of laboratory capacity to ensure investigation of abortions.

5.3.2 Case definition

40. The audit team verified the use of "case definition" in the vaccination zone, and it was mainly applied according to the Point 4.4.6 of the Programme. The testing schemes comply with the requirements in Annex C of Council Directive 91/68/EEC.

5.3.3 Vaccination

41. Vaccination of female lambs and kids aged over 3 months which are kept for breeding purposes and adult non-pregnant ewes and goats is implemented in the vaccination zone, as mentioned in the Point 4.4.7 of the approved Programme. Males are not vaccinated, in line with the Programme.

42. Procurement of vaccines has been lagging behind the schedule for many years. At the time of the audit, the tender for 2015 had not been finalised yet. The vaccine used during 2015 was acquired through a tender according to the 2014 plan.

43. The CCA has established control of vaccine batches before their use in the country. These checks are carried out by the NRL, according to the Terrestrial Manual of the World Organisation for animal health.

44. The audit team checked the conditions for vaccine storage of in two RUs. The records included vaccine doses received and delivered (including the name of the veterinarian, number of doses and date). This allows the competent authority to trace all vaccine batches. The records on doses received and delivered tallied with the doses available on the stock. Instructions on vaccine storage provided by the CCA include temperature of storage as this is crucial for live vaccines (such as Rev-1). In one RU visited, the vaccine was kept in the refrigerator without a thermometer and no records on temperature monitoring were kept. In that RU the regional authority informed the audit team that 10% and 30% of vaccine doses are lost annually (e.g. 15 350 expired doses were found on the stock during the audit). In another RU visited the situation as regards vaccine storage was adequate, very good records were kept on daily temperature monitoring and they regularly calibrated their min/max thermometer for accuracy.

45. The time to carry out vaccination is flexible and not presenting animals for vaccination has no direct consequences for farmers. Vaccination takes place all through the year with the majority of animals being vaccinated by August. The CCA indicated that its primary objective is to vaccinate animals up to 6 months before animals move to transhumance, but this objective has not been achieved in many RUs. The OV in one RU stated that a second visit was needed for the majority of holdings during the year in order to complete vaccination and sampling, which results in bigger demands for human resources and many animals vaccinated when being older than six months.

46. PVs involved in vaccination, provide the RU with the list of holdings and number of animals to be vaccinated on a weekly or monthly basis. The RU uses those data to provide PVs with adequate number of vaccine doses. Before a PV is involved in the Programme, the OV verifies if the PV's premises are equipped with a refrigerator with a

lock and whether he/she can ensure adequate storage of vaccines. The reports checked by the audit team on these controls were comprehensive and fit for purpose.

47. After 2012, the veterinarian (private or official) carrying out vaccination has to record the individual identification of vaccinated animals in the vaccination form established by the CCA. The form is signed by both farmer and a veterinarian. The audit team checked documents on vaccination and sampling and they did not present major discrepancies as regards of number of animals vaccinated. The information on vaccinated animals was documented in a paper form and largely fit for purpose of traceability of vaccinated animals. The document management system verified in one RU allowed for fast tracking of records/documents on vaccination (as well as sampling, measures on infected holdings, investigations) over the past several years.

48. The percentage of herds vaccinated between January and August 2015 varies among RUs. Out of those planned, around 40% of herds have been vaccinated (range from 0% to 100% per RU). In 63% of RUs less than 50% of herds have been vaccinated by the end of August of 2015 while in 10% of RUs more than 80% of herds have been vaccinated.

5.3.4 Testing of male animals

49. Point 4.4.7 of the approved Programme requires male animals over six months of age to be serologically tested. At the end of August of 2015, 29% of herds had been tested and in 78% of RUs, only 50% of herds had been tested.

50. The serological testing schemes are implemented according to the Point 4.4.6 of the approved Programme.

51. The CCA had developed clear instructions on taking and submission of samples to the laboratory as well as sampling forms. The audit team verified that standard forms for submission of samples to the laboratory have been used.

52. In the same way as for vaccinated animals, records are kept on sampling of male animals on a form established by the CCA. Records were available for verification on all RUs visited.

5.3.5 Classification and maintenance of a herd health status

53. The CA has not set up a system, using the criteria described in Annex A, Chapter 2(I)(A) of Council Directive 91/68/EC, to grant the health status of holdings for *B. melitensis* in the vaccination zone.

54. In the eradication zone, the criteria for granting a *B. m*elitensis officially free (BMOF) status established in the Article 11 of the Ministerial Decision Ref. 4888/130873, are in compliance with Annex A, Chapter 1(I)(A) of Council Directive 91/68/EC, but the CCA does not follow them. Instead, they decided that as a "first test", representative sample (minimum 25% and minimum 50 animals) is taken in order to upgrade an "*unknown*

herd status" to a "*brucellosis free*". After this "first test", all animals over six months of age are tested, in order to classify the herd as BMOF. This amended and applied testing scheme is not in line with Annex A, Chapter 1(I)(A) of Council Directive 91/68/EC. The issue has already been mentioned in the DG Health and Food Safety report from 2008 and relevant recommendation (No 2) was issued in this report (DG(SANCO)/2008-7793-MR Final).

5.3.6 Measures in case of positive results

55. Measures implemented in case of positive result of testing largely comply with Point 4.4.9 of the approved Programme.

56. Animals positive to brucellosis (*B. melitensis*) are identified by an additional mark (Δ shape punch) in the right ear.

57. The CCA also orders vaccination of all unvaccinated adult female animals on infected holdings provided they are not pregnant or diseased. However, no testing is carried out to verify their health status.

58. In the vaccination zone there is no additional testing of animals (both males and females) in infected herd to speed up the detection and removal of all positives (so to reduce the probability of spread) or to confirm that the disease has been eliminated. Although not required in the Programme, such testing is required in the Article 3(13)(c) and Article 5(5)of Council Decision 90/242/EC. The next testing generally takes place the next year when annual sampling of male animals is scheduled. The CCA explained that as some female animals have been vaccinated as adults, the reliability of serological testing of females would be questionable (due to expected false positive results). However, the fact that females older than 18 months and vaccinated at age of 3 to 6 months are eligible for testing, was not taken into account by the CCA[2].

59. The audit team followed up a case of a herd where male animals were found positive in 2015 (26% of tested males were positive). The holding was positive in both 2014 (17.4% positives) and 2013 (40% of positives). The measures taken after the detection of positive animals were well documented and they included the slaughter of positive animals, cleaning and disinfection on the holding after positive animals were removed, epidemiological investigation, tracing and investigation on contact holdings. The measures did not prevent prolonged persistence of infection on that holding. On three neighbouring (contact) holdings, positive male animals were also detected in 2013 and 2014. On one out of three contact holdings, males were also found positive in 2015. One of these holdings was using common pastures and long distance grazing of animals.

[2] ***In their response to the draft report the Competent Authority noted that when the Ministerial Decision on the implementation of the programme was adopted (31 December 2012), there were no individual vaccination data, only the information that animals on the holding had been vaccinated. Now the vaccination forms indicate the age of the animals at the time of their vaccination. It will be possible to use this information widely and take blood samples from female animals over 18 months of age within the vaccination zone only if replacements are vaccinated.***

5.3.6.1 Movement restrictions

60. According to the Ministerial Decision Ref 4888/130873 as well as Official Decisions on measures to be implemented on infected holdings in the vaccination zone, verified by the audit team on the spot, restrictions on movements apply to positive animals only. This is not in line with the Point 4.4.9 of the BMEP nor with the Article 3(13)(a) of Council Decision 90/242/EC, where the prohibition of exit and introduction of animals (except movements for immediate slaughter) applies to the infected flock.

61. The Ministerial Decision Ref 4888/130873 does not require application of measures to infected pastures. Pastures that held infected animals are not forbidden to be used for at least two months, which is not in line with Article 5(1) of the Council Decision 90/242/EC. None of the Official Decisions verified by the audit team included a requirement as regards pastures used by animals from infected herds.

5.3.6.2 Slaughter of positive animals

62. When animals are found positive, they are slaughtered as required in Point 4.4.9 of the Programme. The audit team verified that animals that are positive either to the Complement Fixation test and/or to the Rose Bengal test were slaughtered.

63. Positive animals are sent for immediate slaughter accompanied by a form containing the information on an animal to be slaughtered due to brucellosis (including identification number and age of an animal). The form is filled and signed by the OV.

64. According to the documentation verified, time from the confirmatory laboratory results to issuing the Official Decisions, took between seven days to three weeks. In all cases verified, positive animals had been sent for slaughter within 30 days from the date of notification of the farmer about the measures.

65. No bacteriological confirmation of the infection in the flock was required nor carried out, which is not in line with Point 4.4.6 of the approved Programme. The CCA explained that this is due to the lack of capacity to perform such testing.

5.3.6.3 Cleansing and disinfection

66. Requirements and instructions for cleaning and disinfections of premises and equipment are given by the OV as required by Article 5(1) of Council Decision 90/242/EEC. This includes procedures for manure and litter, cleaning and disinfection of sheds, living quarters for animals and equipment. The cleaning and disinfection is implemented after slaughtering of infected animals, under the supervision of the OV, who issues a holding cleaning and disinfection report. The audit team checked the cleaning and disinfection report at one infected holding and found it correct. The OV advised the farmer on appropriate disinfectants and to repeat the cleaning and disinfection of the premises three to four times a year, in cooperation with his PV. All files on management of positive cases verified by the audit teams in different RUs visited contained the OV report on cleaning and disinfection.

5.3.6.4 Controls on milk

67. Since 2014 holdings supplying milk to processing establishments should obtain an attestation, issued by the OV, that they have implemented required vaccination and sampling in the herd of origin of the milk.

68. In the vaccination zone, female animals are not tested on infected holdings, which results in an unclear health status of females on such holdings.

69. Milk from vaccinated animals on infected holdings is considered as milk from non-infected animals. According to the Article 16(7) of the Ministerial Decision Ref. 4888/130873, milk from non-infected animals from an infected holding has to be used according to the provisions of Annex III, Section IX, Chapter I, Paragraphs 3 to 5 of the Regulation (EC) No 853/2004. However, no Official Decisions reviewed by the audit team, imposed restrictions or requirements regarding the use of milk from animals from the infected holding on the same or other holdings. Also, Official Decisions reviewed, did not specify any restrictions as regards the use of milk from infected animals as mentioned in Point 4.4.9 of the approved Programme and Article 3(13) of the Council Decision 90/242/EC.

5.3.6.5 Epidemiological investigation

70. Epidemiological investigations are not carried in all positive herds, which is not in line with Points 4.4.8 and 4.4.9 of the BMEP.

71. Epidemiological investigations are carried out by an OV according to the predefined questionnaire. It includes factors to establish disease introduction and spread (e.g. introduction of new animals, illegal movements, movements to common pastures), history of vaccination, abortions, identification of contact holdings. The audit team verified that contact holdings have also been subject to epidemiological investigation. The source of infection remained undetected in the majority of cases reviewed.

72. In one RU visited, the audit team noted that epidemiological investigation was not conducted on all infected holdings. The OV explained that it is implemented in case of detection of positive herds which are associated with human cases. The audit team reviewed one such example. The investigation covered five herds (three with more than 60 animals and two with up to 60 animals). Four out of five herds were *B.melitensis* positive. The common risk factor identified was deficient vaccination or sharing common pastures.

73. The CCA collects information on re-occurrence of positive herds. For example in 2014, around 22% of herds were also positive in the previous testing. In 2015, this was found for 36% of the herds. The re-occurrence of infection varies among RUs. For example, in one RU visited, the OV pointed out that the majority of positive holdings were newly

3 In their response to the draft report the Competent Authority noted that in many cases, the percentage increase described in finding 73 is not due to an actual increase but to better and more systematic recording.

infected and only 10% of holdings were repeatedly found positive. There is little evidence of work being done to discover the factors associated with persistence or re-occurrence of infection[3].

5.3.6.6 Compensation schemes

74. The value of an animal is estimated by the evaluation committee before slaughter as mentioned in Point 4.4.10 of the approved Programme.

75. The payments are mainly linked with full compliance of implementation of the Programme, subject to evaluation by the OV. Farmers are required that positive animals (to either test) are slaughtered within 30 days. In addition, they are required to implement risk reduction measures (such as cleaning and disinfection) after slaughtering of positive animals.

76. The audit team verified on several occasions the time to slaughter of positive animals and in all cases they were slaughtered within 30 days since the operator has received the Official Decisions by the RVD.

77. In 2014, farmers received compensation for 70% of sheep and goats found positive. In 2015, compensation for 55% of animals was paid within 90 days after slaughter and for 30% of animals between six and seven months after slaughter. The CCA explained this was due to lack of funding.

Conclusions on implementation of the eradication measures

78. The CCA has established the system for implementation of the Programme measures. However, the deviation from the vaccination and testing targets set in the approved Programme, in the major part of the country, significantly affect the progress in controlling/eradicating the disease in the country.

79. In addition, some practices which deviate from the approved Programme (such as movement restrictions applying only to positive animals, absence of testing of all eligible animals on positive holdings, absence of bacteriological testing on positive holdings, no investigation of abortions, application of EU non-compliant testing scheme to classify a holding as BMOF, no restrictions of use of pastures used by infected animals). These practices have an adverse effect on elimination of the infection and hamper achievement of the Programme objectives to the detriment of the overall cost-effectiveness of the Programme.

80. The serological testing of unvaccinated males does not give a full picture of the distribution of the problem as it is implemented on a small percentage of herds. Although the impact of non-vaccinated male animals on persistence and spread of infection has not been evaluated, some evidence suggests that keeping unvaccinated males may support the persistence of infection within a herd as well as its spread among herds (in particular in case of animals sharing a common grazing areas). Furthermore,

absence of effective controls of animal movements from infected herds increases the risk of spread of the infection among herds.

81. Limited epidemiological investigations prevent the gathering of information on major factors associated with brucellosis seropositivity. This also prevents identification and deployment of additional measures or interventions to mitigate the impact of such factors on the disease spread.

82. The absence of measures as regards the use of milk from animals in an infected holding on the same or on another holding in the vaccination zone, prevent minimisation of possible risk of infection of humans or animals. This is in particular relevant for infected herds where vaccination coverage is low.

83. Established compensation schemes, linked to adequate implementation of risk reduction measures (such as timely slaughter of positive animals, cleaning and disinfection), have resulted in a good response from farmers and encouraged cooperation with implementation of the required disease control measures on infected holdings.

5.4 DIAGNOSTIC SUPPORT

Legal Requirements

Article 4(2)(c) of Regulation (EC) No 882/2004, Article 18 of Commission Regulation (EC) No 2076/2005 and Annex C to Council Directive 91/68/EEC.

Findings

84. The CCA has designated a NRL for brucellosis. In addition, seven national laboratories have been designated to carry out serological testing for brucellosis. The CCA has not established the capacity of the designated laboratories to perform bacteriological investigation, which is not in line with Points 4.4.6 and 4.4.9 of the Programme.

85. The NRL has been evaluated by the national accreditation body and accredited in accordance with EN ISO/IEC 17025 on "General requirements for the competence of testing and calibration laboratories" *(The Accreditation Certificate No 834, to ELOT EN ISO/IEC 17025:2005).* The accreditation document lists all the methods included in the scope of accreditation (Rose Bengal test, Complement fixation test).

86. The NRL is subject to annual audit by the national accreditation body to maintain the accreditation. The last audit, carried out in September 2014, issued three recommendations and the required corrective actions were undertaken (e.g. amendment of the process of distribution of documents, internal management of files and an internal audit, which is now carried out according to the accreditation standard).

87. The NRL participated in the EURL-organised inter-laboratory proficiency tests regarding performance of serological methods (Rose Bengal test, Complement fixation test and iELISA in 2012 and 2014, as well as in iELISA in 2013 and 2015). Results

were satisfactory for years 2012 to 2014 for all tests. Results for 2015 trial were pending at the time of this audit. One expert from the NRL participated in a serology EURL training session in 2014. The training covered complement fixation and Rose Bengal antigen control.

88. The standard operating procedures developed and used in the NRL and the required testing schemes (when applicable), are also applied in other designated laboratories.

89. In 2013/2014 and 2014/2015, the NRL organised the national inter-laboratory proficiency trials for the other designated laboratories in order to verify the quality of their work. All designated laboratories participated for the methods they perform:

    - The 2013/2014 trail uncovered problems about complement titration in one of the laboratories. The NRL organised, in April 2014, training on Complement fixation test for three staff from two regional laboratories.

    - In 2014/2015, performance of one laboratory was not satisfactory due to false classification of positive samples, probably because a new staff member has not received a proper training prior being involved in brucellosis testing. The NRL has scheduled at the end of 2015, specific training for that laboratory worker.

90. Two other designated laboratories have been accredited. For one, the accreditation scope includes Rose Bengal test, Complement fixation test and iELISA. For the other, the Rose Bengal test is included in the accreditation scope. Six laboratories have not started accreditation procedures, which is not in compliance with Article 18 of Commission Regulation (EC) No 2076/2005. The NRL explained that financial and human resources are the factors that prevent other laboratories to introduce a full accreditation scheme for laboratory methods used. All laboratories participate in national inter-laboratory proficiency trials for methods they perform.

91. The NRL provides for technical specification for reagents. The reagents are centrally purchased. Some reagents (for example Rose Bengal test) come exclusively through the NRL, others are distributed to all laboratories by the manufacturer. The NRL checks only those reagents used in the NRL. Representatives of the NRL indicated that other laboratories also check reagents and contact the NRL in case of issues.

92. The documented procedures for reception, verification of adequacy for testing, identification of samples have been followed in the NRL. Procedures in case of non-compliant samples have been established in the NRL. The audit team verified that on the sampling/reporting form the column to report the results of testing has been crossed in case of inadequate samples. No written procedure has been established to require implementation of corrective actions (for example, additional sampling) nor additional (replacement) samples are submitted to the NRL triggered by the fact that the report sent back to RVD contained no information on the results of the analysis. Annually 1 to 2 % of samples are rejected because they are not adequate for analysis[4].

93. The audit team verified that the NRL follows serological testing schemes established by the CCA. In cases where up to 6% of samples tested by Rose Bengal test are positive, only positives samples are retested with Complement fixation test. In cases where 6% to 50% of samples tested positive, all samples were retested with the Complement fixation test. In cases where more than 50% of samples tested are Rose Bengal test positives, the testing stops and the decision on slaughter is made based on the results of the Rose Bengal tests alone.

94. The CAs stated that there was shortage of laboratory staff and certain reagents at a certain periods (when the majority animals are sampled) and indicated that efforts were under way to hire additional staff. According to current national rules, seasonal staff can be hired for no longer than eight months and only unexperienced staff can be recruited. This allows recruitment of auxiliary and administrative/data entering staff, but not experienced laboratory technicians or other experts. At the time of the audit, the NRL was expecting to hire two additional permanent staff in 2016 which, in their view, would allow the NRL to proceed with the bacteriological testing. The CCA acknowledged that current laboratory capacities are not adequate to support the implementation of the Programme as planned.

Conclusions on diagnostic support

95. The quality of work of the NRL has improved since the previous DG Health and Food Safety audit on the same subject in 2008 and it delivers results of the serological tests at the required quality standards. By organising the proficiency testing for other designated laboratories for brucellosis, the NRL ensures an oversight of the quality of work of these laboratories. Also, by organising training for staff from other laboratories, it ensures continuous improvements of their work. This is particularly positive for those laboratories which have not yet included the methods for brucellosis testing in the scope of accreditation. On the other hand, the absence of accreditation in some designated laboratories means it cannot be assured that all practices to prevent mistakes in

4 In their response to the draft report the Competent Authority noted that the NRL has pledged to the CCA that it will amend the relevant procedure and require veterinary laboratories to take corrective measures involving additional sampling, if blood samples are found to be inappropriate (haemolysed), in the course of 2016.

diagnostic testing are in place.

96. The laboratory capacity in Greece is still not sufficient to support the full implementation of the approved Programme for 2015. This in particular applies to confirmation of infection (isolation and identification of *Brucella spp*), as at the moment none of the designated laboratories performs bacteriological testing. Therefore, obligatory testing schemes required in the EU legislation cannot be implemented and the objective of using abortions as a tool for an early detection and for confirmation of an infection in a herd with seropositive animals is currently not achieved[5].

5.5 HUMAN CASES

97. From 2010 to 2014 incidence of brucellosis (*B. melitensis*) in humans, per RU, varied from 0.13 to 5.36 cases per 100 000 of inhabitants. In 2014 and 2015 (by September) the number of human cases shows a decreasing trend.

98. In 2014 and 2015 human cases of brucellosis (*B. melitensis*) occurred in 60% of RUs in the mainland of the country. Regarding risk factors, around 27% of cases have been associated with infected herds, 65% of cases with consumption of non-pasteurized milk products and 53% of cases were livestock farmers. Around 28% of cases did not belong to the group of high risk professions (such as livestock farmers, veterinarians, slaughterhouse workers).

99. The CCA has established procedures to be followed in case of notification of human cases of brucellosis to the RVD by the public health authorities. This includes identification and investigation of holdings which are directly or indirectly associated with the human cases. The RVD reports back the results of the investigation to the local public health authority.

100. The audit team noted that the detection of human cases often triggers the detection of positive holdings. One such example was mentioned by the OV from one island in the eradication zone. Also in the RUs visited (in the vaccination zone) the audit team was presented the examples of investigation and detection of infected herds following the detection of cases in humans.

101. There is well established communication between the public health and veterinary authorities as regards brucellosis. Monthly and annual data on human cases have been communicated to the CCA.

5 In their response to the draft report the Competent Authority noted that the laboratory staff at the NRL for brucellosis, will be increased by one veterinarian in 2016 who will be posted to the bacteriology laboratory and his main tasks will be the bacteriological diagnosis of diseases, including the investigation of abortions.

5.6 VERIFICATION, EVALUATION OF THE RESULTS AND FOLLOW-UP ACTIONS

Legal requirements

Grant Decision approving national programmes and associated funding, of 30 January 2015 (SANTE/VP/2015/EL/SI2.70077), Point 4.4.11 of the approved Programme.

Findings

102. The CCA has established mechanisms to monitor implementation of the Programme activities as described in the Point 4.4.11 of the approved Programme. The monitoring is carried out at both central and regional level. This includes the comparison of planned and achieved activity indicators (such as number of herds/animals vaccinated/sampled) at the RU level. At the central level monthly reports on implementation of the Programme submitted from the RVDs, are checked for errors or inconsistences. This is followed by the letter (circular), sent to the RVD concerned, communicating the deficiencies detected as well as proposed actions to ensure improvement.

103. The CCA produces monthly news on brucellosis with an aim to keep veterinarians informed and motivated. These are sent electronically to each PVD and RU.

104. On the spot supervision of the work of PVs (including the maintenance of cold chain, administration of the vaccine, sampling, protection of vaccinators) has not been in place or it is very limited. On the other hand there is a system of verification of the reports on vaccination and sampling, submitted by the PVs. This includes cross checking of the number of animals in the NHD and those vaccinated/sampled.

105. The CCA recommends testing of 25% of the vaccinated female animals three to four weeks after vaccination, in order to check the development of the immunity and as an indirect method of control of the work of PVs. This tool however, is not widely used. In 2014, 561 female animals were checked three to four weeks post vaccination. In 2015 (by September) 166 vaccinated females were tested. During the audit the CCA was not able to indicate from how many holdings tested female animals did come nor how these holdings and animals had been selected for testing. Satisfactory level of protective antibodies was found in around 90% of tested animals.

106. As the data are mainly kept in a paper format, the CCA would require substantial amount of time to carry out comprehensive analysis of the impact of the Programme measures. This applies to, for example, evaluation of expected protection (direct and indirect) at the herd level, as a result of vaccination.

107. In 2011/2012, an internal audit on implementation of the Programme has been carried out in five peripheries (six RUs). The CCA for the Programme was also subject to internal audit in December 2012. The scope included verification and evaluation of the design, implementation, monitoring and evaluation of the effectiveness of the Programme. The 2011/2012 audit identified number of systemic weaknesses in horizontal issues influencing insufficient functioning of the veterinary services and

affecting the implementation and effectiveness of the Programme. This resulted in an increased risk for public health due to brucellosis and the reduction of productivity of sheep and goat farming which is the most dynamic livestock sector of the country. The 2011/2012 internal audit identified the need for better planning of vaccination. Also the issue of limited scale of testing of male animals resulting in unclear situation as regards the disease prevalence has been recognised by the internal audit. The 2011/2012 internal audit also identified weaknesses that lie outside the responsibilities of the veterinary services, such as acute shortage of staff and resources (which affect the mobility and efficiency of existing staff). The audit also pointed out that high levels of bureaucracy result in delays of recruitment of seasonal staff and the organisation of calls for tenders. The internal audit 2011/2012 recognised good cooperation between public health and veterinary authorities regarding cases of *B. melitensis* in humans.

108. The 2011/2012 internal audit issued 12 recommendations to the CCA, out of which 33% are closed so far as satisfactorily. Recommendations not yet closed are mainly associated with lack/inadequate administrative support required for the implementation of the Programme.

109. The 2011/2012 audit also issued 85 recommendations to the RDVs (with a range between eight and 17 recommendations, the average number of recommendations per RVD was 14). So far, 65 recommendations have been closed (76.5%). The rate of closed recommendations per RU varies from 37.5 % to 100%. For 20 recommendations not closed yet, corrective actions are pending or have not yet been taken. The representative of the internal Audit department explained that non-closed recommendations are mainly associated with the shortage of staff and financial resources. According to the data provided to the audit team, shortage of staff, lack of days allocated to current staff for the implementation of the Programme, inadequate means of transport for staff and shortage of equipment would explain the lack of progress in around 60% of situations.

110. The internal audit 2011/2012 has identified some good practices such as, electronic management of reports on implementation of the Programme at both central and regional level, development of the Manual of Instruction, development and distribution of leaflets for public and farmers on the disease prevention and control measures in place as well as online access to documents / manuals / leaflets related to the Programme (the CCA websites).

111. The situation regarding the implementation of the Programme is also examined by the CCME. The audit team was provided with the minutes from the last meeting of this committee in September 2015. The CCME discussed vaccination of male animals. General position is that, in RUs with high prevalence of brucellosis, vaccination of male animals would bring more benefit than problems. On the other hand, the CCME considers that in areas where the vaccination coverage is 90% or higher, vaccination of male animals would not bring much benefit. One proposed solution was to allow for flexible (regional) approach. The concern was that introduction of specific movement restrictions would be required among RUs applying different control measures. The

issue of false positive results due to imperfect serological tests (Rose Bengal test and Complement fixation test) as well as the fact that the tests can only provide an indication that infection may be present and not the evidence of actual infection was also discussed.

112. Although identified as an issue by the 2011/2012 internal audit and the CCME, the true impact of unvaccinated male animals have not been evaluated so far. This concerns both, impact in terms of resources required for implementation of the unvaccinated male policy and its impact on the disease persistence and spread. Also, detection of seropositive male animals, in absence of additional/repeated testing of other animals as well as bacteriological confirmation of the infection in a herd, may raise a question of the confidence in the true health status of the herd.

113. Analysis of epidemiological data collected during epidemiological investigations is limited or it is not carried out at regional nor at the central level. The CCA has pointed out that the existing staff are well trained and aware of the need to make a better use of epidemiological information. However, the staff at the moment do not have time to focus on issues such as analysis of the factors that impact the epidemiology of the disease in the country.

Conclusions on verification, evaluation of the results and follow-up actions

114. Documented monitoring of implementation of the programme measures has improved since 2012.

115. Both internal audits and the CCME contribute to improve the implementation of the Programme. Factors associated with under-implementation of the Programme (e.g. the lack of human and financial resources, high bureaucracy) are well understood and recognised, but little has been done to amend or change the strategy, objectives and targets, in order to adjust them to the existing resources. For example, the CCA still has to evaluate the added value of the non-vaccinated male policy (in terms of reduction of the disease incidence and prevalence).

116. Lack of use of epidemiological data is a missed opportunity to trigger evidence based change of the current strategy and focus on measures that are critical for improvement. This in particular applies to understanding the impact of factors such as long delays in re-testing of animals in infected herds, mixing of animals on common pasture, reoccurrence of infection over several years and impact of non-tested male animals on persistence and spread of the infection.

117. Long term under-implementation of the Programme with a lack or unreliable progress, may also result in lack of collaboration and timely support of the farmers communities to the Programme measures (in particular vaccination).

5.7 FOLLOW-UP

118. The table below summarizes the follow-up to the relevant recommendations made in report DG(SANCO)2008-7793

No	Recommendation	Assessment
1	To provide sufficient resources, staff, equipment and adequate training to implement the eradication programmes in order to guarantee that official controls are performed competently and in a consistent manner and that procedure are in place to verify the effectiveness of the control carried out, as required by Regulation (EC) No 882/2004.	Partly addressed. See findings No 9.
2	To guarantee that conditions and procedures for achieving and maintaining the health status of bovine and ovine/caprine herds are performed in accordance with Council Directives 64/432/EEC and 91/68/EEC.	Not addressed. See findings No 54.
3	To take action in order to guarantee that all eligible herds and animals are tested at the due intervals and that the official controls are properly documented so that data provided about prevalence and incidence will be reliable.	Not addressed. See findings No 35.
4	To carry out studies on the efficacy of vaccination in order to assess the level of protection in the ovine population and reconsider the importance of testing all males to disclose all possibly infected herds, as prescribed in the ovine caprine brucellosis eradication programme.	Not addressed. See findings No 105.
5	To improve the coordination between the DZ, the PVDs and the LVS, as required by Article 4.3 of Regulation (EC) No. 882/2004, by establishing a reliable system for generating, transmitting and analysing the data about the implementation of the programmes so they can be usefully used to assess the impact of the measures and to set targets for future programmes that should be realistic, achievable and proportionate to the available resources.	Addressed. See findings No 5.
6	To guarantee that the Brucellosis NRL will start the accreditation procedures, as required by Article 18 of Commission Regulation (EC) No. 2076/2005 and that	Addressed. See findings No 85.

	the TB NRL will be equipped in order to start the activities foreseen by Annex B, paragraph 4 of Council Directive 64/432/EEC.	

6 OVERALL CONCLUSIONS

The Programme measures such as vaccination and sampling are not implemented to the extent planned. There are significant differences between regions. Under-implementation of vaccination significantly affects it effectiveness in reducing the disease prevalence. Measures on positive holdings are generally implemented according to the Programme, but their effectiveness is compromised by a failure to test all eligible animals in infected herds and insufficient controls of movements of animals from such herds. This may result in prolonged duration and spread of infection. The suitability of the current Programme hampered by a significant mismatch between the Programme targets and human resources available for its implementation. The Central competent authority had made efforts to overcome the problem of staff resources, e.g. the involvement of private veterinarians but solutions are not operational yet.

Monitoring and review of the progress of the Programme have improved. However, there has been no adjustment of the Programme objectives and targets in order to take into account the available resources. The lack of analysis of existing data on risk factors for introduction and spread of *B. melitensis* and in particular of the impact of non-vaccinated male animals, prevented adjustment of the Programme measures to the epidemiological situation.

The control of sheep and goat brucellosis is compromised by absence of reporting and analysis of abortions. This results in a lack of detection or late detection of positive holdings, which is often triggered by the investigation of cases in humans. The fact that 65% of human cases are associated with consumption of unpasteurised dairy products and the same proportion of cases come from farming and non-farming communities, indicate that the zoonotic risk is insufficiently controlled in infected dairy herds.

Additional constraints that hamper the elimination of infection in infected herds arise from vaccination of adult animals. This limits the use of serological tests. However, around 50% of animals are vaccinated at age of 3 to 6 months meaning they are eligible for serological testing when older than 18 months. However, they are not tested in positive herds. Effective actions are required as regards updating the national herd database and in particular registration of very small holdings to ensure that planning and evaluations are based on reliable data.

Considering the current level of achievements of the Programme objectives and targets on one hand, and available human resources on the other, the Programme and its implementation need major adjustments to deliver its intended results.

7 CLOSING MEETING

The closing meeting was held in Athens on October 16, 2015. The audit team presented to the CCA the main findings and preliminary conclusions of the audit. During the meeting the CCA did not expressed any major disagreement with the main findings and preliminary conclusions. Also, the representative of the internal audit department has informed the audit team that the supervision and the data cleaning of the NHD have already been discussed in the department. The cleaning of the NHD data has not been carried out due to lack of veterinary staff. The CCA also pointed out that three pillars are required to be in place to fully implement the Programme. These include adequate number of staff, full use of information technology (electronic databases) and active involvement of farmers. They also recognised the need to involve relevant payment agencies to put pressure on farmers to comply with the Programme measures.

8 RECOMMENDATIONS

Number	Recommendation
1.	To ensure that the central register of holdings (NHD) comprise up-to-date information of all sheep and goats keepers as required in Article 7 and Section D.1 of the Annex of Regulation (EC) No 21/2004. ***Recommendation based on conclusions No.:35.*** ***Associated findings No.:23.***
2.	To ensure that remaining animals in a positive flock are subject without delay, to an official brucellosis test, as required by the Article 3(13)(c) and Article 5(5)of Council Decision 90/242/EC. ***Recommendation based on conclusions No:.79.*** ***Associated finding No.:58.***
3.	To ensure implementation of movement restriction according to the Article 3(13)(a) of Council Decision 90/242/EC. ***Recommendation based on conclusion No.:79.*** ***Associated finding No.:60.***
4.	To ensure that re-use of pastures which have contained infected animals must not take for 60 days after the removal of infected animals from pastures, as required in Article 5(1) of Council Decision 90/242/EC. ***Recommendation based on conclusion No.:79.*** ***Associated finding No.:61.***

Number	Recommendation
5.	To ensure that milk from animals from an infected herd, used on the same or other holdings undergo adequate heat treatment or is subject to other risk reduction measures as set in Annex III, Section IX, Chapter I, Paragraphs 3 to 5 of the Regulation (EC) No 853/2004. Also, ensure that measures as required in Article 3(13) of the Council Decision 90/242/EC are applied as regards the use of milk from infected animals. ***Recommendation based on conclusions No.:82.*** ***Associated finding No.:69.***
6.	To ensure that all designated laboratories start the accreditation procedures, as required by Article 18 of Commission Regulation (EC) No 2076/2005. ***Recommendation based on conclusion No.:95.*** ***Associated finding No.:90.***

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2015-7571

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 652/2014	OJ L 189, 27.06.2014, p. 1-32	Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC
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. 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
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

Dec. 90/242/EEC	OJ L 140, 1.6.1990, p. 123-127	90/242/EEC: Council Decision of 21 May 1990 introducing a Community financial measure for the eradication of brucellosis in sheep and goats
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. 2014/288/EU	OJ L 147, 17.5.2014, p. 88-113	2014/288/EU: Commission Implementing Decision of 12 May 2014 as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004