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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and Food Audits and Analysis

DG(SANTE) 2024-8011

FINAL REPORT OF A COMMISSION CONTROL OF
ITALY
CARRIED OUT FROM 12 TO 14 NOVEMBER 2024
IN ORDER TO EVALUATE THE MONITORING AND CONTROL SYSTEMS
FOR BOVINE, OVINE AND CAPRINE BRUCELLOSIS

Executive summary

This report describes the outcome of a control of Italy carried out from 12 to 14 November 2024 as part of the Directorate-General for Health and Food Safety work programme.

The objective of the control was to evaluate how Italy supports the Brucellosis status indicated for its territory in Regulation (EU) No. 2021/620.

*Most of the regions in Italy are recognised as officially free from Brucellosis (infection with *Brucella abortus* in bovines and *Brucella melitensis* in ovines and caprines) and the remainder of the territory is under an approved eradication programme. The Commission control evaluated the measures that Italy is taking to maintain its disease-free status in the free areas and the measures taken in the non-free areas to control and eradicate the disease.*

A strong administrative framework, based on appropriate legal powers, resources (e.g. sufficient well-trained staff, well designed IT systems, good laboratory support), is in place to implement the surveillance and eradication programme. Regular reports indicate that approved programme is generally implemented as intended. Some opportunities for improvement lie in passive surveillance and epidemiological enquiries after outbreaks for strengthening controls in officially free areas.

Nevertheless, the veterinary authorities face several challenges, which hinder the achievement of brucellosis-free status for all parts of Italy. These include sporadic outbreaks in disease-free regions and provinces, which are often linked to illegal movements from non-free areas; the continued circulation of the disease in several high incidence/cluster areas, such as Sicily (for all species) and in the buffalo population in the province of Caserta. The competent authorities are continually adapting measures to try to address these challenges (such as re-introducing vaccination in Caserta in 2023 or working with other state bodies to detect and stop illegal movements) but have made little progress.

The increased reporting of human Brucellosis in 2024 (74 confirmed cases) is notable. In part, this may be due to improvements in the reporting system. The veterinary authorities have little information about the infection pathway in these cases, nor have they taken reinforced preventive measures.

The report concludes that in general, there is a well-performing system of official controls for surveillance and eradication of brucellosis in relevant species which complies with EU rules. The Commission control detected no critical shortcomings in the system design. However, the lack of progress towards eradication targets and the alarming number of human cases of the disease pose serious questions on possible shortcomings in how the system is being applied in practice. The Commission intends to analyse further the root causes of these shortcomings.

No specific recommendations are addressed to the competent authorities in this report.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ADIS	Animal Disease Information System of the European Commission
CCA	Central Competent Authority
CFT	Complement Fixation Test
DG SANTE	Directorate-General for Health and Food Safety of the European Commission
EU	European Union
EURL	European Union Reference Laboratory
IZS	Experimental Zooprophyllactic Institute <i>Istituto Zooprofilattico Sperimentale</i>
MH	Ministry of Health
NRL	National reference laboratory
NAS	Carabinieri Health Protection Unit <i>(Comando Carabinieri per la Tutela della Salute - Nuclei Anti-sofisti cauzione e Sanità dei Carabinieri)</i>
RBT	Rose Bengal Test

1 INTRODUCTION

The Commission control took place remotely from 12 to 14 November, as part of the work programme of the Directorate-General for Health and Food Safety of the European Commission (DG SANTE). The control team was comprised of two officials from DG SANTE.

At the outset, the control team confirmed the objectives and scope of the Commission control, and the agenda. Throughout the Commission control, the competent authority of Italy (Directorate General for Animal Health and Veterinary Medicines, Ministry of Health), along with representatives of veterinary services of the Regions and the National reference laboratory provided all information required for its successful completion.

2 OBJECTIVES AND SCOPE

The objective of the control is to evaluate the system implemented in Italy to support its officially free status (in part of the territory) regarding bovine, ovine and caprine brucellosis and assess the implementation and impact of the eradication programmes (in the remaining parts of the territory).

The scope of the control covered *Brucella abortus* and *B. melitensis* in bovine, ovine and caprine animal populations during 2022 and 2023 in Italy.

The control team evaluated both the free areas and the areas under eradication for:

1. Surveillance systems. Coverage, sampling strategies, and data collection methods.
2. Laboratory support. Diagnostic capacity and tests, reliability of results.
3. Disease reporting and data management.
4. Control measures for positive cases. Animal movement control, quarantine, containment, and hygiene practices.
5. Wildlife management and monitoring.
6. Control of movements of animals between areas with different disease status.
7. Review of eradication program evolution.

The Commission control did not cover the areas of animal identification and registration, hygiene controls or intra-Union trade.

The Commission control team participated in videoconference meetings with the Directorate General for Animal Health and Veterinary Medicines, Ministry of Health (MoH), the central authority responsible for the monitoring, coordination and evaluation of the national eradication programme for brucellosis. Other authorities, such as regional authorities responsible for the implementation of the programme, representatives from the laboratory network and from the national reference laboratory for brucellosis joined the meetings as needed.

The control was conducted through data and document review, interviews with officials and, where appropriate, other parties concerned.

3 LEGAL BASIS

The control was carried out under the general provisions of EU legislation (see Annex 1) and in particular, Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

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

4 BACKGROUND

Disease prevention and control

The European Union has established rules under Regulation (EU) No. 2016/429, known as the Animal Health Law, to prevent and control important animal diseases including those that can spread between animals and humans. These diseases are referred to as "listed diseases," and the law also identifies certain animal species that might pose a higher risk of spreading them.

The Animal Health Law outlines specific prevention and control measures depending on the disease and the animal species involved. When dealing with bovine brucellosis (*B. abortus*) and ovine/caprine brucellosis (*B. melitensis*), EU countries must take strict measures to *control and eliminate* the disease in those species; *prevent the disease from spreading* and undertake *ongoing monitoring*. The same law provides guidelines for when a country or area can be officially recognised as free from a particular disease.

This framework helps ensure that animal health standards across the EU remain high, protecting both animals and people from the spread of dangerous diseases.

The rules in Regulation (EU) 2016/429 are supplemented by the rules in Commission Delegated Regulation (EU) 2020/689. Those supplementary rules provide for definitions for a suspected case or a confirmed case (Article 9).

Bovine and ovine/caprine brucellosis in Italy

There are 5.8 million bovines Italy (5.4 million cattle in 124,368 establishments and 400,000 buffaloes in 2,365 establishments) and 6.9 million sheep/goats in 112,385 establishments.

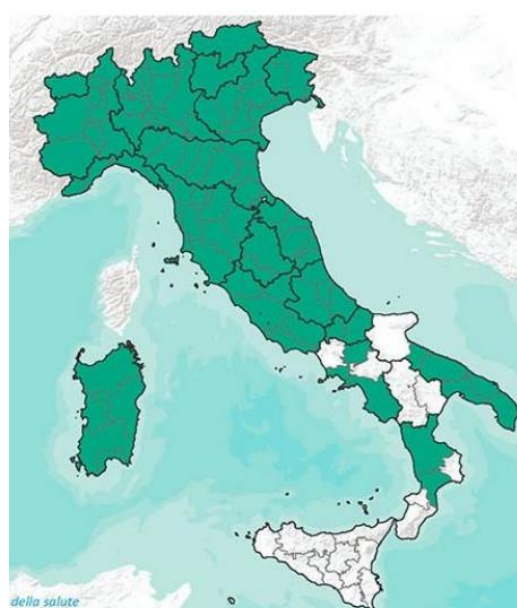
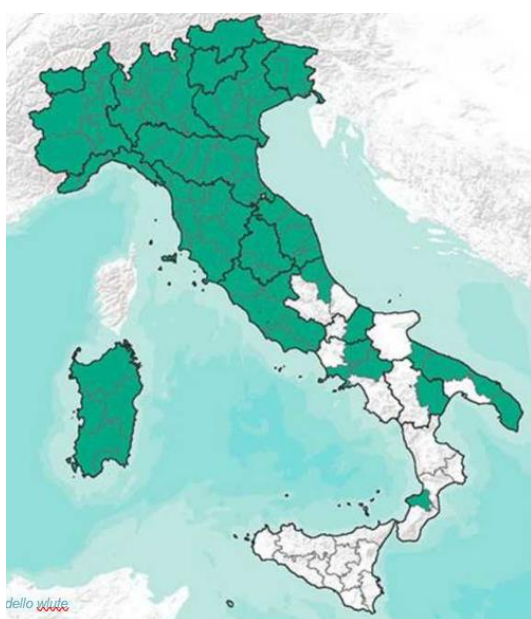
Number of outbreaks of Brucellosis		
	Bovine	Ovine/caprine
2023	217 (136 bovines + 81 buffaloes)	34
2022	346 (254 bovines + 92 buffaloes)	66

	Brucellosis in bovines		Brucellosis in ovines/caprines,	
	National prevalence	Prevalence in non-free areas	National prevalence	Prevalence in non-free areas
2023	0.18%	0.75%	0.04%	0.19%
2022	0.28%	0.86%	0.06%	0.26%
2021	0.34%	0.97%	0.1%	0.40%

Bovine brucellosis

2023

Ovine/caprine brucellosis



Green = Officially free areas (as listed in Chapter 1 for bovines and Chapter 2 for ovines/caprines of Part I, Annex I of Regulation 2021/620)

White = Approved eradication programme (as listed in Chapter 1 for bovines and Chapter 2 for ovines/caprines of Part II, Annex I of Regulation 2021/620).

Regulation 2021/620 has been amended five times since 2021 to add additional zones in Italy to the list of officially brucellosis free areas and once (in 2024) to remove an area from officially free into the list of areas implementing an approved eradication programme.

In November 2024, out of 19 Regions and 2 Autonomous provinces:

- 13 of the Regions plus 13 Provinces from the remaining six Regions, i.e. Abruzzo, Basilicata, Calabria, Campania Molise, Puglia and Sicily had been **declared free from B. abortus** according to EU legislation.

- 14 of them, plus 18 Provinces of the remaining five Regions: Basilicata, Calabria, Campania, Puglia and Piemonte Regions had **been declared free from B. melitensis**.

Other information

Further information on the national control systems for animal health can be found in the Country Profile for Italy at: <https://ec.europa.eu/food/audits-analysis/country/profile/details/IT>

A brucellosis-related audit took place in Italy in October 2013, DG(SANCO) 2013-6979 and the report is available at: <https://ec.europa.eu/food/audits-analysis/audit-report/details/3287>

5 FINDINGS AND CONCLUSIONS

5.1 IMPLEMENTING MEASURES

A clear legal basis is in place for Brucellosis control programmes which are aligned with EU requirements.

The current programmes came into effect from 01 July 2024.

1. The Decree of the Ministry of Health of 2 May 2024 provides the legal basis to support Italy's officially free status (in part of the territory) and for the implementation of the eradication programmes regarding bovine, ovine and caprine brucellosis. It was published in the Official Gazette on 30 June and came into force on 1 July 2024.
2. It consists of:
 - Part A (Programme for the eradication of bovine and ovine/caprine brucellosis in non-disease-free Provinces) and
 - Part B (Surveillance programme for bovine and ovine/caprine brucellosis in disease free Provinces).
 - A number of annexes which deal with specific issues, e.g. Annex 1a: Diagnosis of Brucellosis and Annex 1c: Guidelines on epidemiological investigations.
3. The current decree has evolved from earlier documents, such as a 10-year national eradication and surveillance programme for Category B Diseases which was approved by the European Commission on 31 May 2021. That programme was amended to harmonize the Italian legislation with the EU Animal Health including implementing regulations such as Commission Delegated Regulation 2020/689.
4. The Decree of 2 May 2024 allocates responsibility to the Directors-General of the Local Health Authorities “the objective of achieving and/or maintaining the disease-free status of the territory by carrying out 100 % of the planned checks on holdings

and animals in accordance with the legislation in force and a planned reduction of at least 10 % per year on a provincial basis in the prevalence of each disease.”

A range of user-friendly information systems are in place to support implementation of the programmes.

5. The achievement of the above objective shall be assessed by means of the information recorded in the national veterinary information system (“VETINFO”). The upload of the planning of controls in “VETINFO” is the base of calculation of a “DASHBOARD”, which provides a weekly update on the completion of planned veterinary activities performed during the implementation of the programme. These indicators are used at local, regional and national level to monitor the correct application of the plan and prevalence of the disease. The various IT platforms/databases were examined during the videoconferences and were found to be comprehensive and easy-to-use.
6. The Decree includes a comprehensive set of requirements for eradication and surveillance programmes (most of which existed previously but some are expanded/amended, e.g.:
 - Requirement for electronic identifications of animals;
 - Controls on movement of animals including to mountain pastures;
 - Controls on livestock dealers;
 - Guidelines for stamping-out;
 - Guidelines for epidemiological investigations;
 - Requirements for laboratory support.

Good cooperation between competent authorities.

7. The competent authorities have considerable experience implementing eradication plans and reporting on their implementation. They have developed sophisticated IT systems to help with the planning and reporting process.
8. There is good cooperation between competent authorities at different levels (central, regional, local). The Carabinieri Health Protection Unit (NAS) (a special department of the Carabinieri) operates in cooperation with the MH, e.g. for detecting illegal movements of animals.
9. The increased reporting of human Brucellosis in 2023 (74 confirmed cases¹ compared to 48 cases in 2022; 32 cases in 2021; 18 cases in 2020 – source the European Union One Health 2023

¹ For 2023, Italy did not provide EFSA with information on the origin (domestic/acquired overseas) of infection or any information regarding the typing of Brucella isolates in human cases.

74 human cases of Brucellosis in 2023.

One Health networks beginning to be developed.

Zoonoses report²) is notable. In part, this may be due to improvements in the reporting system. However, the veterinary authorities had little information about the infection pathway in these cases nor had they taken reinforced preventive measures. For example, they were unable to distinguish between occupational (e.g. farmers acquiring the disease when handling infected livestock) and foodborne (e.g. acquired as a result of consuming contaminated dairy products) cases. No specific campaigns to raise awareness of the potential risks or to mitigate them had been initiated. The competent authority stated that a One Health approach was being discussed and that One Health networks between veterinary, public health and environmental authorities were starting to be developed, especially in relation to Avian Influenza, but could also be relevant for Brucellosis.

Conclusions on implementing measures:

10. Official control activities undertaken within the eradication and surveillance programmes for brucellosis are well-organised and follow EU requirements for official control and activities. Overall, sustained progress is being made to reduce the national prevalence of Brucellosis in livestock species, in both disease-free and eradication areas. However, the upward trend in human cases has not yet been addressed.

5.2 CONTROLS IN OFFICIALLY FREE AREAS

Risk-based surveillance and monitoring activities are being implemented in officially brucellosis free areas.

11. There are comprehensive rules in Part B of the Decree of 2 May 2024 regarding risk-based surveillance and monitoring activities in officially brucellosis free areas. For example, the criteria for selecting and testing establishments differ depending on how long an area has been recognised as disease free.

There is a legal requirement that all cases of abortion are promptly investigated.

12. There is a legal requirement in the Decree that all cases of abortion are promptly investigated by means of diagnostic investigations at the IZS when the cause of the abortion has not yet been established by laboratory investigations. There was a similar requirement in a previous legal act (Article 6 of Decree 651, 1999).

CCA does not have direct access to data on the level

13. There were 2 positive results for brucella in abortions in officially free areas during 2022 and 2023. Although official laboratories in Italy carry out surveillance for Brucellosis on abortions (the control team saw evidence of 51 investigations of abortions in officially free

² <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.9106>

of surveillance being implemented on abortions throughout Italy.

areas during 2023 by the NRL), only positive results from free areas are notified to the national information system and the CCA does not have direct access to data on the level of surveillance being implemented on abortions throughout Italy. According to the CCA, this situation will change under the new Decree and it is planned that data for all abortions tested in official laboratories will be forwarded to the national informatics system once relevant IT systems have been updated.

14. The situation is different in the case of infected establishments. Here, the results of all investigations of abortions (positive and

Number of abortions tested for Brucellosis in official laboratories from infected establishments in non-free areas			
	Bovines	Buffalo	Sheep and Goats
2023	3 (2 positive)	45 (0 positive)	3 (0 positive)
2022	23 (3 positive)	64 (0 positive)	5 (0 positive)

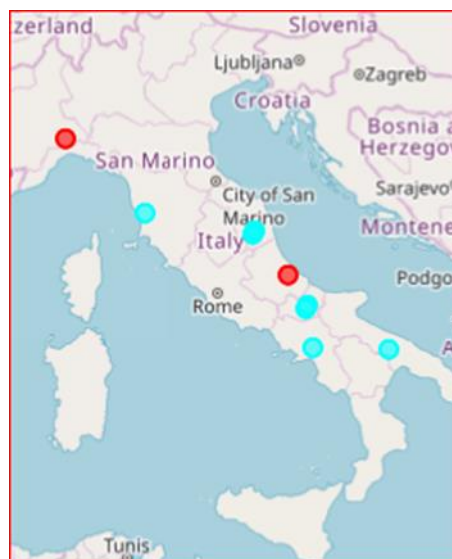
11 outbreaks of Brucellosis notified via ADIS in officially free areas in 2022/2023.

negative) are available to the CCA on the national IT system.

15. Between 2022 and 2023 there were 11 outbreaks of Brucellosis notified by Italy in officially free areas via the Animal Disease Information System of the European Commission (ADIS).

Map from ADIS indicating the location of outbreaks of during 2022 and 2023 in officially Brucellosis free areas

(Red= B Melitensis, Blue= B abortus)



2023 = 4 outbreaks (2 B. abortus and 2 B. melitensis)
 2022 = 7 outbreaks (6 B. abortus and 1 B. melitensis)

16. Up to 2022, many of the outbreaks in officially free areas were linked to legal movements from non-free areas. The competent authority strengthened the movement protocols and outbreaks originated via legal movements from non-free areas were reduced.
17. Since 2022, outbreaks in officially free areas have increasingly been linked to illegal movements, with Sicily often being suggested as the original source, based on genomic characterisation. The competent authority is still developing plans to detect and deter illegal movements in cooperation with other state bodies.

Management of outbreaks

Up to 2022, outbreaks in officially free areas often linked to legal movements from non-free areas.

Since 2022, outbreaks in officially free areas often linked to illegal movements from non-free areas.

Appropriate rules for managing outbreaks exist and are implemented with the exception of epidemiological enquiries.

18. The Decree of 2 May 2024 contains details for the “Management of suspected and confirmed cases” which are harmonised with the requirements of Regulation (EU) No. 2020/689. (Section 7 of Part A for non-free area and Section 5 of Part B for officially free areas.) The measures include restrictions on movements of animals and animal products, isolation of animals that might be infected, follow-up herd tests or stamping out with cleaning and disinfection as required.
19. An epidemiological enquiry is required for each outbreak and should be registered in the “DASHBOARD” IT system. The records indicated that 61.5% and 62.5% of epidemiological enquiries started in each year had been completed.
20. The control team examined the enquiry report for an outbreak confirmed in July 2023. It had several fundamental weaknesses including: no explanation why only 3 samples from a group of 13 seropositive animals were submitted for bacteriological testing; incomplete details (gender, age, breeding history) of the animals kept on the infected establishment; and no records/reference to forward tracing of relevant material or products that left the establishment.
21. The competent authority stated that it was aware of issues with epidemiological enquiry reports in the past and had drafted a specific Annex (1.c) for the Decree of 2 May 2024 in order to provide expanded guidance and instructions to official veterinarians in order to assist them to properly complete and record the reports.
22. The competent authority does not consider that wildlife plays any significant role in the spread of brucellosis in bovines, ovines or caprines. In recent years, *Brucella suis* has been isolated from wild

boar as part of specific studies.

Conclusions on controls in officially-free areas

Guidance for completing epidemiological enquiry reports has been strengthened due to issues in the past.

23. Appropriate programmes for surveillance and monitoring activities are being implemented in to maintain the officially free status. However, the central competent authority does not have access to the total number of abortions investigated throughout Italy. As a result, the sensitivity of the passive surveillance system cannot be assessed.

Wildlife is not considered to play any significant role in the spread of brucellosis.

24. Outbreaks of brucellosis in officially free areas in recent years are mostly linked to illegal movements from non-free areas in Italy and are controlled in accordance with the national programme. Expanded guidance on completing epidemiological enquiry reports has been provided in the Decree of 2 May 2024 in order to help address previous issues with reports.

5.3 CONTROLS IN AREAS UNDER ERADICATION PROGRAMMES

25. There are comprehensive rules in Part A of the Decree of 2 May 2024 regarding the eradication programmes of bovine and ovine/caprine brucellosis in non-disease-free areas which are harmonised with the requirements of Regulation (EU) No 2020/689.

26. The main objectives of the programme include:

Eradication programmes which are aligned with Regulation (EU) No 2020/689 are being implemented in non-disease-free areas.

- The regions and autonomous provinces shall submit eradication programmes for Brucellosis in a) bovines and b) ovines/caprines to the Ministry of Health, by a set date set in the year preceding the reference year.

- The objective of achieving brucellosis-free status shall be achieved by carrying out 100 % of the planned checks on establishments and animals in accordance with the legislation in force and a planned reduction over the five-year period of at least 10 % per year in the incidence of brucellosis in ovine and caprine animals and cattle on a provincial basis, and shall be assessed on the basis of the information recorded in the information systems, until the requirements for obtaining disease-free status are met, as provided for in Delegated Regulation (EU) No 2020/689.

- Recording implementation of the programme activities (e.g., annual testing of bovines 12 months old or more and ovine and caprine animals 6 months old or more on establishments, abortion surveillance and checks on animal movements) and their monitoring/assessment take place via the VETINFO portal.

27. Section 7.4 of the Decree deals with the “Identification and management of clusters of infection with brucellosis throughout the national territory” and requires a specific eradication programme to be drawn up by the relevant region containing the cluster area, in collaboration with the Regional Epidemiological Observatory, after consulting the NRL for Brucellosis. These programmes are included in the VETINFO portal.

Specific eradication programmes apply in cluster areas.

28. Several clusters have been identified, such as in buffalo establishments in the Province of Caserta in Campania Region and in both bovines and ovines/caprines in Sicily.

29. The Campania Region ascribe the persistence of the disease in the Province of Caserta to problems of biosecurity of establishments (irregular movement of the animals), contiguity of establishments and environmental contamination. There has also been a number of court cases in recent years brought by some keepers of buffalo who object to elements of the eradication programme and this has slowed down implementation.

An “extraordinary plan” is being implemented in Caserta since 2022 that includes vaccination of the young buffaloes.

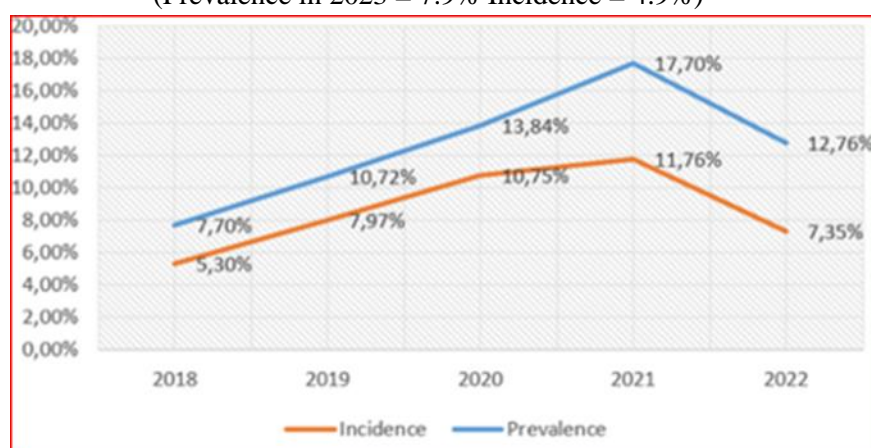
30. To address these critical points, the Campania region has prepared, with contributions from stakeholders, an “extraordinary plan” that includes increased controls and the vaccination of young buffaloes to limit the circulation of the disease between the animals but also the environmental contamination. This plan was approved by the European Commission and has been applied since 2022. (Vaccination had been implemented in Caserta between 2003 and 2014. Vaccination was stopped after the prevalence of brucellosis had fallen to acceptable levels.)

31. The plan is reviewed every six months by a group of representatives from the Ministry of Health, Campania Region, NRL for brucellosis and a few other bodies. This monitoring group ensures the implementation of the plan, propose solutions to any issues that arise and reports to stakeholders on the results of the plan.

32. In 2023, 6,634 female buffalo between 6-9 months of age on 267 establishment were vaccinated, along with 74 cattle of the same age on 23 establishments. Vaccination is obligatory in cluster areas and voluntary in surrounding buffer zones.

The prevalence in Caserta has decreased in recent years.

33. Data re Brucellosis in buffalo in the Province of Caserta (Prevalence in 2023 = 7.9% Incidence = 4.9%)



Sicily reports the most outbreaks of any region in recent years.

34. Sicily is the region with the most outbreaks of brucellosis in bovines and in ovines/caprines during 2022 and 2023 and has been implicated as the probable source of several outbreaks in free areas.

Brucellosis in Sicily

	Brucellosis in bovines		Brucellosis in ovines/caprines	
	Prevalence	No of outbreaks as % of national total	Prevalence	No of outbreaks as % of national total
2023	1.11 %	96 / 217 (44%) (not including buffalo = 71%)	0.36%	28 / 34 (82%)
2022	3.41%	187 / 346 (54%) (not including buffalo = 74%)	0.65%	59 / 66 (76%)

Conclusions on controls in areas under eradication programmes

35. Eradication programmes are achieving progress in some areas but not in all areas due to several significant challenges such as illegal movements from non-free areas; the continued circulation of the disease in several high incidence areas, such as Sicily (for all species) and in buffalo in Caserta. The competent authorities are continually reviewing measures to try to address these challenges but progress is slow and a constant threat to human and animal health remains.

5.4 LABORATORY SUPPORT

The NRL carries out a range of activities as required in Regulation 2017/625.

36. The Ministry of Health, by Decree of October 4, 1999, established the National Reference Laboratory (NRL) for Brucellosis at the central headquarters of the Experimental Zooprophyllactic Institute (Istituto Zooprofilattico Sperimentale - IZS) of Abruzzo and Molise in Teramo.

37. The NRL carries out a range of activities including:

- collaborates with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;
- coordinate the activities of official designated laboratories with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;
- organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;
 - validate the reagents and lots of reagents; and
 - conduct training courses for the staff of officially designated laboratories.

The NRL participates in the annual proficiency tests organised by the EURL with satisfactory results.

38. The NRL has participated in the annual proficiency tests organised by the EURL (ANSES, FRANCE) with satisfactory results over recent years, e.g.:

- Serological methods: Rose Bengal test and Complement Fixation test
- Culture and isolation of Brucella species.

39. The network of IZS's in Italy include 10 central offices and 79 peripheral laboratories, for a total of 89 laboratories covering almost all territorial provinces. All IZS's are accredited according to ISO/IEC 17025.

The NRL organises biennial proficiency tests for the 58 regional laboratories involved with brucellosis testing.

40. The NRL conducts proficiency tests every two years for IZS's that carry out tests for Brucella included in Section 1 of Annex III of Regulation 2020/689. 58 IZS's participated in the proficiency testing for the Rose Bengal Test (RBT), 32 laboratories for the Complement Fixation Test (CFT) and 15 for the milk ELISA test. One of the 58 laboratories involved in the RBT test and one for the milk ELISA test both had an incorrect result but the NRL followed up these results with both laboratories and helped rectify the situation.

Conclusions on laboratory support

41. The well-coordinated laboratory network provides appropriate support for the implementation of the national brucellosis control programme by providing reliable, high-quality diagnostic results and advice.

5.5 VERIFICATION OF IMPLEMENTATION OF BRUCELLOSIS PROGRAMMES

Legal requirements existed during 2022 and 2023 for the competent authority to verify the implementation of the brucellosis programmes.

42. Article 12.1 of Ministerial Decree No 28/05/2015, as amended (“Extraordinary veterinary policy measures concerning tuberculosis, bovine and buffalo brucellosis, ovine/caprine brucellosis and enzootic bovine leucosis”) states that the heads of the veterinary animal health services of the local health authorities carry out and document, as part of the checks on the effectiveness of the controls:
- “a) field checks on compliance with the procedures followed for the activities provided for by the provisions of this ordinance and the regulations in force on the subject;
 - b) checks, at least every 4 months, of compliance with the percentages and timing of the activity carried out monitored through ... “relevant IT systems, for a range of activities within the national control programme.

43. Article 12.2 requires the heads of the veterinary animal health services to report to the Ministry of Health on the findings of their verification of effectiveness and any corrective actions taken related to Art 12.1. Article 12.3 requires the national reference centres to periodically verify the quality and completeness of a significant number of epidemiological investigations, and to share their results with the relevant Region or autonomous province and the Ministry of Health.

Similar legal requirements exist under the Decree of 2 May 2024.

44. The Decree of 2 May 2024 continues this legal requirement with section 9 of Part A (area under an eradication programme) and section 8 of Part B (officially free areas) setting out responsibilities for the veterinary services of the local health authorities to implement various verification procedures, take corrective actions as required and record evidence of checks and corrective actions in the “VETINFO” IT system.

Every annual programme is drafted using the experience gained by implementing previous ones.

45. The NRL for brucellosis in collaboration with several other national bodies, prepares an annual report on the epidemiological situation and the surveillance and eradication activities, based on the data in VETINFO, and sends it to the Ministry of Health. The Ministry of Health convenes the Regions and Autonomous Provinces together

with the NRL and other national bodies, for a joint assessment and for the preparation of the new annual programmes.

Conclusions on verification of implementation of programmes

46. A well-developed system is in place to verify that the control programmes are implemented as planned and past experience is used to amend future programmes.

6 OVERALL CONCLUSION

In general, there is well-performing system of official controls for surveillance and eradication of brucellosis in relevant species which complies with EU rules. The Commission control detected no critical shortcomings.

A strong administrative framework, based on appropriate legal powers, resources (e.g. sufficient well-trained staff, well designed IT systems, good laboratory support), is in place to dynamically implement the surveillance and eradication programme. Regular reports indicate that the approved programme is generally implemented as intended. Some opportunities for improvement lie in passive surveillance and epidemiological enquiries after outbreaks for strengthening control in officially free areas.

The veterinary authorities face several challenges, which hinder the achievement of brucellosis-free status for all parts of Italy. These include sporadic outbreaks in disease-free regions and provinces, which are often linked to illegal movements from non-free areas; the continued circulation of the disease in several high incidence/cluster areas, such as Sicily (for all species) and in the buffalo population of Caserta. The competent authorities are continually adapting measures to try to address these challenges (such as re-introducing vaccination in the province of Caserta in 2023 or working with other state bodies to detect and stop illegal movements) but progress is slow.

The increased reporting of human Brucellosis in 2024 (74 confirmed cases) is notable. In part, this may be due to improvements in the reporting system. The veterinary authorities have little information about the infection pathway in these cases, nor have they taken reinforced preventive measures.

The above compounded with the lack of progress towards eradication targets pose serious questions on how the control system for surveillance and eradication of brucellosis in relevant species is being applied in practice.

7 CLOSING MEETING

The Commission team presented the main findings and preliminary conclusions, at the conclusion of the Commission control. The competent authorities thanked the team for its work and remained available to provide any additional information needed for the preparation of the report.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Regulation (EU) 2016/429	OJ L 84, 31.3.2016, p. 1–208	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')
Regulation (EU) 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)
Regulation (EU) 2018/1882	OJ L 308, 4.12.2018, p. 21–29	Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases
Regulation (EU) 2020/687	OJ L 174, 3.6.2020, p. 64–139	Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases

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Regulation (EU) 2020/689	OJ L 174, 3.6.2020, p. 211–340	Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases
Regulation (EU) 2020/2002	OJ L 412, 8.12.2020, p. 1–28	Commission Implementing Regulation (EU) 2020/2002 of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification and Union reporting of listed diseases, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system
Regulation (EU) 2021/620	OJ L 131, 16.4.2021, p. 78–119	Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases