European Commission

DG Health and Food Safety

COUNTRY PROFILE

Progress made in the implementation of audit recommendations

Health and Food Safety

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INTRODUCTION

The Directorate-General (DG) for Health and Food Safety of the European Commission carries out controls, primarily audits, aimed at verifying that EU legislation on food and feed, animal health and welfare, plant health and plant protection products, is properly implemented and enforced. This means EU citizens enjoy a high level of safety, and that goods are traded under safe conditions.

DG Health and Food Safety makes recommendations to Member States to deal with any shortcomings revealed during its audits. Member States are requested to present action plans on how they intend to address these shortcomings. Article 119(a) of Regulation (EU) 2017/625 requires that Member States take appropriate follow-up action in the light of recommendations resulting from European Commission controls.

DG Health and Food Safety evaluates these action plans and systematically monitors their implementation through a number of follow-up activities. Verification of the completion and effectiveness of corrective action is an integral part of this activity.

In 2005, DG Health and Food Safety introduced the instrument of general follow-up to review Member States' progress on the implementation of recommendations made. This general follow-up is carried out at regular intervals and provides an opportunity to discuss the full range of unresolved issues with the competent national authorities. In the period between general follow-ups, the competent national authorities may provide additional information on progress made in addressing recommendations and, following assessment by DG Health and Food Safety, this may result in some recommendations being closed.

The information in this part of the country profile has been compiled in the context of a general follow-up carried out by DG Health and Food Safety in May 2022. It provides a summary of progress made by Portugal on the implementation of DG Health and Food Safety's recommendations.

This part of the country profile will be updated at regular intervals based on the results of future DG Health and Food Safety audits and other relevant information received by Commission services from the authorities in Portugal.

SUMMARY OF THE PROGRESS MADE BY THE MEMBER STATE IN THE IMPLEMENTATION OF RECOMMENDATIONS MADE BY DG HEALTH AND FOOD SAFETY

The following table gives an overview of DG Health and Food Safety's audits in Portugal and shows the Commission services' assessment of actions taken in response to the recommendations contained in the reports of those audits. This assessment is based on a review of the information and documentation provided by the competent authorities.

The basis for the assessment of actions in relation to individual recommendations is presented in Sections 2.A and 2.B.1 to 2.B.12. Recent published audit reports that are not yet ready for follow-up are listed in Section 3.

Overview of DG Health and Food Safety's audits in Portugal 2011-2022

Control system	Total number of finalised audits	Recommendations				
		Total	Closed for Action taken	Closed for other reasons	In progress	Action Still Required
Horizontal	1	3	3	-	-	-
Animal Health	3	20	17	1	-	-
Food of animal origin	7	38	37	-	-	-
Import of animals and food of animal origin	4	11	8	3	-	-
Feedingstuffs and animal nutrition	2	13	13	-	-	-
TSE/ABP	3	10	7	3	-	-
Veterinary medicinal products and Residues	2	8	5	3	-	-
Foodstuffs and Food hygiene	6	36	32	3	-	-
Imports of food of plant origin	2	16	16	-	-	-
Plant Protection Products (Authorisation, Sustainable use and Residues)	4	28	23	4	-	-
Animal welfare	3	11	11	-	-	-
Plant health	13	79	35	37	-	-
Quality Labelling	2	24	17	7	-	-
Sub-total	52		-	-	-	-
Audits without recommendations	4					
Total	**56**	**297**	**224**	**61**	**12**	**0**
General follow-ups/Administrative follow-ups: 5						

The audits without recommendations mentioned above were related to nutrition and health claims (2017-6058), food labelling (2017-6062), import controls on transit (2018-6329), and animal welfare during export to non-EU countries (2022-7523).

1. ISSUES ARISING FROM DG HEALTH AND FOOD SAFETY AUDITS

The issues identified in Portugal through DG Health and Food Safety's audits that still need to be addressed by the authorities include:

1.1. Main issues covered in this country profile

1.1.1. Horizontal issues

There are no outstanding or longstanding recommendations concerning horizontal issues.

1.1.2. Sector specific

The competent authorities have proposed suitable corrective actions for all significant issues identified in Portugal through DG Health and Food Safety's audits.

1.2. Issues arising from published audit reports not included in this country profile

For three published audit reports, the related recommendations have not yet reached the follow-up stage for inclusion in the current country profile. The follow-up of these recommendations will be published in future country profile updates:

- The audit on official controls on animal by-products (ABP) and derived products (DP) (2022-7421) concluded that the infrastructure in place for collection, transport, handling, processing, and disposal of ABP and DP is largely satisfactory. Domestic legislation ensures the implementation of EU rules for ABP but contains some provisions that are not in line with EU legislation, for example the national rules for disposal of ABP from on-farm slaughter and the designation of areas categorised as remote. Other than in remote areas, official controls are in place along the chain of production of ABP and DP. While these controls are largely effective in ABP plants, they cannot reliably verify compliance with all the relevant requirements at food business operators, in particular dairy plants, slaughterhouses (for ungulates) and retail operators. The report contains six recommendations to the competent authorities to address the shortcomings identified.
- The audit on official controls relating to microbial safety of food of non-animal origin (2023-7739) concluded that the official control system is largely capable of identifying and rectifying deficiencies in the implementation of food safety requirements in the production chain for food of non-animal origin. However, its effectiveness is impacted by the fact that, first, not all processors are identified as such and therefore not covered by the controls and, second, that it is not geared towards those crops at primary production level which pose the greatest microbiological risks. In addition, the audit identified certain shortcomings in the controls over the application of good hygiene practices, *Listeria monocytogenes*, and the verification of Hazard Analysis and Critical Control Points systems. The audit also established that a suitable laboratory capability is in place but that the competent authority has not designated a national reference laboratory for foodborne viruses. Concerning follow-up of recommendation 2015-7461_1, progress was noted but the recommendation is not yet fully addressed. The report contains three recommendations to the competent authority to address the identified

shortcomings.

- The audit on monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (2023-7692) concluded that the official monitoring framework developed by the Portuguese competent authorities can, for the most part, achieve the objectives of Commission Implementing Decision (EU) 2020/1729. However, issues with delays in implementation and with temperature control may affect the comparability of data submitted to the European Food Safety Authority. The report contains three recommendations to the competent authorities aimed at rectifying the shortcomings identified and at enhancing the implementation of control measures in place.

Chapter 3 contains a list of published audit reports for which the follow-up status is not reflected in the current country profile, and a list of ongoing and planned audits.

The five most recent published reports are available at:

https://ec.europa.eu/food/audits-analysis/country/profile/details/PT

2. FOLLOW-UP STATUS OF RECOMMENDATIONS

This part of the country profile gives the current status of actions undertaken in response to DG Health and Food Safety's recommendations. The aim is to provide a summary of progress by Portugal on the implementation of our recommendations.

For the purpose of assessment, the terms: "Action taken," "In progress", "Closed for other reasons" and "Action still required" are defined as follows:

"Action taken": The competent authority has implemented appropriate measures to address the recommendation. The recommendation is therefore closed.

"In progress": The competent authority has initiated appropriate measures to address the recommendation but not all of the measures have been implemented. The recommendation therefore remains open.

"Closed for other reasons": For administrative, technical or legal reasons, follow-up of the recommendation is no longer appropriate. The recommendation is therefore closed.

"Action still required": Appropriate measures to address the recommendation have not been initiated by the competent authorities or are longstanding (i.e. not addressing the shortcomings in a timely fashion). The recommendation therefore remains open.

Given the nature and scope of the general follow-up, no verification through on-the-spot audits was carried out. The general follow-up is considered complementary to other follow-up actions and verifications that may be necessary and carried out as part of future sectoral audits by DG Health and Food Safety. Recommendations classified as “In progress" or "Action still required" are not necessarily considered to require immediate specific legal or administrative action on the part of the Commission services. These recommendations will remain the subject of monitoring by the Commission services to assess progress. If as a result of this monitoring the Commission services consider the situation in regard to any of these recommendations warrants additional action on its part, it will take the appropriate measures.

It should be noted that the number of recommendations in this overview does not represent, of itself, a measurement of the degree of responsiveness by the competent authorities or of the seriousness of the shortcomings. Some recommendations may be related to minor technical aspects while others may refer to more problematic, systemic, issues. Some may be resolved quickly, while others will require more complex and time-consuming action.

Acronyms are used throughout the following chapters for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex I as a guide for the reader.

2.A HORIZONTAL RECOMMENDATIONS

Audit 2017-6027 of 04 September 2017 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
2017-6027-1 To ensure that the audit process is subject to independent scrutiny as required by Article 4(6) of Regulation (EC) No 882/2004. Recommendation based on conclusion 18. Associated finding: 16.	**Closed due to action taken** IGAMAOT has not put in place arrangements for independent scrutiny of the audit process. As a consequence it misses an opportunity to receive inputs for promoting continuous improvement of the audit process. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 6 of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:* *IGAMAOT has defined in Dispatch No I/00028/DIR/18 the rules for the independent scrutiny of internal audit systems of the authorities within the framework of the official control systems for food safety, in order to comply with Regulation (EU) 2017/625, and for its own independent scrutiny.* *IGAMAOT's Management and Information Control Team (EM CGI) carried out an independent scrutiny between 30 May and 22 July 2022 on IGAMAOT's Multidisciplinary Audit Team of Regulatory Systems and Official Control Systems in the scope of Food Safety (EM AS), for audits carried out between 2019 and 2021. The final report was provided and presented satisfactory results, including recommendations for the continuous improvement of the EM AS.* ***The action taken addresses the recommendation.*** **<u>Background</u>** <u>First response (19/12/2017)</u> IGAMAOT stated that it asked the Minister of Agriculture, Forests and Rural Development to implement regular independent scrutiny, and proposed some solutions. <u>Second response (22/05/2018)</u> IGAMAOT clarified that the solution chosen was for regular external scrutiny of the IGAMAOT audit system to be based on: a) A review of the audit process, regularly carried out by the IGAMAOT internal audit service; and

Audit 2017-6027 of 04 September 2017 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
	b) An approval of the audit universe and the analysis of a risk-based planning carried out by the entities of the National Audit System on Regulation (EC) No 882/2004. Third response (29/05/2018) IGAMAOT clarified that: • IGAMAOT's independent scrutiny would take place approximately every three years, starting beginning from 2020. • For DGAV, IGAMAOT's Audit Team for Regulatory Systems and Official Control Systems in the scope of Food Safety (EM AS) will provide the independent scrutiny of their internal audit process. In the context of the 2019 GFA, IGAMAOT presented a copy of the Dispatch No I/00028/DIR/18 and stated that it endorsed the proposed solution. Section G of the Dispatch defines the competences and tasks of the Audit Team for Regulatory Systems and Official Control Systems in the scope of Food Safety (EM AS), and in point 2(f) and (g) indicated that the team is responsible for: (f) assessing the internal audit systems of the bodies referred to in (d), in particular within the framework of the official control systems for food safety, in complying with the same Regulation (Regulation (EC) No 882/2004); (g) conducting studies, investigations, surveys, analysis of exposures or claims, or other actions in its area of intervention. Moreover, Section I defines the competences and tasks of the Management and Information Control Team (EM CGI), and point 1(e) and (f) stipulate that the team is responsible for: e) evaluating internal control procedures in the IGAMAOT areas of activity, contributing to its continuous improvement; f) carry out analyses and issue recommendations on the revised activities to improve the internal functioning of the services. IGAMAOT stated that, in accordance with the endorsed EM CGI Plan, the review of the audit process will take place in 2020. During the 2022 GFA IGAMAOT is responsible for ensure the coordination of the National Audit System in the field of food safety under Regulation (EU) 2017/625 of the European Parliament and of the Council, of 15 March 2017, and also, under the

Audit 2017-6027 of 04 September 2017 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
	same regulation, for the development of external audits (horizontal) and evaluation of the internal audits made by the competent authorities. The organic unit that develops this audits in IGAMAOT is EM AS - *Multidisciplinary Audit Team of Regulatory Systems and Official Control Systems in the scope of Food Safety*. The independent scrutiny of its auditing procedures will be carried on 2022, by EM CGI – *Management and Information Control Team*. Despite the fact that the external scrutiny was scheduled for 2020, the same did not occur, given the reorganization of EM AS, with the appointment of a new Director Inspector, the departure of 4 senior inspectors, and the entry of 3 more trainee inspectors, precisely in January/2020, hampered by the COVID-19 pandemic, between 2020-2021. However, it is important to note that since 2018 all the control mechanisms listed in the 2nd response to the Directorate-General for Health and Food Safety of the European Commission, have already been implemented: all procedures have already been registered, through their computerization in an information management system, with control of entries, exits, reports, development of a risk analysis system, sample and criteria, adversarial procedure and audience of interested parties, as well as the publication of reports prepared in the respective institutional portal, ensuring transparency. Our reports are subject to approval by the Ministerial Guardianship and IGAMAOT develops *follow-up* actions in order to monitor the recommendations made, through follow-up actions to assess whether the proposed corrective and preventive action are sufficient to address the recommendations of the audit reports. The audits carried out by IGAMAOT, within the scope of Reg. UE 2017/625, comply with the provisions of the Commission Notice on a guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 of the European Parliament and of the Council 2021/C 66/02, of February 26, 2021. In fact, the external scrutiny is being prepared and will be accomplished in 2022, with the preparation of a report that will be send by IGAMAOT to the European Commission. In July 2022, IGAMAOT provided a copy of the final report of an independent scrutiny carried out between 30/05 and 22/07/2022 on the EM AS by the EM CGI, which covered EM AS activities from 2019 to 2021.

2.B SECTORAL RECOMMENDATIONS

2.B.1 Animal Health

Audit 2012-6402 of 24 September 2012 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
2012-6402-8 The CA should ensure that while keeping on working toward ISO 17025 accreditation of the tests performed for epizootic diseases (as required by Article 12 of Regulation (EC) No 882/2004) at the NRL, at short term is is also ensured that all tests are performed following complete and accurate standard operating procedures, in accordance with the European diagnostic manuals when available; Deviations from EU-reference laboratories protocols are adequately documented and validated;Equipment maintenance can guarantee compliance with relevant specifications.	**In Progress** This recommendation was based on the conclusion from Section 5.4 and related findings of the audit report. Although the NRL had the capacity to diagnose the main epizootic diseases, and its grade of preparedness in case of contingency was being improved with the development of its own contingency plan, it had not secured or adequately documented the alternative path for diseases it could not confirm. Despite the fact that none of the methods used were accredited, important elements of quality assurance were in place but they were still incomplete; moreover the tests lacked formal validation, which affected the assessment of the reliability of the laboratory performance. Regulation (EU) No 882/2004 has been repealed. The new relevant requirements are in Article 100(1), (2) and (3)(c) and (d) of Regulation (EU) 2017/625. ***Assessment (January 2024)**:* *INIAV underlined that the NRL for epizootic diseases participated in proficiency tests by EURL and succeeded with satisfactory results.* *In addition, INIAV presented information on the* status quo *of other validations and accreditations for epizootic diseases, including the validation of laboratories and equipment and accreditation of the laboratory for several epizootic diseases.* *The competent authority confirmed the accreditation for ELISA methods for peste des petits ruminants, sheep and goat pox and lumpy skin disease had been completed.* *The competent authority provided evidence that the NRL for peste des petits ruminants, sheep and goat pox and lumpy skin disease was visited by the accreditation body in May and June 2023 to assess the accreditation for PCR methods.* ***The recommendation status remains "in progress", until the competent authorities provide evidence (accreditation certificate) that the PCR methods for peste des petits ruminants, sheep and goat pox and lumpy skin disease are part of the accreditation scope of the NRL.***

Audit 2012-6402 of 24 September 2012 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
	Background First response (16/01/2013 - Ares(2013)53530): a) INIAV would continue with the accreditation of the tests for diagnosis of epizootic diseases, an evaluation audit by the Portuguese Accreditation Institute (IPAC) was scheduled for the second half of 2013, b) INIAV would carry out internal audits of all the technical procedures for assessing the degree of compliance with recommendations of the EU Reference Laboratories and the World Organisation on Animal Health - OIE Manual. c) INIAV would produce validation reports to demonstrate the equivalence of test methods other than the recommended ones (Bluetongue, African horse sickness and Epizootic haemorrhagic disease). During the 2014 GFA the Portuguese authorities stated that all test procedures are developed and are in accordance with protocols recommended by the European Union Reference Laboratories (EURLs) and their technical guidance. The maintenance of equipment was being carried out in accordance with operating procedures that were subject to an assessment by the Portuguese Accreditation Institute (IPAC). While they provided lists of tests approved by IPAC as part of their accreditation assessments, these lists contained no information on animal diseases. During the 2016 GFA INIAV stated that due to delays of construction works of the Virology laboratory in Oeiras, installation of the diagnostic equipment and accreditation have been postponed. INIAV expects installation and calibration of the equipment to be finished in June 2016. Only then it will request an accreditation audit from IPAC. Expected deadline for accreditation process to be completed is the first quarter of 2017. Despite of the above, INIAV stated that some departments of the laboratory already work according to the quality system established in the ISO 17025, and regularly participate in proficiency testing. Reference materials are ensured by access to certified reference materials provided by the EURL or available in the market. DGAV and INIAV provided copies of technical procedures for Avian Influenza tests (ELISA, Haemagglutination Inhibition Test and Blocking ELISA) and Bluetongue test (ELISA for Detection of antibodies), developed in accordance to protocols recommended by the EURLs and their technical guidance. INIAV stated that analytical laboratory procedures for these diseases are in place but some have not been validated yet. INIAV stated that an Annex to the Quality procedure for INIAV laboratories provides with the reference methods for sheep and goat pox, Rift valley fever and epizootic haemorrhagic disease of the deer. As so far diagnostic methods

Audit 2012-6402 of 24 September 2012 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
	for Rift valley fever and epizootic haemorrhagic disease of the deer are validated, while validation of analytical methods for remaining diseases is ongoing. In the context of the 2019 GFA INIAV stated as regards the three diseases, the status of validation and accreditation is the following: - for peste des petits ruminants, control materials and laboratory techniques (PCR and ELISA) are validated, and accreditation of the laboratory would take place by June 2020; - for sheep and goat pox, control materials and laboratory techniques (PCR) are validated too, and accreditation of the laboratory would take place by June 2020; - for lumpy skin disease, control materials and laboratory techniques (PCR and ELISA) are validated, and accreditation of the laboratory would take place by June 2020. INIAV underlined that the NRL for epizootic diseases participated in proficiency tests by EURL and succeeded with satisfactory results. INIAV stated that IPAC would carry out accreditation audit on the NRL for epizootic diseases in June 2019. Once the audit is completed the accreditation process would begin. In addition the INIAV presented information on the *status quo* of other validations and accreditations for other epizootic diseases; in brief: a) validation of control materials is in place for: FMD, HPAI, Newcastle disease, ASF, CSF, AHS, contagious bovine pleuropneumonia, glanders, Bluetongue and epizootic haemorrhagic disease. b) validation of laboratory equipment is in place for FMD (PCR and ELISA), HPAI (PCR, HI and ELISA), Newcastle disease (PCR and HI), ASF (IF, VI, PCR and ELISA), CSF (PCR and ELISA), AHS (PCR and ELISA), contagious bovine pleuropneumonia, glanders, Bluetongue (PCR and ELISA) and epizootic haemorrhagic disease (PCR). c) accreditation of the laboratory is to be completed by June 2020 for FMD, HPAI, Newcastle disease, ASF, glanders and epizootic haemorrhagic disease, and by December 2019 for CSF, AHS and contagious bovine pleuropneumonia. During the 2022 GFA The competent authority provided an update clarifying that: "*NRL for the epizootic diseases peste des petits ruminants, sheep and goat pox and lumpy skin disease is accredited for the laboratory technique ELISA since 2020/02/04."* The accreditation certificate was produced as evidence.

Audit 2012-6402 of 24 September 2012 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
	"NRL accreditation for the epizootic diseases peste des petits ruminants, sheep and goat pox and lumpy skin disease by PCR techniques could not be concluded in 2020, due to the pandemic situation, which occurred in 2020 and 2021. INIAV expects to complete the accreditation process during 2023 (PCR)", based on an IPAC audit to be carried out in October 2022. In November 2023, in the reply to the draft Country Profile, INIAV, I.P., indicated that and IPAC audit occurred in May/June of 2023 for the PCR tests but it was still waiting that IPAC sends the new accreditation certificate. The request to extend the scope of accreditation and the report of the IPAC audit report were provided.

Audit 2016-8773 of 29 February 2016 in order to evaluate the implementation of the bovine brucellosis and tuberculosis eradication programmes	
Recommendation	Basis for assessment/Information Requested/CA response
2016-8773-4 To ensure that laboratories that carry out the analysis of samples taken during official controls are designated, assessed and accredited by the CA as required by Article 12 of Regulation (EC) No. 882/2004. Recommendation based on conclusion No.:119. Associated finding No.:111.	**In Progress** The NRL was not accredited; this put in questions the quality and reliability of obtained test results. Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 100(2) of Regulation (EU) 2017/625. ***Assessment (January 2024)**:* *The competent authority addressed the part of the recommendation concerning bovine brucellosis providing evidence of the accreditation of the NRL.* *INIAV presented evidence of the progress in the validation and accreditation of the NRL for bovine tuberculosis (TBC) confirming that validation of control materials for TBC and validation of laboratory techniques is already in place (HP, BAC, PCR);* *The competent authority provided evidence of the accreditation body visit in May and June 2023 for obtaining accreditation for BAC and PCR methods for bovine tuberculosis.* ***The recommendation status will remain as "In Progress" until the competent authority provides evidence (e.g. accreditation certificate) that the NRL for bovine tuberculosis obtained the accreditation for BAC and PCR methods for bovine tuberculosis.***

Audit 2016-8773 of 29 February 2016 in order to evaluate the implementation of the bovine brucellosis and tuberculosis eradication programmes	
Recommendation	Basis for assessment/Information Requested/CA response
	https://www.dgav.pt/animais/conteudo/animais-de-producao/bovinos/saude-animal-em-bovinos/doencas-dos-bovinos/brucelose-bovina/ https://www.dgav.pt/animais/conteudo/animais-de-producao/bovinos/saude-animal-em-bovinos/doencas-dos-bovinos/tuberculose-bovina/ The NRL for bovine tuberculosis obtained accreditation for the laboratory technique HP in 2020. The accreditation certificate was provided as evidence. The NRL's accreditation for bovine tuberculosis BAC and PCR techniques could not be concluded in 2020, due to the COVID-19 pandemic situation, which occurred in 2020 and 2021. INIAV expects to complete the accreditation process during 2023 (BAC and PCR). In November 2023, in the reply to the draft Country Profile, INIAV, I.P. indicated that the IPAC audit occurred in May/June of 2023 for the Tuberculosis tests but it is still waiting that IPAC sends the new accreditation certificate. The request for the extension of the accreditation scope and the report of the IPAC audit were provided.

2.B.2 Food of animal origin

Audit 2013-6667 of 18 September 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
2013-6667-5 To ensure that sampling plans to check the microbiological quality of live bivalve molluscs take particular account of the likely variation in faecal contamination and certain parameters related to pollution, as required in Point B.3(a) and (b) of Chapter II of Annex II to Regulation (EC) No 854/2004.	**Closed due to action taken** This recommendation is based on findings from Section 5.3.2 and related conclusion of the audit report. The microbiological quality of live bivalve molluscs (LBM) is undermined by weaknesses in the monitoring programme, as the likely variation in faecal contamination in different species of molluscs and parameters related to pollution is not taken into account. *Regulation (EC) No 854/2004 has been repealed. The relevant requirements are in:* *- Article 18(1), (6), (7)(g), (8)(a) and (b) of Regulation (EU) 2017/625.* *- Article 61(2) of Implementing Regulation (EU) 2019/627* ***Assessment (July 2023)**:*

Audit 2013-6667 of 18 September 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
	IPMA provided an update of the sanitary surveys progress and provided evidence that all relevant harvesting areas were surveyed. T hese surveys help the IPMA identify, monitor and take into account the likely variation in faecal contamination and certain parameters related to pollution for the classification of the areas. ***The actions implemented by the competent authority (IPMA) address the recommendation.*** **<u>Background</u>** <u>First response (16/03/2014)</u> IPMA stated that by the end of 2014 it will finalise desk studies and compilation of historical microbiological data as part of the sanitary surveys. Final sanitary survey reports will be ready by the end of 2015. <u>Second response (23/06/2014)</u> IPMA stated that is enlarging the sampling to the species that exist in the different production areas. IPMA also initiated studies that will enable to consolidate the choice of some species as indicators. <u>During the 2016 GFA</u>, IPMA provided a copy of the updated sampling programme which includes all species, sample locations and the frequency. IPMA stated that currently conducts sanitary surveys for 40 areas and expects to conclude the surveys for all these areas between 2016 (desk studies) and 2017 (margins assessments). IPMA presented a summary table illustrating the progress of the sanitary surveys for different LBM production areas. <u>In the context of the 2019 GFA,</u> IPMA confirmed that sanitary surveys have been completed for 31 production areas; for the remaining 10 production areas, desk studies are in progress. IPMA explained that delays are a consequence of late approval of financial support and consequently delays in contracting further human resources. They expect to complete all the sanitary surveys by the beginning of 2020. <u>During the 2022 GFA</u> IPMA indicated that two reports with 2nd edition have already been finished due to the fact that there have been significant changes in the existing species in the harvesting area and/or boundaries of the area. Currently, only 7 reports need to be finished (1st edition), with 4 expected to be completed in 2022 and 3 in 2023 (ref doc: 2013-6667_5Annex I). The referred extension of the deadline for completion of the latest reports are a consequence of the data being dispersed by different entities and sometimes are difficult to obtain, and in particularly also due to periods of

Audit 2013-6667 of 18 September 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response

	confinement and the imposition of minimum services during the COVID-19 pandemic felt in 2020 and 2021 in Portugal, delaying the sampling and subsequent analyses in the laboratory.
	The reduced number of sanitary studies reports related to the harvesting areas numbers is due to the fact that some authors have chosen to combine more than one harvesting area in just one report due to the area of influence being the same.
	The main consequence of one report having more than one harvesting area is the increased complexity in its elaboration due to the compilation of information as well as a greater extension of places to visit during the shoreline surveys and a greater number of samples to be collected for microbiological analyses within the scope of the sanitary study.
	IPMA provided information that points to sanitary studies (17) being completed for 25 harvesting areas, out of 43 (13 coastal and 30 estuarine or lagoon) in total (58,2%). The sanitary studies were completed between May 2018 and January 2022 (1st editions). One sanitary study (2nd edition), for 1 harvesting area, was completed in March 2022. The dates to complete the remaining sanitary studies range from end of 1st semester of 2022 (4 surveys for 15 harvesting areas) to end of 1st semester of 2023 (3 surveys for 3 harvesting areas).
	IPMA further confirmed that:
	• The total number of active harvesting areas in Portugal is 40 (27 estuarine/lagoon areas + 13 coastal areas), instead of 43, as publicly available at https://www.ipma.pt/pt/bivalves/zonas/ and in Despacho n.º 1550/2022 of 8 February:
	  ○ three areas (Mondego EMN and EMN 1/2) no longer have natural banks of live bivalve molluscs, which is stated in the sanitary surveys for these areas.
	  ○ one area (POR 1) is not listed due to a prohibition of harvesting on the basis of non-compliant results.
	• There are fewer reports of sanitary surveys than harvesting areas because in some cases it was decided to make a report on several areas (ex: Ria de Aveiro (RIAV1/2/3/4), Ria Formosa (FAR1/2, OLH1/2/3/4/5, FUZ, TAV and VT)
	• The current status of the sanitary surveys is:

Audit 2013-6667 of 18 September 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
	○ Complete – L1, L2, L3, L5, L7a, L7b/c1/c2, EMI, ELM (Ed. 01), ELM (Ed. 02), Ria de Aveiro, Mondego (EMN1/2 – Ed. 01), Mondego (EMN – Ed. 02), LOB, LAL, Mira, Sado, Arade (POR3) and Guadiana ○ Final Review – Ria de Alvor, Ria Formosa and Tagus ○ Complete desk studies – L4, L6, L8 and L9 ○ Total gives 25 and there are only 23 final reports because 2 of them are second editions.
2013-6667-13 To ensure that the recognised testing methods established in Article 3 of Regulation (EC) No 2074/2005 are used to determine marine biotoxins, that the methods used are accredited according to Article 12.3 of Regulation (EC) No 882/2004 and that the monitoring of lipophilic toxins includes the testing of all the compounds described in Chapter III of Annex III to Regulation (EC) No 2074/2005.	**Closed due to action taken** This recommendation is based on findings from Section 5.6 and related conclusion of the audit report. The laboratory testing for biotoxins uses analytical method for detection of lipophilic toxins that had not been validated by EU legislation. Moreover detection of pectenotoxins, yessotoxins and azaspiracids is not performed. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 37(5)(c) of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:* *IPMA confirmed that monitoring and testing for lipophilic toxins includes the testing of all the compounds described in Chapter III of Annex III to Regulation (EC) No 2074/2005, including azaspiracids, pectenotoxins and yessotoxins and presented copies of validation reports for paralytic shellfish toxins and lipophilic toxins.* *During the 2022 GFA, IPMA provided the accreditation certificate of IPMA's laboratory for the method liquid chromatography coupled with mass spectrometry for testing of lipophilic toxins.* ***The action taken addresses the recommendation.*** **<u>Background</u>** <u>First response (16/03/2014)</u> IPMA stated that, in 2013 it began validation of the analytical method for determination of lipophilic biotoxins following the reference method (LC-MS/MS) stipulated in Regulation (EC) No 15/2011. IPMA expects to finalise the validation process in the first half of 2014. IPMA scheduled the accreditation process for early July 2015. Once the method receives validation IPMA will include all lipophilic biotoxins (stipulated in Regulation (EC) No 2074/2005) in regular monitoring programme.

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Recommendation	Basis for assessment/Information Requested/CA response
	During the 2016 GFA IPMA explained that following a significant investment in new equipment for the Biotoxins laboratory (to improve laboratory analytical performance), the validation of the analytical method for determination of all lipophilic biotoxins has been completed. In the 3rd semester of 2016 IPMA expects to submit accreditation request to IPAC. IPMA stated that: a) the Biotoxins laboratory follows the European reference method for lipophilic toxins (EU-Harmonised-SOP-LIPO-LC-MS/MS), b) the laboratory participated in proficiency test for lipophilic toxins promoted by the European Reference Laboratory (EU-RLM), and c) it obtained satisfactory results in 2014 (okadaic acid group) and in 2015 (okadaic acid group, azaspiracids and yessotoxins). While in 2014 and 2015, the monitoring of lipophilic toxins in LBM from classified production areas was made (using the European Reference method) for the okadaic acid group only, during the second trimester of 2016 IPMA began monitoring for the remaining lipophilic toxins groups such as azaspiracids, pectenotoxins and yessotoxins. In post GFA correspondence (October 2016) IPMA presented the validation report of the method for lipophilic toxins (European reference method EU-Harmonised-SOP-LIPO-LC-MS/MS). IPMA stated that following the acquisition, in 2016, of a second LC-MS/MS equipment, the Biotoxins laboratory started validation process of the analytical method for determination of lipophilic biotoxins also in the new LC-MS/MS equipment. This validation is ongoing. In the context of the 2019 GFA IPMA confirmed that monitoring and testing for lipophilic toxins includes the testing of all the compounds described in Chapter III of Annex III to Regulation (EC) No 2074/2005, including azaspiracids, pectenotoxins and yessotoxins. IPMA stated that: - it awaits the final document from accreditation body (IPAC) confirming obtaining the accreditation according to ISO/IEC 17025 for liquid chromatography coupled with mass spectrometry for testing of lipophilic toxins - group okadaic acid (OA, DTX2 and DTX1). - validation study was currently ongoing for Paralytic shellfish toxins (liquid chromatography with fluorescence detection), lipophilic toxins - group (pectenotoxins, azaspiracids and yessotoxins - liquid chromatography coupled with mass spectrometry) at the time of this GFA.

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Recommendation	Basis for assessment/Information Requested/CA response
	IPMA expects that IPAC would carry an accreditation audit in July 2019. In its response to the Draft Country profile (June 2019) IPMA presented copies of validation reports for paralytic shellfish toxins and lipophilic toxins. During the 2022 GFA IPMA stated that PTX have been removed from the health standards for live bivalve molluscs in Commission Delegated Regulation (EU) 2021/1374 of 12 Abril 2021 and Commission Implementing Regulation (EU) 2021/1709 of 23 September 2021. IPMA's laboratory has the accreditation certificate for the liquid chromatography coupled with mass spectrometry for testing of all lipophilic toxins method (ref doc: 2013-6667_13Annex II).

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Recommendation	Basis for assessment/Information Requested/CA response
2018-6378-1 To ensure that the implementation of the approval procedures followed respect the EU rules, in particular Article 31 (2) (c) and (d) Regulation (EC) No 882/2004, and that those procedures are correctly applied by all relevant competent authorities. Recommendation based on conclusion No 44 Associated findings Nos 41 and 42	**Closed due to action taken** In one autonomous region, the approval of a freezer vessel did not respect the EU rules, in particular Article 31(2)(c) and (d) of Regulation (EC) No 882/2004. *Regulation (EC) No 882/2004 has been repealed. The new relevant requirements are in Article 148(3) and (4) of Regulation (EU) 2017/625.* ***Assessment (January 2024)*** : *DGAV provided examples of official controls for approval and conditional approval of establishments (including for fishery products) and requests for clarifications to the regional services.* *DGAV (DSSA) confirmed that the documented procedure for approval of establishments was updated in May 2022 and that the draft Manual of Procedures for the Approval of Food Establishments, as well as the respective attached documents - Operating Procedures, Work Instructions, and forms of official documents, was completed on 4 July 2022 and communicated to all DSAVRs and autonomous regions for implementation.* ***The actions taken address the recommendation.***

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Recommendation	Basis for assessment/Information Requested/CA response
	Background First response (13/05/2019) Currently, both the DGAV and the Autonomous Region of Madeira follow the approval procedures described in point 7 "Approval" of the Plan for the Approval and Control of Establishments, 2012-2016 The Autonomous Region of the Azores has its own documentation, and the approval procedures are described in the document "Pace-Açores-Instruções de Trabalho". ("Pace- Azores-Working Instructions"). However, it should be noted that, since the separation between the Establishments' Control Plan (official control) and the approval procedures (official control task as defined in Regulation (EU) 2017/625) was carried out in 2018, the DGAV is currently in the process of finalizing the Manual of Approval Procedures, which shall be used by all the Entities with competence to Approve. In this Manual, in addition to all the procedures to be adopted following an application for approval of an establishment/activity, there are checklists adaptable to each activity, which shall be used in the inspection prior to the approval. These lists, allow verifying and confirming that the establishment complies with all legal requirements for final or conditional approval. This Manual also contains the obligation for the team responsible for the control prior to approval to be mixed, i.e. consisting of a technical officer assigned to the approval and a technical officer assigned to the official control. This Manual of procedures, and in particular the use of specific checklists, will make it possible to verify that the approved establishment complies with the relevant requirements as regards food law. Second response (02/10/2019): The Manual of Approval Procedures will be completed by the end of this year and will be implemented in 2020, not only in the Mainland, but also in the Autonomous Regions. The approval procedures adopted by the DGAV will be supervised in 2020 by the Central Services (Directorate for Food Safety) and will be included in the audit programme of the Audit Centre of the DGAV as of 2021. Attached Draft Manual, Related Work Instructions, and Checklists. Third response (21/07/2021 - Ares(2021)4957125) DGAV stated that it has not yet been possible to complete the Approval Procedures Manual. The COVID-19 pandemic, coupled with the fact that DGAV has applied for and been involved in a funded project for the development

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Recommendation	Basis for assessment/Information Requested/CA response
	of a new SIPACE information system, was the reason for the delay in completing this Manual. However, DGAV expects to be able to finalize it by the end 2021 (a draft copy of the Manual dated 18/12/2017 was attached) The procedure implemented for the approval of establishments includes the evaluation by the Central Services (DSSA) of the result of the control (official control report) that led to the proposal for approval. • Final approval is only granted if compliance with all legal requirements for food hygiene and safety is demonstrated. • Conditional approval can only be granted if compliance with all legal requirements regarding infrastructure and equipment is demonstrated. When the conditions are considered not to be met, no approval or conditional approval is granted. In the SIPACE system, the control performed prior to approval is registered and the respective report file is attached, after approval is granted, and the system automatically schedules the next control for one year later (if final approval) or 3 months later (if conditional approval). The procedures described above are already in point 2 of annex IV to the PACE-GA. Examples of conditional approval, final approval, favorable opinion to final approval and unfavorable opinion to final approval were provided. Copies of checklists (templates) used during the official controls of operators and of the PACE - GA 2020-2021 (version 31/01/2020) were provided. <u>During the 2022 GFA</u> DGAV (DSSA) indicated that the Manual of Procedures for the Approval of Food Establishments, as well as the respective attached documents - Operating Procedures, Work Instructions, and forms of official documents, are currently being debated with the Regional Services in monthly meetings, so that in July 2022 these new documents can be fully implemented. Thus, given the need for standardization of procedures, in addition to the Procedures Manual, the following documents are being debated: • Operational Procedure applicable to the Approval of industrial establishments. • Operational Procedure applicable to the Approval of commercial establishments (cold stores); • Form of the Official Control report applicable to approval official controls; • Work Instruction for registration of Approval procedures in the official database - SIPACE; • Working Instruction in the case of Controls with other competent authorities;

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Recommendation	Basis for assessment/Information Requested/CA response
	After the conclusion of the discussions, expected to take place in June 2022, we will conclude the release of the Manual. DGAV confirmed that, since 2018, all requests for approval (under licensing process, where DGAV issues a technical opinion) are reviewed by DSSA. Regional directors draft reports on official controls for approval (all legal requirements met), which accompany a note to the Director General proposing a decision. Another official control after approval will be carried out within (maximum) a year. There are differences in the format of the DSAVRs reports and templates will be included in the Manual of Procedures. DGAV provided a copy of the procedure for approval *PROCEDIMENTO OPERACIONAL PO1 Aprovação de estabelecimento industrial – Fase de vistoria prévia). DGAV provided examples of official controls for approval and conditional approval (including for fishery products operators) and requests for clarifications to regional services. With regard to internal audits, in September 2021, the Directorate for Food Safety was audited within the scope of PACE - foodstuffs - meat and milk, including approval procedures (audit no. 11/DGAV/NA/2021), with a very satisfactory outcome: • Audit programme of DGAV's Audit Centre for 2021 (2018_6378_1_annex I) • Audit programme of DGAV's Audit Centre for 2022 (2018_6378_1_annex II) • Report of audit nº11/2021 (2018_6378_1_annex III) In November 2023, in the reply to the draft Country Profile, the competent authority indicated that the DGAV's Manual of Approval Procedures was finalised and released in July 2022 and implemented from that date by the DGAV and the Autonomous Regions. Evidence of an email of 04/07/2022 addressed to all DSAVRs and the autonomous regions of Azores and Madeira, with the new Manual and respective working instructions, was provided.
2018-6378-2 To ensure the timely and effective follow-up of the correction of deficiencies identified during controls and the implementation of	**Closed due to action taken** Inspections to establishments within the frequencies set in the official control programmes and timely and effective follow-up of the correction of deficiencies noted during the controls presented shortcomings due to unavailability of human resources in one region, and incorrect implementation of the programmes in another region. This non-

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Recommendation	Basis for assessment/Information Requested/CA response
controls on the production chain following the frequency defined in the in the official control plans. Recommendation based on conclusion 34, 88 and 89 Associated findings 12, 65, 66, 69, 80, 81 and 83	adherence to the set frequencies weakens the ability of the control system to effectively verify and enforce compliance of the EU rules by the operators. ***Assessment (May 2022):*** *A new supervision manual, prepared by DGAV, in response to changes in official control plans, risk analysis and measures in case of non-compliance, contains provisions and actions taken by DGAV to ensure that official controls are consistent and effective. This manual lays down procedures and inspection frequencies that, although postponed due to the COVID-19 pandemic, were implemented accordingly in 2021. Examples of supervision activities and follow-up were provided.* ***The actions taken address the recommendation.*** **Background** First response (13/05/2019) The main objective of the revision of the PACE plan in 2018 was to improve the effectiveness of the official controls. The adoption and taking of more serious sanctioning measures in case of non-compliance with G3 and G4, associated with the payment, by the Economic Operators, of additional controls (unplanned or regular) carried out when there are serious non-compliances, has shown an increase in the effectiveness of controls. This can be seen in the reduction in 2018 of establishments with GC3 and establishments with GC4. Between 2018 and the present date, 14 establishments and/or activities have been suspended for serious non-compliances (repeated GC4 or GC3). The lifting of the suspensions of these establishments/activities only occurred after the correction of all non-conformities detected. By increasing the effectiveness of the official controls, we will be able to reduce the effort of controls to ensure the correction of non-compliances, and thus meet the defined frequency of regular controls. In April 2014, Circular 14_DSSA_2018 was sent to all associations and Economic Operators, informing them of the measures that would be adopted by the DGAV in the event of non-compliance. It should be noted that the 'SIPACE COD' is being implemented, a computer tool which will increase the efficiency of official controls, since Control Reports and notifications will henceforth be produced automatically, just by filling in the check list. This tool will make it possible to reduce the "time" spent on the official control, in particular on the

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Recommendation	Basis for assessment/Information Requested/CA response
	manual preparation of the Control Reports and the notifications. Second response (02/10/2019): The DGAV has authorized the external procurement of 20 veterinarians to strengthen the staff of technical staff performing official controls of the Regional Services. This procurement is currently awaiting approval from the Ministry of Finance. For the region identified in the Report, it has already been strengthened with 2 new senior officers in order to ensure that controls are carried out as planned. Authorization Document from the DGAV Secretariat of State for the opening of tender procedures for the reinforcement of human resources for official controls. Third response (21/01/2020): In 2019 the affected region had 8 official controls (OC) planned in fishery products establishments. From these planned controls, 6 OC were carried out by this region in 2019 and the remaining 2 are going to be carried out until the end of the month. Attached you will find the data of the official controls carried out and planned for this region. In conclusion, 75% of the planned OC in fishery products establishments were carried out in the affected region. As for the supervisory oversight regarding the action taken by the CA in case of non-compliance, it is established that the central coordinator (DSSA) of each specific area of this control plan (PACE - Food) is responsible for the regular monitoring of the OC with compliance degree 3 and 4. In 2019 there were no OC in fishery products establishments, in the affected region, with compliance degree 3 and 4. Additionally this official control plan establishes 10 documentary supervisions to be carried out by the central services (DSSA). The controls with compliance degree 3 and 4 are the ones which are primarily subject to documental supervision, that's why there was no documental supervision in 2019.

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Recommendation	Basis for assessment/Information Requested/CA response
	Fourth response (07/05/2021): In 2020, a new Manual of Verification Procedures (Supervisory Manual) was prepared and disseminated by the Regional Directorates, which contains the provisions and actions taken by the DGAV to ensure that the Official Controls, under the Official Control Plans to establishments, are consistent and effective. The need to draft this Manual to replace the previous Manual resulted from the fact that the official control plans, including the risk analysis and the measures in case of non-compliance have undergone changes in 2018 and from the need to harmonize and adapt the verification of official controls according to the new rules. (Annex - Supervisory Manual) The strategic objectives of this new Verification Procedures Manual are: a) To ensure the effectiveness of Official Controls; b) To promote uniformity of procedures and actions, including actions taken following Official Controls: I. By the Technical Executives, within each region; II. By the different DSAVR/DR-RA. c) To foster an attitude of constant improvement of the Official Control system, ensuring that the necessary conditions are created to diagnose the weaknesses of the Official Control system and the opportunities for improvement, in order to take the necessary corrective measures to maintain a high level of consumer protection and food safety; d) To improve the quality of the information entered into the system for registering establishments and Official Controls (SIPACE); And the operational objectives are: a) To carry out the number of local/regional supervision actions defined annually by the DSSA; b) To carry out the number of central/national supervision actions defined annually in the different official control plans; c) To carry out the verification controls as defined in this Manual. This Manual also includes the types of supervision (documentary and on-site), the methodology to be used and the documents to be used in supervisions carried out both centrally and regionally. (Annex: Supervision Report/ PACE/Supervision

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Recommendation	Basis for assessment/Information Requested/CA response
	Registration map/PACE) At central level, as described in the Control Plan of Approved Establishments (PACE GA), the coordinator of each section (Meat and Meat Products, Fishery Products, VML, Dairy Products, Eggs, and others) must carry out 10 inspections per year, covering all regions including the Autonomous Regions. Given the atypical year of 2020, as a result of the Pandemic, the procedures in this Manual only started this year. The number of supervisions that each Region must perform is proposed centrally and disclosed annually. (attached email 2021) (Annexes: Supervision_Unit_ objectives/ Numerical objectives_Supervision/Supervision objectives /PCON) The measures taken in the event of nonconformities detected by the Regional Directorates for Food and Veterinary (DSAVRS) include clarifications requested from the DSAVR coordinator of the Directorate for Food Safety (DSSA), raising the awareness of the technical staff involved, holding a meeting with the DSSA, carrying out training and proposing the amendment of the Official Control Plan. The measures in case of non-conformities detected by the Central Services include clarifications provided by the DSSA coordinator to the DSAVR coordinators, a meeting held between those involved in supervision, training and a proposal to amend the Official Control Plan. We are sending examples of supervisions (6 documents annexed). We send an example of central supervision carried out in 2019 prior to the procedures implemented with the Handbook: (1 document annexed) We also attach evidence of the completion of the two C.O.'s that remained to be controlled in 2019 in the region under review. (4 documents annexed).
2018-6378-3 To ensure that establishments freezing in brine shall have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of no more than -18°C as required	**Closed due to action taken** The methods/equipment used to freeze tuna fishery products, in particular the brine freezing in one establishment on land, do not comply with the EU rules. Despite that the food business operators are allowed by the competent authorities to operate and freeze products not in accordance with those EU rules. ***Assessment (May 2022)*:** *The competent authority provided evidence that it suspended the activity of freezing in brine in the relevant establishment since 2020.* ***The action addresses satisfactorily the recommendation.***

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Recommendation	Basis for assessment/Information Requested/CA response
under Section VIII, Chapter III point B of Regulation (EC) No 853/2004. Recommendations based on conclusion 90 Associated findings 78 and 79	**Background** First response (13/05/2019) In response to the draft report the CA noted that the Regional CA has instructed the operator to address the non-compliance and some measures will be in place during the 2019 season to ensure compliance with Section VIII, Chapter III, Point B of Regulation (EC) No 853/2004. The Regional Competent Authority has notified the operator to resolve this non-compliance and the operator has replied that it will do so immediately. As described above, in order to comply with the provisions of Annex III, Section VIII, Chapter III, Part B of Regulation (EC) No. 853/2004 of 29 April 2004, the freezing procedure for brine tuna during the 2019 season will be carried out in such a way that freezing reaches -18°C as soon as possible, with monitoring of the temperature of the brine water and the product three times a day, until continuous monitoring is in place. Frozen tuna in brine is intended exclusively for the canning industry, and this mention is made on each batch of tuna shipped and appears on its labelling. Second response (02/10/2019): The supplementary response received from the CA did not provide further clarification for recommendation 3. Third response (21/01/2020): The establishment 'Entreposto Frigorífico do Caniçal' (Caniçal Cold Storage) registered with the Veterinary Control Number (VCN) 1349 PP, is equipped with a system for freezing fishery products in brine, in particular small tunas (skipjack 5 to 6 kg). This fish freezing tank, in brine cooled to -20°C, allows the fish to be frozen at -18°C. Considering what was found during the audit, and that it did not meet the 'requirements for frozen products', in particular those laid down for freezer vessels in Chapter I, Part I.C, point 1. "Have freezing equipment with sufficient power to rapidly lower the temperature of the products to an internal temperature not exceeding - 18 °C". The following was requested from the operator at a meeting held between the two parties on 15 January 2020 at 10:00 a.m. (according to the attached minutes): 1- The freezing of tuna in brine shall comply with Regulation (EC) No 853/2004 of 29 April 2004 «the premises must be equipped with freezing equipment of sufficient power to lower the products to a rapid internal temperature below

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Recommendation	Basis for assessment/Information Requested/CA response
	- 18 °C.» 2- Thus, the operator must demonstrate in his system, based on the HACCP principles: 2.1- To set the amount of fish to be frozen in the freezing tank in brine to ensure a rapid lowering of the temperature to -18 ºC; 2.2- To monitor the temperature of the brine water at the beginning and during freezing, in order to maintain a temperature of -20ºC, and thus submit the fishery products to a rapid temperature lowering. 2.3- To monitor the principle Temperature/Time of Frozen Fishery Products so that the freezing is fast and the internal temperature does not exceed - 18 °C. This action plan will be established as soon as the tuna harvest begins in the Autonomous Region of Madeira, usually in April and/or May 2020, under the supervision of the official entity. It has been agreed with the operator that, if the freezing equipment does not allow for the provisions of Regulation (EC) No 853/2004 of 29 April 2004, the activity of freezing in brine will be suspended until it is guaranteed that it complies with the provisions of the above mentioned law. Fourth response (07/05/2021): The competent authority chose to refer only to recommendation 2, as the others have already been accepted. Fifth response (21/07/2021 - Ares(2021)4957125) DGAV indicated that the activity of freezing in brine of the establishment "Entreposto Frigorífico do Caniçal", with the approval number 1349 PP, was suspended from the year 2020. Copies of message from DRADR Madeira and relevant records from SIPACE were provided.
2018-6378-4 To ensure that official controls cover all the checks described in Annex III, Chapter II of Regulation (EC) No 854/2004, in order to ensure compliance with Regulation (EC) No 1881/2006 as regards the	**Closed due to action taken** The official controls of fishery products are carried out by DGAV and ASAE as planned and, in general, in line with the EU rules except for testing for the presence of inorganic tin in canned fishery products, which is not in line with Chapter II (D) of Annex III to Regulation (EC) No 854/2004. *Regulation (EC) No 854/2004 has been repealed. The new relevant requirement is Chapter I(D) of Annex VI of Commission Implementing Regulation (EU) 2019/627.* ***Assessment (July 2023)***:

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Recommendation	Basis for assessment/Information Requested/CA response
testing for inorganic tin in canned foods. Recommendation based on conclusion 112 Associated finding 98	*DGAV provided a final report on the monitoring of total tin in the eight operational canneries in Portugal, including in the Azores. 17 samples were collected and the results obtained were all below the detection limit (LD). The operators' past own-controls on tin in fishery products did not detect non-compliances. Therefore, they decided to stop doing the analyses and trust on the DoC (Declaration of Conformity) of the cans.* *As for the detection method, the approach was, in the absence of a method for researching inorganic tin, to research the total tin and, if this value was high, proceed with the quantification of inorganic tin, as provided for in Regulation (EC) No 333/2007. The laboratory used was the LFQ - Physical-Chemistry Laboratory, of the DRAL - Department of Food Risks and Laboratories of ASAE and the test method used was by Atomic Absorption Spectrometry, QMI method code - 126. Both laboratory and method are accredited to EN ISO/IEC 17025.* ***The actions taken address the recommendation.*** **Background** First response (13/05/2019) The DGAV, in the official control of the FBO premises, uses a Checklist set up within the official control plan for the establishments (PACE), that includes the verification of the legal requisites for contaminants provided by REG 1881/2006 (point G26) and also FCM provided by REG 1935/2004 (point G20). DSAVRs inspectors check the auto control measures set up by the FBO to evidence the compliance of the requisite regarding tin maximum level, which are set within HACCP plan. No non compliances were detected on our official control regarding this matter. Moreover we could not find any other evidence that indicates tin in canned fish is an actual risk, for instance RASFF. So, in conclusion, the compliance with Regulation (EC) No. 1881/2006 for tin in canned fish is assured by the tools that the DGAV has in place within the official control. Second response (02/10/2019): The ASAE reaffirms that its Food Safety Laboratory (LSA) determines annually total tin in canned fish products, within its National Sampling Plan (PNCA), which has the objective to verify and assure that the food placed on the market does not represent a risk to human health. ASAE's LSA is actually studying the possibility of the separation of organic and inorganic tin to be able to implement and validate the method. It is currently not possible to guarantee its immediate inclusion in the mentioned sampling plan.

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Recommendation	Basis for assessment/Information Requested/CA response
	Third response (21/01/2020): In recent years, the DGAV has not considered inorganic tin as a relevant hazard in our risk assessment. After the consultation made by the DGAV with associations and authorities in the sector, it was reported that it is currently rare that canning fish industries use tin foil as packaging material in cans. The vast majority or almost all of the canning industries use aluminum. In order to meet the Commission recommendation, a survey is being carried out with the services that regularly monitor the canning industries and it has not yet been possible to find exhaustive data to highlight this situation. To address the tin control requirement, the DGAV will develop the following measures in the 2020 control plans that will involve the regional services: 1. During 2020, on the basis of the existing monitoring reports and monitoring visits the Regional Directorates (DSAVRs) shall make a comprehensive survey of the canned fish establishments using the packaging material concerned; 2. During the course of this year, in establishments still using tin, samples will be taken for analytical control of the tin. For that purpose, as part of the PACE (Control Plan for Approved Establishments) controls, a specific instruction concerning establishments in the fish canning industry will be included, which includes: - as a first step, the risk assessment of this contaminant which involves the checking of the material used as packaging material, - in a second stage, if tin-coated sheet metal is used (e.g. tinplate), a sample will be taken to determine the tin content. 3. The expenditure relating to the determination of tin in an official control laboratory shall be covered by the budget of the DGAV. Fourth response (07/05/2021): The competent authority chose to refer only to recommendation 2, as the others have already been accepted. Third response (21/07/2021 - Ares(2021)4957125) Due to the COVID-19 pandemic, the DGAV indicated that the controls planned for 2020 could not all be performed, so regretfully the DGAV could not carry out the actions proposed to address the recommendation.

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Recommendation	Basis for assessment/Information Requested/CA response
	As in the first part of 2021 the situation was also particularly difficult, the DGAV is now implementing the control in question and expects to have the data to answer the recommendation in the end of the year. The analyses will be carried out at Neotron, the Italian laboratory that quantifies the inorganic tin in the product. During the 2022 GFA In July 2022, DGAV submitted the Total Tin Monitoring Report in tuna cans. DGAV carried out a monitoring plan that included the collection of samples in canned goods that currently work with tuna in the country (8) (mainland Portugal and the Autonomous Region of the Azores) and resulted in the collection of 17 samples. The results obtained – all below the detection limit (LD) corroborate the information that DGAV had already sent to the Commission, that operators, faced with the history of regular negative controls, withdrew this analysis from their control, always based on the DoC (Declaration of Conformity) of the cans to support this decision. As for the detection method, the approach was, in the absence of a method for researching inorganic tin, to research the total tin and, if this value was high, proceed with the quantification of inorganic tin, as provided for in Regulation (EC) No 333/2007. The laboratory used was the LFQ - Physical-Chemistry Laboratory, of the DRAL - Department of Food Risks and Laboratories of ASAE and the test method used was by Atomic Absorption Spectrometry, QMI method code - 126 of 07/09/2021. Both the laboratory and the method used are accredited to EN ISO/IEC 17025.

Audit 2020-7119 of 09 November 2020 in order to evaluate the control system in place for live bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
2020-7119-1 To ensure that the classification of production areas, the monitoring of production areas for microbiological quality and for biotoxins and the decisions taken following the microbiological monitoring are	**Closed due to action taken** As, in general, the classification of production areas is consistent with the EU classification requirements and supported by recommendations from sanitary surveys, there is confidence that the level of contamination of molluscs harvested corresponds to the value expected according to their classification. The provisional classification based on a reduced number of results may overestimate the microbiological quality of molluscs.

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Recommendation	Basis for assessment/Information Requested/CA response
carried out in line with Articles 54.2 and 3, 57, 61 62 and 63 of Regulation (EU) 2019/627. Recommendation based on conclusions Nos 24, 27, 28 and 29. Associated findings Nos 4, 8, 13 and 16 (a)(b) and (d).	The few cases where the results of the microbiological monitoring of class B production areas do not provide an exact result (number) pose a challenge to the decisions for reclassification and/or closure of these production areas. The fact that IPMA: • i) does not close or reclassify the production area when certain regulatory limits for microbiological quality are exceeded; • ii) reverts the classification downgrade without an evaluation of the results for the review period; • iii) excludes unexpected results without conclusive investigation, may result in the placing on the market of bivalve molluscs not meeting the health standards. The current monitoring programme for biotoxins covers most of the requirements of EU legislation but the fact that the IPMA does not fully respect the sampling points and frequencies diminishes its value. ***Assessment (May 2022):*** *The competent authority (IPMA) has reviewed and implemented a procedure for the reclassification and monitoring of production areas for microbiological quality and for biotoxins, which is now in line with EU legislation. A list of sampling points for marine biotoxins was provided.* ***The actions satisfactorily address this recommendation.*** **Background** First response (17/03/2021) IPMA indicated that it would review its procedure MB01 in line with Articles 54(2) and (3), 57, 61, 62 and 63 of Regulation (EU) 2019/627, and review the proposal of next classification accordingly, until the end of 2nd semester in 2021. Second response (13/07/2021) IPMA indicated that the revision of procedure MB01 includes the reclassification and monitoring methodologies according to the Articles 54(2) and (3), 57, 62 and 63 of Regulation (EU) 2019/627, and provided a copy of the procedure. An example of reclassification of European Oyster in ESD1, according to Articles 54(2) and (3) of Regulation (EU)

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Recommendation	Basis for assessment/Information Requested/CA response
	2019/627 was provided. The list of indicator species and sampling points for marine biotoxins, according to procedure MB03 was provided.
2020-7119-2 To ensure that the training and supervision of non-official samplers when sampling classified production areas for monitoring according to Article 59 of Regulation (EU) 2019/627, provide enough guarantee that the sampling is reliable. Recommendation based on conclusion No 25. Associated finding No 5.	**Closed due to action taken** IPMA staff take monitoring samples, but also individual harvesters, harvesters' associations or aquaculture production companies with a contract with IPMA. In the last years, IPMA started to supervise these samplers; since the beginning of 2020, its objective is to supervise 35% of them every year. IPMA confirmed its intention to formalise all this in a procedure to ensure that samples taken in the context of official monitoring are reliable. ***Assessment (May 2022):*** *IPMA developed a new procedure to reflect the current practice on training and supervision of official and non-official samplers and has implemented it.* ***The action addresses the recommendation .*** **<u>Background</u>** <u>First response (17/03/2021)</u> IPMA indicated that a new procedure to reflect the current practice on training and supervision of official and non-official samplers was concluded and provided a copy. <u>Second response (13/07/2021)</u> IPMA provided an example of training and supervision procedure of non-official samplers.
2020-7119-3 To ensure that analytical method used for classification and for microbiological monitoring of production areas, required respectively by Articles 52 and 59 (b) of Regulation (EU) 2019/627, provides reliable analytical results; and that the analytical method to	**Closed due to action taken** The results of microbiological analysis using non-accredited testing methods are not reliable and thus they generate the risk of misclassification of the areas. However, this risk is limited to only some of the monitoring samples of two of the 39 classified production areas. Although the IPMA laboratory for lipophilic toxins routinely uses the EU analytical reference method to determine these toxins, the use of a non-recognised method on certain occasions means that the result in this biotoxin group, could be sporadically non-reliable or underestimated. ***Assessment (July 2022):***

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Recommendation	Basis for assessment/Information Requested/CA response
detect lipophilic toxins comply with the requirements of Chapter III.B of Annex V to Regulation (EU) 2019/627 in all the cases. Recommendation based on conclusions Nos 26 and 53. Associated findings Nos 7 and 47.	*IPMA implemented a number of measures to address the recommendation, including a statistical study on the influence of time between sample collection and analytical result and consequent impact on result reliability, and the acquisition and date for validation (end 2022) of LC-MS/MS equipment.* ***The actions satisfactorily address the recommendation.*** **Background** First response (17/03/2021) IPMA indicated that it is carrying out a statistical study on the influence of time in sample results to prove that arrival later 24h up 36h does not affect results, until the end of 2nd semester of 2021. It also informed that, until the end of the 1st semester of 2022, it will acquire and validate the LC-MS/MS equipment, to reinforce the analytical capacity of the Biotoxins Laboratory. Second response (13/07/2021) IPMA indicated that the statistical study is ongoing and provided a copy of the official request for the acquisition of LC-MS/MS equipment. During the 2022 GFA IPMA informed that: Due to periods of confinement and the imposition of minimum services during the Covid-19 pandemic that continued to be felt in 2021 in Portugal, it was not possible to meet the date set for the conclusion of the study. A statistical study was performed to determine the maximum period (hours) acceptable between the sampling collection time and the start time of the microbiological test so that the results can be used for the sanitary classification of the harvesting areas (The final version of this study was provided). The LC-MS/MS equipment was delivered at IPMA Marine Biotoxins Laboratory on the April 5th of 2022. The equipment installation should be completed by the end of May 2022 and the equipment results' validation should be completed by the end of 2022 (The equipment's delivery document was provided). DGAV informed that: *Finding 17*- This is not the responsibility of the DGAV. IPMA classifies the production areas, determines and communicates to the competent entities and operators, according to the results of the monitoring carried out, the prohibition of harvesting and marketing of live bivalve molluscs.

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Recommendation	Basis for assessment/Information Requested/CA response
	Finding 18- Until the end of 2019, RASFF notifications were sent to ASAE, IRAE and the competent services of DGAV and the respective competent services of the autonomous regions. Whenever deemed necessary, coordination with the other CAs was carried out. Since the beginning of 2020, the SCP of the RASFF began to communicate directly, and depending on the subject. This includes also the contact points of IPMA and DGRM. *Finding 21*- The DGAV elaborates, coordinates and executes the official control plan for establishments approved under Regulation 853/2004 (PACE-GA), which includes the control of establishments with activities in Section VII and VIII of Annex III of that Regulation. In the framework of these official controls, compliance with the requirements for establishments handling marine gastropods, tunicates and echinoderms, as provided for in Article 11 of Regulation (EU) 2019/624, is checked. The Information system for the management of these controls allows the identification of establishments handling those species.
2020-7119-4 To ensure that there is a competent authority with responsibilities to withdraw from the market molluscs that can pose a risk for consumers, in line with Article 14 of Regulation (EU) No 178/2002, and to carry out official controls of marine gastropods harvested outside classified production areas, as required by Article 11 of Regulation (EU) 2019/624. Recommendation based on conclusion No 30.	**Closed due to action taken** The flow of information regarding monitoring results and the prompt update of available information helps the system to avoid mistakes due to delays. However, the cooperation between authorities could be improved and the absence of designated authorities for some parts of the food chain create the risk of molluscs unsafe for human consumption being placed on the market. ***Assessment (July 2022):*** *IPMA provided evidence that the two competent authorities that were contacted (ASAE and DGAV) have clarified their powers and competence to withdraw molluscs from the market, when they may pose a risk to consumers.* ***The action addresses the recommendation.*** **Background** First response (17/03/2021) IPMA sent letters to the potential competent authorities that may be appointed to deal with withdraw from the market molluscs that can pose a risk to consumers. Copies of letters addressed to ASAE and DGAV were provided. Second response (13/07/2021) IPMA sent reminder letters to the potential competent authorities requesting an update and provided copies. During the 2022 GFA

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Recommendation	Basis for assessment/Information Requested/CA response
Associated findings Nos 17, 20 and 21.	IPMA informed that: • ASAE's competencies can be consulted on pages 2 and 5-7 of the document "Promoção da cooperação operacional entre as Autoridades Competentes responsáveis pelo controlo oficial/fiscalização de moluscos bivalves vivos (MBV)" of March 15th of 2021, and • DGAV's competencies can be consulted on pages 2 and 7-9 of the same document.
2020-7119-5 To ensure that the harvesting of live bivalve molluscs in closed classified production areas is prevented, as required in Article 62.1 of Regulation (EU) 2019/627. Recommendation based on conclusion No 31. Associated finding No 23.	**Closed due to action taken** There are indications that Japanese clams harvested in forbidden areas regularly reach the market. The current design and implementation of official controls on licensed harvesters and registration documents does not prevent the placing on the market of quantities of molluscs much higher than those physically possible to catch by licensed harvesters and of molluscs from forbidden areas. ***Assessment (July 2022):*** *IPMA provided evidence that the two competent authorities that were contacted (Maritime Police and GNR) have clarified their powers and competence to withdraw molluscs from the market, including when illegal harvesting is identified, when the molluscs may pose a risk to consumers.* ***The action addresses the recommendation .*** **<u>Background</u>** <u>First response (17/03/2021)</u> IPMA sent letters to the potential competent Authorities that may be appointed to deal with preventing harvesting of LBM in closed classified production areas. Copies of letters addressed to PM & GNR-UCM were provided. <u>Second response (13/07/2021)</u> IPMA sent reminder letters to the potential competent authorities requesting an update and provided copies. <u>During the 2022 GFA</u> IPMA informed that: • Maritime Police's (PM) competencies can be consulted on pages 1 and 3-5 of the document "Promoção da cooperação operacional entre as Autoridades Competentes responsáveis pelo controlo oficial/fiscalização de moluscos bivalves vivos (MBV)" of March 15th of 2021, and

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Recommendation	Basis for assessment/Information Requested/CA response
	• GNR's competencies can be consulted on pages 2 and 12-16 of the same document. DGAV informed that: The AMN-PM is responsible for the policing, surveillance and monitoring of port areas and their activities (including harvesting of LBMs), as well as for monitoring aquaculture establishments. Port captains' offices post notices announcing the start or end of the prohibition of harvesting. The ASAE inspects the entire food chain of LBMs, including the production and fine-tuning of LBMs, the purification and dispatch centres, distribution (which includes transport, logistical distributors, warehouses and distributors), retail and catering. The GNR, specifically the Coastal Control Unit, has supervisory responsibilities in the phases of harvesting, transport and commercialization of LBMs.

Audit 2022-7438 of 07 February 2022 in order to evaluate the control systems in place governing slaughter hygiene and meat inspection requirements	
Recommendation	Basis for assessment/Information Requested/CA response
2022-7438-1 The central competent authority should ensure that the relevant guidelines concerning the poultry meat sector (including those related to ante-mortem inspection at the holding of provenance) are updated to ensure that they are in line with the requirements of relevant EU legislation. Recommendation based on conclusion No 6.	**In Progress** National legislation and guidelines necessary to ensure implementation and/or enforcement of the EU requirements applicable to the meat sector are in place and they are largely in line with EU legislation, with the exception of one guideline, which was not up-to-date and, as a result, certain provisions of its content are contrary to EU legislation. ***Assessment (January 2024):*** *The competent authority proposed to repeal an outdated order and to update the "Poultry Meat Inspection Manual" (on ante-mortem inspection) to remove the references to the outdated dispatch and to ante-mortem inspection in the holding of provenance. Nonetheless, this action can only be implemented when more staff are recruited.* *For this purpose, a Common tender procedure to fill 90 posts in the DGAV in the special career of Veterinary Inspection, was published on 26/01/2024 (Aviso nº 2063/2024).* ***The recommendation status will remain as "in progress", until the competent authority provides evidence of the amended "Poultry Meat Inspection Manual".*** **<u>Background</u>**

Audit 2022-7438 of 07 February 2022 in order to evaluate the control systems in place governing slaughter hygiene and meat inspection requirements	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings Nos 3 and 48.	First response (24/05/2022) DGAV Dispatch 23/G/2016 will be repealed and Chapter III Part A of the Poultry Meat Inspection Manual (on ante-mortem inspection) will be adapted to remove the references to this dispatch and to AMI in the holding of provenance. The repeal document is being prepared. The amendments are expected to be completed by the end of June 2022. In November 2023, in the reply to the draft Country Profile of the 2022 GFA, the competent authority indicated that the repeal of the DGAV Dispatch 23/G/2016 will only be possible with the reinforcement of resources, the authorisation of which is awaited. A Common tender procedure to fill ninety (90) posts in the special career of Veterinary Inspection in the form of appointment, to the DGAV was published on 26/01/2024 (Aviso nº 2063/2024).

2.B.3 Imports of animals and food of animal origin

There are no recommendations currently open for follow-up.

2.B.4 Feedingstuffs and animal nutrition

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6633-1 To ensure that official controls are capable of verifying that feed business operators meet the requirements on hazard analysis and critical control points (HACCP) in accordance with Articles 6 and 7 of Regulation (EC) No 183/2005, and that the effectiveness of such controls is guaranteed, as required	**Closed due to action taken** Although the inspection planning system was based on appropriate risk-related factors and thus ensured that the official controls were carried out regularly, on a risk-basis and with appropriate frequency, the effectiveness of the inspections was weakened by under-implementation and deficient assessment of operators' HACCP-plans. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 5(1)(a) of Regulation (EU) 2017/625.* ***Assessment (January 2024)**:* *DGAV delivered training sessions at national level, including in the autonomous region of the Azores and for stakeholders. Seven training sessions were organised from April 2022 to October 2023, emphasizing the relevant hazards connected to feed according to the nature and origin of feed additives and other ingredients, which would*

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
by Article 4(2(a)) of Regulation (EC) No 882/2004. Recommendation based on conclusion: 34. Associated finding: 22.	*enable inspectors to carry out an adequate evaluation of feed business operators' risk assessment. The competent authority provided copies of the programmes, which covered all the necessary areas of control.* *In terms of ensuring that official controls are carried out as required, the competent authority confirmed that feed controls are supervised centrally and that internal audits were carried out on this area of controls in 2018, 2022 and 2023.* ***The actions address the recommendation.*** **Background** First response (9 and 16/03/2020): DGAV proposed to increase national training, emphasizing the relevant hazards connected to feed according to the nature and origin of feed additives and other ingredients, allowing an adequate evaluation of feed business operator's risk assessment. A course for official inspectors was already proposed for 2020, to be conducted in three training sessions to involve all five regional services (DSAVRs) of DGAV and if possible the Autonomous Regions of Madeira and Azores. In the context of the 2022 GFA, the competent authority explained that training had been delayed due to the COVID-19 pandemic but that the first session had already been held in April 2022 for the official staff dealing with feed in the Azores. The Competent authority provided a copy of the programme, which covered all the necessary areas of control. However, it was uncertain how many more sessions would be organised and how these sessions would cover the necessary numbers of staff carrying out controls on feed. Attendance to BTSF training was also confirmed and the competent authority explained how the knowledge gained during these sessions was disseminated to other officials. In terms of ensuring that official controls are carried out as required (including verification on the effectiveness of training), the competent authority confirmed that feed controls are supervised centrally and there are internal audits carried out on this area of controls. In November 2023, in the reply to the draft Country Profile, the competent authority indicated the training activities that have been carried out in 2022 and 2023 (the programmes of the training sessions were provided): • 2022-04-26 to 29: Azores (Terceira), DSV/ DRA Açores, 26h, 14 trainees. • 2022-10-24 to 27: Barcelinhos, DSAVRN, 26h, 11 trainees.

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
	• 2022-11-23 and 24 and 29 and 30: Lisbon, DSAVRLT / DSAVR Alentejo, 26h, 16 trainees. • 2023-01-23 and 24 and 2023-03-16 and 17: Viseu, DSAVRC, 26h, 19 trainees. • 2023-10-23 to 25: Santarém, Stakeholders and DSNA/DAA, 21h, 25 trainees. Due to lack of human resources at central level (DSNA/DAA) no supervision checks have been carried out at regional level. Documentary checks are carried out at central level on the execution of the physical control under the Animal Feeding Official Control, which samples are inserted by regional services into the data base system SIPACE. DSNA/DAA also evaluates the labels of products sampled, as well as the technical evaluation of laboratory results, which are communicated to regional services for eventual further actions. The last audits carried out in the scope of animal nutrition were as follows (copies of the audit reports for the first two were provided): • An audit was carried out in 2018 at DSNA-DAA regarding the Official Animal Feed Control Plan. This is an audit that is Open, due to the lack of presentation of concrete actions related to a Recommendation described in the Final Audit Report and which is as follows: "Establish supervision mechanisms in order to monitor documentary controls inserted in the SIPACE platform, taking into account what is described in point 4.1.21." • An audit carried out at the Veterinary Services of the Regional Directorate of Agriculture in the Autonomous Region of the Azores regarding the Animal Feed Control Plan; Approval, Operation and Control of Centers, Organisations and Activities Related to Semen, Ova and Embryos. In this audit, situations relating to animal nutrition were verified, the responsibility of which lies with the Central Service responsible for the matter (DSNA-DAA), and which gave rise to 3 Recommendations. The recommendations were closed because they were accepted by the Audit Unit, the corrective actions presented by that Unit. • An audit was carried out in 2023, in a Regional Service (DSAVRA) regarding the Official Animal Feed Control Plan. In this audit, situations were verified, the responsibility of which lies with the Central Service responsible for the matter and which, in this case, is the DAA. The Preliminary Report of this audit was prepared by the Audit Center and this Report contains a chapter dedicated to the central service where the situations mentioned above are described. The DSNA-.DAA is currently in the process of presenting comments on the findings.
2019-6633-2	**Closed due to action taken**

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
To ensure that official controls are capable of verifying feed business operators' fulfilment of obligations on appropriateness of retained samples taken, as required by the section on "Quality control" of Annex II to Regulation (EC) No 183/2005. Recommendation based on conclusion: 34. Associated findings: 28 and 29.	The new inspection planning system is based on appropriate risk-related factors and thus ensures that the official controls are carried out regularly, on a risk-basis and with appropriate frequency. However, the effectiveness of the inspections is weakened by under-implementation, deficient assessment of operators' HACCP-plans and incomplete verification of the appropriateness of operators' retained samples. ***Assessment (May 2022):*** *DGAV updated and improved the checklist for official controls on feed establishments for 2020 under the national feed official control plan (CAA). It also sent an email to the Secretariat of the translation services of the Council of the European Union in order to amend the Portuguese version of part 4 of section "Quality control" of Annex II to Regulation (EC) No 183/2005 where requirements on the taking retained samples of ingredients had been missing (Annex III).* *DGAV sent a notice to the National Association of Compound Feed Manufacturers (IACA) in order to clarify the requirements and mistranslation and the need to inform stakeholders (Annex IV).* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (9 and 16/03/2020):</u> In what concerns Finding 28, DGAV has already taken actions. For this check list inspection report for 2020 under national feed official control (CAA) at establishment level was already updated and improved (Annex II, Section 6.3.5.). In what concerns Finding 29, DGAV has already sent an email to the Secretariat of the translation services of the Council in order to amend the Portuguese version of part 4 of section "Quality control" of Annex II to Regulation (EC) No 183/2005 where requirements on the taking retained samples of ingredients had been overlooked (Annex III). DGAV has also sent a notice to the National Association of Compound Feed Manufacturers (IACA) in order to clarify this situation and the need to clarify stakeholders (Annex IV).
2019-6633-3 To ensure that official controls are designed and implemented in such a	**Closed due to action taken** The many minor deficiencies in the quality of labelling suggested that the competent authority's verification of the correctness of labelling was not sufficient to guarantee operators' compliance with labelling requirements.

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
way as to allow the compliance of feed business operators with labelling requirements, stipulated by Article 16 of Regulation (EC) No 1831/2003 and Chapter 4 of Regulation (EC) No 767/2009, to be verified consistently. Recommendation based on conclusion: 34. Associated finding: 33.	***Assessment (January 2024):*** *DGAV provided evidence of an improved "Guidance for non-compliances under Feed Official Control" in order to define the subsequent measures to take in case of non-compliances, i.e. after identification of labelling deficiencies at operator level.* *IACA with DGAV had also developed a national Code of Good Practices (CGP) for labelling.* *DGAV strengthened the official controls under the official feed control plan (CAA) aiming to verify that feed business operators comply with relevant labelling requirements by organising reinforced checks in the submission of labels by feed business operators to regional DGAV Services (DSAVR) followed by documentary evaluation with an adequate checklist based on a template. This was a one-off exercise to provide an initial view of the issues identified and inform the next steps. Checks on labels have been included in planned inspections and carried out routinely as part of controls since 2020.* *DGAV provided a summary of the outcome of checks on labels and non-compliances detected during reinforced checks and a summary of the non-compliances detected during the checks carried out between 2020 and 2022.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (9 and 16/03/2020)</u> Guidance for non-compliances under Feed Official Control issued by DGAV central level was already improved in order to define the subsequent measures to adopt after the verification of a non-compliance label at feed business operator establishment level (Annex V, Sections I.1., III.2.and III.3.). <u>Second response (23/06/2020)</u> Reinforce label controls will be considered under the official feed control plan (CAA), by regular submission of labels by feed business operators to regional DGAV Services (DSAVR) followed by documentary evaluation with adequate check list according to annexed template. DGAV is also working with IACA (National Association of compound feed manufacturers) on a national CGP for labelling. <u>In the context of the 2022 GFA</u>, the competent authority confirmed: "IACA with DGAV have developed a national CGP for labelling" (this was provided as evidence).

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
	In what concerns the submission of labels from FeBOs for DSAVR, under a reinforced labelling control, it has commenced in 2020 following the message from DAA on September 2020 to all DSAVR. (Copies of the answers from regions was provided as evidence). The competent authority explained that the submission of regional labels for central checks was a one-off exercise to provide guarantees of awareness and inform the next steps. Checks on labels were then added to the requirements for official controls and added to planned inspections. In November 2023, in the reply to the draft Country Profile, DGAV provided the following data: • Data from reinforced labelling control – 2020 DSAVR No FeBO No Labels No Officials No Incorrect Norte 11 48 1 6 Centro 26 115 5 25 LVT 26 123 7 17 Alentejo 14 57 * 9 Algarve 2 4 1 2 TOTAL 79 347 15 59 * Control carried out by DAA • Frequency for labelling checks and expected number of checks under CAA A. Labels evaluation at inspection level B. Labels evaluation from sampling for analysis (a copy of the label is required) All data inserted in SIPACE 2020 - A. Inspections (76) - 60 (79%) / B. Physical control (667) - 170 (25,5%) - TOTAL=230 2021 - A. Inspections (120) - 81 (67,5%) / B. Physical control (1564) - 225 (14,4%) - TOTAL=306 2022 - A. Inspections (127) - 59 / B. Physical control (1641) - 262 - TOTAL=321 • Findings from labelling checks – Inspections 2020 - Conformity (CD1) - 34 (57%) / Non-conformity (CD2) - 26 (43%) 2021 - Conformity (CD1) - 49 (60,5%) / Non-conformity (CD2) - 30 (37%) / Non-conformity (CD3) - 2 (2,5%) 2022 - Conformity (CD1) - 33 (55,9%) / Non-conformity (CD2) - 19 (32,2%) / Non-conformity (CD3) - 7 (11,9%) CD – Compliance Degree on labelling indicator evaluation during inspection

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
	• Findings from labelling checks – Physical control 2020 - Conformity - 149 / Non-conformity - 21 (a) 2021 - Conformity - 194 / Non-conformity - 31 (b) 2022 - Conformity - 200 / Non-conformity - 62 (c) (a) 4 inadequate labelling + 17 analytical tolerances deviation (b) 31 analytical tolerances deviation (c) Findings from labelling checks – Inspections
2019-6633-4 To ensure that staff carrying out official sampling, laboratories performing analytical testing and staff interpreting the analytical results, follow the requirements laid down by Article 1 and Annex I and II to Regulation (EC) No 152/2009. Recommendation based on conclusions: 51 and 52. Associated findings: 49 and 50.	**Closed due to action taken** The effectiveness of official sampling was weakened by the competent authorities' failure to adhere to planned arrangements and by the fact that the representativeness of sampling, and thus samples' legal and analytical validity, was not ensured for substances with a non-uniform distribution. The interpretation of the analytical results did not take into account all required parameters thus weakening the legal validity of the decisions made by the competent authority on compliance. ***Assessment (January 2024):*** *DGAV's DAA confirmed that it had acquired mechanical dividers for all regional units involved in carrying out controls under the feed official control plan.* *DGAV provided a copy of three analytical reports (October, November and December 2020); these reports, among other required parameters, specified the moisture content, showing a result close to 12%. The required parameters are specified in the report and the interpretation of the analytical results did take into account all parameters. In addition, DGAV provided a copy of three other analytical reports (April and November 2021 and March 2023) concerning respectively samples of feeding fats (moisture content of 13,5%), feeding additive and pre-mixture (moisture content of 11%) and feeding additive (moisture content of 2,3%). The reports make reference to all mandatory parameters.* *DGAV also provided confirmation that the testing laboratory is accredited for the determination of moisture content in feed.* ***The actions address the recommendation.***

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
	Background First response (9 and 16/03/2020) In what concerns Finding 49, DAA has already taken an action for the acquisition of mechanical dividers for all regional units involved in feed official control plan (Annex VI). In what concerns Finding 50, DGAV cannot support the conclusions related to the lack of parameters for interpretation of results in accordance with the requirements laid down by part C(6) of Annex II to Regulation (EC) No 152/2009, and in what concerns recovery and uncertainty. Although in some laboratories, analytical reports do not refer them, a list is available for all the analyses and nature of sample (see comments on report for Finding 50, as well as Annex VII). However, DGAV agrees with the lack of moisture content determination. For this, a letter was already sent to INIAV in order to request determination for moisture content on solid samples collected for analysis under the official feed control plan (Annex VIII). Second response (23/06/2020) Although an official letter has been sent to INIAV in order to correct the expression of results according to Part C of Annex II to Regulation (EC) No 152/2009, until June 2020, INIAV Quality Unit has not improved the analytical report templates, as the official feed control plan physical control for 2020 has not yet been initiated due to the COVID-19 pandemic emergency measures. As part of the 2022 GFA, the competent authority provided a copy of three analytical reports (October, November and December 2020); these reports, although they specify the moisture content, they all show a figure close to 12%. The competent authority confirmed that they do not produce any "wet" feed and that they were finding difficulties in providing examples of an analysis for feed with a humidity significantly different to 12%. In November 2023, in the reply to the draft Country Profile, DGAV provided three analytical reports of samples of feeding fats, feeding additives and pre-mixtures where the moisture content was assessed. DGAV also provided confirmation that the testing laboratory is accredited for the determination of moisture content in feed.
2019-6633-5 To ensure that when official controls identify non-compliance, actions are taken to ensure that the operator	**Closed due to action taken** The fact that DGAV does not ensure that the operators identify the reason(s) for all non-compliances identified and remedy those (contrary to what is required in Article 54 of Regulation (EC) No 882/2004), weakens the effectiveness of the overall control system.

Audit 2019-6633 of 26 November 2019 in order to evaluate official controls on feed additives, their ingredients and traceability	
Recommendation	Basis for assessment/Information Requested/CA response
remedies the situation as required by Article 54 of Regulation (EC) No 882/2004. Recommendation based on conclusion: 57. Associated findings: 55 and 56.	*Regulation (EC) No 882/2004 has been repealed. The new relevant requirement is in Article 138(1)(b) of Regulation (EU) 2017/625.* ***Assessment (May 2022):*** *DGAV amended and improved the "Guidance for non-compliances under Feed Official Control", creating complementary action measures, in addition to penalties, to deal with non-compliances detected concerning analytical constituents, Salmonella, feed additives, undesirable substances, veterinary medicines, forbidden substances and processed animal proteins (Annex V, Section III.).* ***The actions address the recommendation.*** **Background** First response (9 and 16/03/2020) In what concerns Findings 55 and 56, the guidance for non-compliances under Feed Official Control has been already amended and improved, creating complementary action measures, in addition to penalties, whenever non-compliances are detected, namely analytical constituents, Salmonella, Feed additives, Undesirable substances, veterinary medicines, forbidden substances and processed animal proteins (Annex V, Section III.).

2.B.5 TSE\ABP

There are no recommendations currently open for follow-up.

2.B.6 Veterinary medicines and residues

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6344-1 When drafting the residue monitoring plan to broaden the	**Closed due to action taken**

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
scope of analysis for subgroup B1 substances as to ensure that samples can be selected based on the criteria mentioned in point 2.3.3.1. of the Annex to Decision 98/179/EC. Recommendation based on conclusion 7. Associated finding 4.	The scope of the National Residues Monitoring Plan (NRMP) for testing on antimicrobials is limited and does not take into account information on the use of such substances in food producing animals available through the sales data. In particular: a) nine substances [amoxicillin, apramycin, bacitracin (for rabbits), colistin, florfenicol, lincomycin, neomycin, tiamulin, valnemulin] used in premixes of medicated feed were not included in the plan despite their frequent sale, and b) some active substances (tulathromycin, ihydrostreptomycin and dexamethasone) frequently used at farms were not included in the 2017 plan. ***Assessment (May 2022):*** *Based on the assessment of the 2021 NRMP, the Commission considers that the identified substances which are the most sold and which are seen as critical by the World Health Organisation, are now included in the residue monitoring plan, based on a risk assessment.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (21/06/2018)</u> In April 2018, DGAV with the Veterinary Medicines Unit, the Animal Feed Unit and the Public Health Unit carried out an exhaustive survey to compare the molecules of group B1 mentioned in Table 1. of Regulation No.: 37/2010, with the most sold molecules and used in medicated feed, with the critical molecules defined by WHO and with those already included in NRMP. Following this exercise DGAV identified molecules that should be included in NRMP and agreed with the National Reference Laboratory (INIAV) to included these molecules in NRMP. DGAV presented a list of molecules identified as priority for testing.
2018-6344-2 To ensure that the residue monitoring plan is implemented as planned and approved by the	**Closed for other reasons** Although the number of samples planned for 2015, 2016 and 2017 complied with the minimum required number, fewer samples were actually taken. As a consequence, in 2016 the NRMP was only 60% fulfilled and in 2017, only 90% (for antimicrobial substances only 80% fulfilled).

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
Commission and thus ensuring that the requirements of Annex IV to Directive 96/23/EC and Annex to Decision 97/747/EC are met for bovines, pigs, sheep and goats, poultry, milk, eggs, rabbit and honey. Recommendation based on conclusion 18. Associated findings 8, 9 and 13.	*Directive 96/23/EC has been repealed. The relevant requirements are in Article 150(1) and (3) of Regulation (EU) 2017/625.* ***Assessment (January 2024):*** *DGAV signed a contract with the Laboratory EUROFINS in October 2018, which stipulates, among other things, the requirements for quality and turn-around times.* *DGAV provided evidence that the implementation of the NRMP for 2019 was satisfactory. For 2020, it is clear the COVID-19 pandemic impacted the implementation of the plan. The Sample Collection Procedures Manual has been updated and specifies an interval of 10 days to deliver the samples to the laboratories for testing (with some exceptions where the interval is shorter).* *The National Reference Laboratory (INIAV) presented their actions to address the issues related to delays in processing and testing samples (namely the 591 samples of 2021) and their commitment to implement the contract signed with DGAV on 23/02/2022 for the 2022 NRMP.* *DGAV provided a summary of the 2021 and 2022 NRMP results, identifying the non-compliant ones (24 in 2021 and 30 in 2022). The justification for not meeting the agreed interval for reception of analytical results (30 days) was given for two non-compliant results in 2021 (8,3%) and for six non-compliant results in 2022 (20%), while waiting for more information from INIAV on other delayed tests..* *Considering that:* • *the currently applicable legislation (Commission Delegated Regulation (EU) 2022/1644 and Commission Implementing Regulation (EU) 2022/1646, both applicable from 15 December 2022) sets different minimum frequencies to those referred to in Directive 96/23/EC (the legislation in force at the time of the audit) and, in addition, spreads the samples across three different control plans, and* • *in relation to the implementation of the NRMP, Portugal, overall, has not underperformed in recent years,* ***this recommendation is closed for other reasons.*** **<u>Background</u>** <u>First response (21/06/2018)</u>

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV underlined that this recommendation is based on the situation from 2016 that was largely corrected and improved in 2017, since INIAV received the accreditation to carry out the analyses of group B1. In 2018, the contracts with the INIAV and the External Laboratory comprise approximately 99% of the total analyses of the plan. These contracts have already been concluded and samples have already been taken regarding these two laboratories. The remaining 1% of samples is supposed to be sent to other national laboratories: Portuguese Institute of the Sea and the Atmosphere (IPMA) and the Economic and Food Safety Authority (ASAE). DGAV has signed a contract with IPMA but ASAE presented a financial proposal exceeding acceptable price therefore DGAV has launched a new international public tender. <u>Second response (12/10/2018)</u> DGAV stated that the tender has been concluded in September 2018 and DGAV signed a contract with the Laboratory EUROFINS, in October 2018. DGAV stressed that paragraph 5 and 6 of clause 5 contains the requirements for the quality and turn-around time. DGAV presented a copy of the signed contract and Excel files containing data on the implementation of NRMP (% of planned samples already analysed) up to 31 July 2018 and the data on the implementation of the residue monitoring programme up to 9 October 2018. <u>During the 2022 GFA</u> The recommendation is based on facts occurred in 2016 and were largely overcome in 2017. In addition to the information presented in 2018, the execution of the National Residues Monitoring Plan in 2018, 2019 and 2020, is presented in the table below: Year Planned Collected Sampled Rate (sampled/planned) 2018 8989 8626 8034 89 % 2019 7723 7837 7559 98 % 2020 3414 2157 1976 58 % In 2020 the initial plan included the collection of 8770 samples. However, given the constraints caused by the control measures of the Sars-Cov-2 Pandemic, the initial planning was reduced to 3414 samples. As could be seen the execution rate of PNPR 2020, fell far short of that obtained in previous years. For 2021, the data analysis is still being completed.

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV further informed that, a New Sample Collection Procedures Manual was implemented in 2019, revising the procedures for collecting, preserving and sending samples to the laboratory (ref doc: 2018_6344_Anexo 1 _ manual Procedimentos_colheita amostras)**.** DGAV expects that INIAV, as the NRL, will commit to comply with the contract signed on 23/02/2022 for the NRMP 2022 (copy provided). INIAV indicated that past issues with the implementation of the NRMP, namely in 2012, were solved with acquisition of new equipment and additional staff. Ten years after, similar issues are affecting the NRMP implementation, where lack of staff (retirement) and obsolete equipment need to be replaced. Additionally, at the end of 2021, one very expensive equipment broke down definitely. This affected the analysis of 4 groups of substances (non-steroidal anti-inflammatory drugs, nitrofurans, anthelmintics, tiriostatics), with no previous history of non-compliant results of significance. INIAV informed that, while planning to buy a new equipment, it considered sending the 591 samples collected in 2021 to another laboratory. Both solutions would be equally expensive and the second option would have the constraints of a laboratory that is also busy with analysing samples for another Member State. In January 2022, INIAV received 300.000€ to buy a new equipment (LC-MS/MS), which was only received and assembled on 25/04/2022. This influenced the decision not to send the samples to another laboratory: • samples already prepared for testing in INIAV (no longer valid for sending them to another accredited laboratory) • different deadlines for delivery of test results would apply. • high cost associated with sending and testing the samples (around 200.000€). • monthly limited authorised budget to spend on these samples. Therefore, INIAV aims to finish the validation of the methods and start testing the 591 samples of 2021 by the end of June 2022, in time for sending data to EFSA. For 2022 samples, another equipment in the INIAV laboratory of Vairão will be used (it needed to be repaired, which took two months). In addition, under the Resilience and Recovery Plan, there will be budget to buy new equipment for backups. 2022 samples will be tested only after the 2021 samples have been tested. The NRMP of 2022 started in April 2022 and not that many samples were taken.

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	In November 2023, in the reply to the draft Country Profile, DGAV provided the following information: Planned Collected Sampled Rate (sampled/planned) 2021 7594 7564 6729 89% 2022 8167 7547 7210 88% Due to internal constraints in 2021 INIAV couldn't test 374 samples. Due to internal constraints in 2022 INIAV couldn't test 264 samples. INIAV need to complete the map with reasons for delayed results.
2018-6344-3 To reduce the time needed between sampling and availability of the analytical result (turn-around time) and the time needed to report results in order to allow effective follow-up measures in line with Articles 15 to 18 of Directive 96/23/EC and timely reporting of results to the Commission and its Agencies as required by Articles 4(2)(d) and 8(3) of Directive 96/23/EC. Recommendation based on conclusions 26 and 50. Associated findings 8, 15, 16, 25, 45, 46 and 47.	**Closed for other reasons** The turn-around time (the time between samples being taken and availability of their analytical results) was too long. This affected the possibility of effective follow-up on cases for which the results were non-compliant. *Directive 96/23/EC has been repealed. The relevant requirements are in Articles 11, 19(2)(a) to (c), 35(3), 34(6), 65 to 72, 105(1), 108(1), 113(1), 138 and 150(1) and (3) of Regulation (EU) 2017/625.* ***Assessment (January 2024):*** *DGAV established contracts with two external laboratories in 2018 to reduce the time needed between sampling and availability of the analytical result (turn-around time) and the time needed to report results in order to allow effective follow-up measures and timely reporting of results to the Commission and its Agencies.* *During the 2022 GFA, DGAV provided evidence that the implementation of the NRMP for 2019 was satisfactory. For 2020, it is clear the COVID-19 pandemic impacted the implementation of the plan.* *DGAV presented data for the NRMP 2020-2021, namely the samples that were tested and found non-compliant, where for 2021, the average turn-around time was 48 days. The Sample Collection Procedures Manual has been updated and specifies an interval of 10 days to deliver the samples to the laboratories for testing (with some exceptions where the interval is shorter). DGAV planned to decrease the time of sample transport (10 days or less in general; 1 day for plasma samples) and had an objective for 2022 to send samples to the laboratories on a weekly basis.* *The National Reference Laboratory (INIAV) presented their actions to address the issues related to delays in processing and testing samples (namely the 591 samples of 2021) and their commitment to implement the contract signed with DGAV on 23/02/2022 for the 2022 NRMP, where the interval to communicate the analytical results is 30 days.*

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV provided a summary of the 2021 and 2022 NRMP results, identifying the non-compliant ones (24 in 2021 and 30 in 2022), where the turnaround times were overall respected, which allowed for follow-up measures *Considering:* • *that Commission Delegated Regulation (EU) 2019/2090, applicable from 14 December 2019, lays down rules on specific requirements for official controls and applicable measures for cases of non-compliance or suspected non-compliance with Union rules applicable to the use of authorised, unauthorised or prohibited pharmacologically active substances on food-producing animals and to their residues (which are more specific than the legislative requriements in force at the time of the audit), and* • *the evidence provided by the Portuguese authorities,* ***this recommendation is closed for other reasons.*** **Background** First response (21/06/2018) DGAV stated that the identified issue concerned mainly national laboratories due to some difficulties with maintenance of the laboratory equipment and lack of consumables. At the beginning of 2018 the INIAV I.P. Management Board undertook: a) Organisation of tenders for purchase of consumables for these analyses, and b) To carry out the multi-annual contracting for the maintenance of the most relevant analytical equipment for the execution of the tests included in the NRMP. DGAV clarified that as regards the external laboratory, DGAV would ship the samples in four different occasions. It did not take place in 2017 because the samples were all collected along the entire year but in a short period of time. DGAV stated that the turn-around time would be a condition for the tender application for external laboratories while with the national laboratories it would be settled individually for each laboratory. Second response (12/10/2018) DGAV stated that in 2018 there were only two external laboratories: Fera, with a turn-around time of 28 days, and EUROFINS with a turn-around time of 20 days.

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	The average turn-around time for all samples collected and analysed, was 45 days. DGAV presented a table with times for turn-around time. <u>During the 2022 GFA</u> DGAV presented data for the NRMP 2020-2021, namely the samples that were tested and found non-compliant: • 1 sample in 2020 was non-compliant (wild fish) and the turn-around time was 19 days. • for 2021, the average turn-around time was 48 days. • 23 samples were non-compliant: 2 of them had a turn-around time of 135 days and 4 are waiting for a second opinion. DGAV informed that, since February 2022, a turn-around time (30 days) was set in the contract with the Governmental laboratory (INIAV) (Ref doc 2018_6344_3_Anexo 1 _Contrato lab).DGAV indicated that the NRMP 2022 started only in April. INIAV indicated that past issues with the implementation of the NRMP, namely in 2012, were solved with acquisition of new equipment and additional staff. Ten years after, similar issues are affecting the NRMP implementation, where lack of staff (retirement) and obsolete equipment need to be replaced. Additionally, at the end of 2021, one very expensive equipment broke down definitely. This affected the analysis of 4 groups of substances (non-steroidal anti-inflammatory drugs, nitrofurans, anthelmintics, tiriostatics), with no previous history of non-compliant results of significance. INIAV informed that, while planning to buy a new equipment, it considered sending the 591 samples collected in 2021 to another laboratory. Both solutions would be equally expensive and the second option would have the constraints of a laboratory that is also busy with analysing samples for another Member State. In January 2022, INIAV received 300.000€ to buy a new equipment (LC-MS/MS), which was received on 04/04/2022 and assembled on 25/04/2022. This influenced the decision not to send the samples to another laboratory: • samples already prepared for testing in INIAV (no longer valid for sending them to another accredited laboratory) • different deadlines for delivery of test results would apply. • high cost associated with sending and testing the samples (around 200.000€). • monthly limited authorised budget to spend on these samples.

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	Therefore, INIAV aims to finish the validation of the methods and start testing the 591 samples of 2021 by the end of June 2022, in time for sending data to EFSA. For 2022 samples, another equipment in the INIAV laboratory of Vairão will be used (it needed to be repaired, which took two months). In addition, under the Resilience and Recovery Plan, there will be budget to buy new equipment for backups. 2022 samples will be tested only after the 2021 samples have been tested. The NRMP of 2022 started in April 2022 and not that many samples were taken. In terms of enforcement, DGAV stated that the delays in processing and testing samples impact the decision to take measures, in particular for fresh products. It is easier to take measures on holdings, although in certain cases (like poultry) the issue may not be present anymore. DGAV confirmed that it carries out investigations and imposes administrative measures. With the introduction of the 30 days interval for analytical results delivery, DGAV expects to have more data (results of the 591 samples from 2021 + results of NRMP 2022) for the planning of official controls in 2023. The 2023 planning will take into account non-compliant results, which can trigger: • re-inforced checks at farm level. • re-inforced checks, during 12 months, on identified forbidden substances. • re-inforced checks, during 6 months, on identified unauthorised substances. DGAV plans to decrease the time of sample transport (10 days or less in general; 1 day for plasma samples) and has an objective for 2022 to send samples to the laboratories on a weekly basis. INIAV acknowledged the problems it creates to competent authorities on the implementation of official control plans. Necessary measures to mitigate these problems have been taken, as far as possible: • repeated requests for recruitment of additional staff sent to the Ministry of Agriculture and Food for NRLs to meet the needs of the competent authorities. • securing budget for acquiring new equipment. INIAV is planning to move all testing related to the NRMP to the laboratory located in Vairão in the next 5 years, while: • adding more substances and new groups of substances to its accreditation (pending the outcome of the IPAC audit in 2023), such as carbamates, pyrethroids, quinoxaline, antibiotics in eggs, and mycotoxins in liver. • additional groups for 2024.

Audit 2018-6344 of 01 March 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
	In an update on July 2022, INIAV provided the following information: • Justifications of the response times for the non-compliant results of 2021. • Documents supporting the acquisition and installation of the LC-MS/MS equipment. • The process of training and revalidation of the various methodologies is being more time consuming than expected due to problems related to equipment and human resources (disease). • Problems in validating the methodology due to technical issues with the equipment, so the number of samples from 2021 remains unchanged. In November 2023, in the reply to the draft Country Profile, DGAV indicated that concerning the information requested in recommendation 2018-6344_2 please see the answer given on that point. INIAV – need to complement information.

2.B.7 Foodstuffs and food hygiene

Audit 2011-6260 of 26 September 2011 in order to evaluate the official controls for genetically modified organisms including their deliberate release into the environment	
Recommendation	Basis for assessment/Information Requested/CA response
2011-6260-4 The National Reference Laboratory for GMO in Portugal is accredited as required by Article 33(3) of Regulation 882/2004 and that it is able to perform the functions of a National Reference Laboratory, in line with paragraph 2 of that Article.	**Closed due to action taken** This recommendation is based on findings and related conclusions in Section 5.2.9 of the report. The National Reference Laboratory (NRL) for GMO in Portugal is not accredited, does not perform official controls with respect to GMO, and thus does not perform the tasks of the NRL for GMO. The two related recommendations from the previous audit report - audit No. DG(SANCO)2009-8160 had therefore not been addressed. *Regulation (EC) No 882/2004 has been repealed. The new relevant requirements are in Articles 100(2) and 101(1) of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:*

Audit 2011-6260 of 26 September 2011 in order to evaluate the official controls for genetically modified organisms including their deliberate release into the environment	
Recommendation	Basis for assessment/Information Requested/CA response
	INIAV indicated that an accreditation audit of the NRL for GMO was carried out in February 2019 by IPAC. The competent authority provided the accreditation certificate (and technical annex), dated 24 March 2020, granting the relevant accreditation to the NRL. ***The action taken addresses the recommendation.*** **Background** During the 2011 GFA the Portuguese authorities stated accreditation request for NRL for GMO is expected to be ready by the end of 2011. During the 2014 GFA the Portuguese authorities stated that the NRL for GMO is not yet accredited. Official samples of imported food and feed collected for examination are dispatched and analysed in a laboratory of another Member State. At that time, the NRL for GMO had no oversight of the scope of accreditation of the laboratory from another Member State. In their further correspondence INIAV stated that the accreditation process for testing GMO in INIAV was still not completed. The first external evaluation by IPAC was expected to take place in the second half of 2015. During the 2016 GFA INIAV stated that NRL for GMO had not been accredited due to some delays in the installation of the laboratories in Oeiras. INIAV had sent formal accreditation request to IPAC by the end of April 2016, and expected that external audit by IPAC would take place in the last quarter of 2016; thus, accreditation process could finish at the beginning of 2017. INIAV presented copy of the accreditation request. INIAV stated that, despite of the above, the laboratory works already in accordance with the quality system established in the Standard NP EN ISO 17025, and regularly participate in proficiency testing. Access to reference materials is ensured by purchases of certified reference materials which are available on the market (see also the answer to the question of the point 1 of the Recommendation 2011-6260-5). INIAV stated that the NRL for GMO performs official control functions for seeds only. INIAV presented examples of invoices for some purchases of certified reference materials. INIAV officially requested IPAC for accreditation audit.

Audit 2011-6260 of 26 September 2011 in order to evaluate the official controls for genetically modified organisms including their deliberate release into the environment	
Recommendation	Basis for assessment/Information Requested/CA response
	In the context of the 2019 GFA INIAV stated that in February 2019 IPAC carried out an accreditation audit of the NRL for GMO. The audit had satisfactory results and indicated 7 administrative and 5 technical issues requiring improvement prior granting accreditation. The NRL prepared an action plan and presented this to IPAC on 26 March 2019 and demonstrated that 4 out of 12 issues had been already resolved. Deadlines for resolving remaining issues are between three to six months therefore INIAV expects that the NRL would obtain accreditation in the last quarter of 2019. During the 2022 GFA The competent authority provided a copy of the accreditation certificate (dated 24/03/2020) and related technical annex. Additionally, a copy of the list of methods included in the flexible accreditation was provided.

Audit 2015-7461 of 23 November 2015 in order to evaluate the system of official controls relating to microbial safety of primary production of food of non-animal origin	
Recommendation	Basis for assessment/Information Requested/CA response
2015-7461-1 The CA should establish procedures for primary producers of FNAO to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004, as required by Article 31(1)(a) of Regulation (EC) No 882/2004. Recommendation based on conclusions set out in paragraph 20.	**In Progress** Due to absence of procedures for registration of some FNAO operators, acting in the primary production area, these producers were not taken into account when planning of official controls took place. This concerned also importers and retailers of seeds intended for sprouting. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 10(2) of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:* *DGAV has adopted an Ordinance requiring official registration of importers and retailers of sprouts (No 256/2019 of 16 August). Information on registered operators would be kept in the SIPACE in contrast with all other operators registered under the IFAP registration project (primary producers holding at least 0.3 ha of land, as is required under the new Common Agriculture Policy).*

Audit 2015-7461 of 23 November 2015 in order to evaluate the system of official controls relating to microbial safety of primary production of food of non-animal origin	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings set out in paragraph No 16, 17.	*The Ministry of Agriculture and Food has adopted an Ordinance (No 273/2022 of 12 November) on the registration of new primary producers in the IFAP platform; a 6 month transition period is defined for existing primary producers who are not registered in the IFAP platform to do so.* *Such registration will take place through a "Registo da Atividade Agricola" (RAG) which is part of the IFAP platform and which is yet to "go live". DGAV expects to use it for planning the official controls on primary producers for the year 2024.* ***This recommendation is classified as "in Progress" and will remain so until the competent authority provides evidence that it has access to the RAG part of the IFAP platform and is actively using it for planning the official controls on primary producers.*** **Background** First response (19/09/2016) DGAV stated that it would develop procedures for registration of primary producers. A working group to complete this task will comprise representatives of the DGAV, IFAP, DGADR and DRAP. In the context of the 2019 GFA DSMDS (DGAV) stated that it diverted from the original action proposed as IFAP is going to implement a project for registration of all primary producers holding at least 0.3 ha of land, as is required under the new Common Agriculture Policy. Due to the above, DGAV developed a proposal of an Ordinance requiring official registration of importers and retailers of sprouts. Information on registered operators would be kept in the SIPACE informatics system contrary to all other operators registered under the IFAP system (project). The Legal Service of the Ministry of Agriculture and the Ministry of Economy reviewed the Ordinance and DGAV expects the Ordinance to be adopted in the second half of 2019. So far, sprouts producers were licensed by DGAV and the outstanding missing issue was registering of importers. In December 2018 DGAV solved this issue by issuing the guidance requiring that if during official controls on sprouts producers, an inspector comes across information on an importer of seeds for sprouting, he would enter this information into the SIPACE system (DGAV).

Audit 2015-7461 of 23 November 2015 in order to evaluate the system of official controls relating to microbial safety of primary production of food of non-animal origin	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV stated that in the country there are only two big domestic producers of sprouts, which obtain seeds for sprouting directly from other MS - mostly from The Netherlands and Spain. Retailers selling seeds for the production of sprouts can only be identified in ASAE controls, DGAV cooperates closely with ASAE on this issue and whenever ASAE would identify such a retailer it would pass the information to DGAV. Both ASAE and DGAV underlined that so far no such retailers were identified as the market is dominated by the two domestic producers of sprouts. The Portuguese MANCP foresees collecting samples of sprouts from the market for microbiological analyses; in 2018 there were 32 samples collected of which 2 produced non-compliant results (for STEC). DGAV presented the 2018 guide (for registering importers of seed for sprouting). <u>During the 2022 GFA</u> The competent authority (DGAV) indicated that: • Until April 2022, IFAP was still progressing in the development of the platform for the registration of primary producers as part of a more ambitious project to register all agricultural activities engaged by farmers/primary producers. This project is called “Registo da Atividade Agrícola – RAG” and was presented to DGAV in October 2021. A copy of an IFAP presentation on RAG indicated that by August 2022 the platform should be ready (production environment). DGAV contacted IFAP recently on this "go live" date and was waiting for a reply. • An Ordinance is under preparation setting rules under article 6 of Regulation 852/2004 for operators of the food sector including primary producers to register themselves and their activity. DGAV confirmed that the Ordinance was going through a last revision by the Ministry of Agriculture, after being revised by IFAP; approval was expected soon. • The Ordinance (Portaria 256/2019 de 16 de Agosto) requiring official registration of importers and retailers of sprouts was adopted in 2019 and is already published (a copy was provided). The registration of three sprout-producing establishments and of one importer of seeds intended for the production of sprouts is kept in the SIPACE System.

Audit 2015-7461 of 23 November 2015 in order to evaluate the system of official controls relating to microbial safety of primary production of food of non-animal origin	
Recommendation	Basis for assessment/Information Requested/CA response
	A further update given by DGAV at the opening meeting of audit 2023-7739, on 28/02/2023, indicated that the methodology of sample selection of primary producers is not yet adequate due to the unknown number of operators, as only the ones registered in IFAP platform are taken into account (sub-universe). A copy of the new Ordinance (Portaria 273/2022 de 12 de Novembro) establishing the new rules for registration on IFAP platform, including for new producers (30 days), but not for farmers who produce for own consumption, was provided. It includes geo referencing for farmers' parcels and 6 months transition period for non-registered active farmers (until 12/05/2023). During the transition period, DGAV is counting on the current IFAP platform allowing the registration of the majority of producers. The IFAP platform was adapted for accommodating many requirements, where the RAG component is the most advanced (expected next weeks to be launched – March 2023). DGAV expects that IFAP will commit to work as expected. Not possible to select sample for 2023, but for 2024 only new IFAP platform to be used. Access is by means of rights for all administrative authorities (DGAV and DRAPs) who need to use the data, to be granted.

Audit 2018-6376 of 26 April 2018 in order to evaluate the system in place for official controls related to food contact materials in EU Member States	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6376-1 CAs should improve the performance of inspectors involved in official controls of FCM by providing them with the relevant tools (i.e. training and technical support) in order to give effect to the requirement set out in Article 3 of Regulation (EC) No 1935/2004 regarding FCM safety and, thus, to ensure effective and appropriate	**Closed due to action taken** During official controls inspectors were able to verify the presence of Declarations of Compliance - DoC and, to a certain extent, to assess the completeness of those declarations. Limited controls were made on the completeness of supporting documentation for the DoC, which would lead to inadequate or incomplete risk assessments/DoCs being overlooked. Thus, noncompliant products might go undetected and correct application of the relevant legislation would not be enforced. The effectiveness of the controls in place is hampered by the fact that inspectors are not suitably trained or experienced to evaluate compliance of FCM legislation, including a thorough analysis of the DoC and supporting documentation. Expertise available at central level is rarely sought. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 5(1)(a) and (e) of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:*

Audit 2018-6376 of 26 April 2018 in order to evaluate the system in place for official controls related to food contact materials in EU Member States	
Recommendation	Basis for assessment/Information Requested/CA response
official controls as required by Article 4 of Regulation (EC) No. 882/2004. Recommendation based on conclusions: 94 and 95. Associated findings: 67, 68, 69, 71, 72, 73, 74, 81, 86, 87 and 91.	*After the audit, DGAV transmitted new procedures to the DRAP/RA regarding the request for evidence concerning the risk assessment of operators and the verification of the organoleptic analyses of the products. These requirements were placed on the new version of the control checklist as mandatory issues to be assessed in the course of official controls. The procedures for documentary analysis of FCM at import control points were prepared at the end of 2017.* *During the 2022 GFA, DGAV organised a variety of appropriate specialised training for its staff and DRAP staff during the period 2018-2021.* *DGAV engaged regularly with the Commission expert group on FCM (2019 and 2021) whenever clarifications on FCM rules were needed and participated actively with ASAE in the EU Coordinated Control Programme on FCM (Commission Recommendation (EU) 2019/794 of 15 May 2019), coordinating the collection and testing of 70 samples of FCM.* *DGAV provided evidence of supervision (with visits or by checking inspection reports) of the DRAPs' verification of operators' compliance with the FCM rules.* *ASAE were also very active in training and supervising staff and participating in EU coordinated control programmes. They also organised targeted campaigns to detect and raise awareness of illegal trade in certain FCM.* *ASAE updated the FCM inspection checklist, in July 2021, covering all legal requirements related to FCM rules and organised an Operation Order for an action on 10 October 2021, which contains the procedures followed by ASAE in the FCM sector.* *A newsletter (November 2021) was dedicated to illegal retail of certain FCM containing bamboo and a press release from January 2022 indicated that ASAE visited 174 operators, during an inspection operation, in the whole country, aimed at verifying compliance with the general principles of safety and stability of FCM.* *ASAE presented two examples of Operational Supervision Reports (RAO): one from November 2018, targeting FCM (bisphenol A) and another of May 2022, targeting restaurants (labelling of FCM was included).* ***The actions taken address the recommendation.*** **<u>Background</u>** <u>First response (25/10/2018)</u> Conclusion: 94, Associated findings: 71, 72, 74.

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Recommendation	Basis for assessment/Information Requested/CA response
	The DGAV has already promoted the disclosure of new procedures to the DRAP/RA regarding the request for evidence concerning the risk assessment of operators and the verification of the organoleptic analyses of the products. These requirements will be placed on the new version of the control checklist as mandatory issues to be assessed in the course of official controls. Associated findings: 91 The procedures for documentary analysis of FCM at import control points were prepared at the end of 2017. These procedures are organized in order to avoid such errors. However the DGAV has already warned about the detected faults during the audit and in the coordination meeting held at the end of September, but will again draw attention to the referred detected faults. Conclusion: 95, Associated findings: 67, 68, 69. The training of the DRAP/RA inspectors who are mostly agronomists or veterinarians is undoubtedly one of the major limitations to the correct implementation of this CPCM plan. However, with the DGAV support, Portugal will continue to invest in the training of inspectors, either through the promotion of training in collaboration with the NRL or through other means, in particular with the support of associations, including: • (very) basic training on materials science composition and applications to FCM; • exchange experiences with similar services of CA from other MS. <u>Second response (10/05/2019)</u> The new version of checklist with the requirements referred in the audit findings already available (copy provided). A training session on FCM of the DRAP/RA inspectors is planned for 2019. A coordination meeting on Import controls of FCM was held in 6 November 2018 in which DGAV recapped the specific procedures regarding the import of plastics and ceramics, namely the assessment of DoC, and the support documentation. Part of the meeting was dedicated to clarify doubts regarding the inspections on FCM. In the end of November 2018 DGAV provided training on Import controls and TRACES to the inspectors of DRAPs. In this training the import procedures of FCM, namely the Reg. 284/2011, were addressed, as well as the specific internal procedure and also IC 119 (Instructions on plastics and ceramics import issued by Customs Authority). The BTSF trainings and workshops provide the opportunities for discussion and sharing experiences and information between the experts/inspectors regarding official control. <u>Third response (25/05/2019)</u>

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Recommendation	Basis for assessment/Information Requested/CA response
	The ASAE will promote training actions for its Inspectors in FCM by the end of 2019 and change its inspection procedures. <u>During the 2022 GFA</u> *DGAV* The following training sessions relevant for this recommendation were organised since 2017: • 2 inspectors participated in a training session on audits to FCM establishments (April 2017). • 2 inspectors participated in a general training session on good practices of sampling of FCM, given by laboratory staff (September 2017) • 6 inspectors participated in the BTSF eLearning module on rules for FCM (May 2018 to May 2020). • 1 inspector participated in a BTSF training session on "The control of food contact materials, their use and marketing" (February 2019). • BCP inspectors participated in a training session on DOCs of FCM (May 2019). • the DRAP LVT participated in a seminar given by European University - "Bureau Veritas" (October 2019) • 3 inspectors participated in a workshop on FCM good manufacturing practices run by the Cantonal Laboratory of Zurich (September 2021). • 1 inspector participated in a BTSF online training session on "Food contact materials official controls" (October 2021). In the FCM control plan (PCMC), 70 samples were to be collected and tested (all paid by DGAV). ASAE collected 25 out of the 70 at retail level. 3 examples of consultation with the Commission expert group on FCM: • From sample collected at import in 2019 - melamine in bamboo coffee cups (tumblers). Accredited laboratory in Stuttgart (Chemical and Veterinary Analysis Agency- National expert from this agency participated in the audit 2018-6376) tested the sample with a non-compliant result. • From sample collected at import in 2019 - Paper/edible straws designated as "safe as food". Consensus at expert group was that product does not fall under FCM rules if it is considered food. Operator was asked to designate product as non-edible. • From 2021 PCMC sampling, on national operators - Metal cuvettes / aluminium pots with very high levels of aluminium - contact in March 2022, for discussion at a future expert group meeting.

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Recommendation	Basis for assessment/Information Requested/CA response
	DGAV, accompanied by 1 staff from DRAP LVT, carried out a supervision visit to DRAP Alentejo on December 2019. The outcome of the visit pointed out relevant shortcomings in the FCM rules. DGAV, following the verification of the report and checklist of an official control carried out by DRAP Centro on 10/15/2020, asked for supporting documentation to confirm the very detailed visit, reporting evidence of all applicable requirements. *ASAE* ASAE indicated that two training courses took place in 2019: • Food Contact Materials (28 hours, 1 participant) • Food Contact Materials Rules (8 hours, 1 participant). ASAE also indicated that it participated in the coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food (Commission Recommendation (EU) 2019/794 of 15 May 2019). It inspected 19 operators. Furthermore, in the context of the 19 proactive checks carried out under the Recommendation, a total of 27 samples were collected, of the 25 planned and previously agreed and articulated with DGAV, at distributors' level. For this implementation, a technical meeting/briefing took place on 18 July 2019 and the Order of Operations PL/257/19 was elaborated on 24 July 2019. ASAE took samples only in the distribution. ASAE has no competence in import controls. In 2019, 57 reactive checks triggered under the RASFF were also carried out. An example of a RASFF Order of Operations (PL/282/19) of August 2019 is attached. ASAE's training plans for new inspectors (dated May 2020 and May 2021) include a session on official control plans, with a mention to the EU Coordinated Control Programme on FCM. ASAE provided a copy of the FCM inspection checklist, dated July 2021, covering all legal requirements related to FCM rules. ASAE also annexed the Order of Operations PL/348/21, for an action on 10 October 2021, which contains the procedures currently in force in the proactive performance of the ASAE. ASAE newsletter No 124, of November 2021, was dedicated to illegal retail of certain FCM containing bamboo. A press release from 04/01/2022 indicates that ASAE visited 174 operators, during an inspection operation, in the whole country, aimed at verifying compliance with the general principles of safety and stability of FCM. 18 administrative offense proceedings were instituted, of which the main infractions were: failure to submit the declaration of conformity of FCM and the non-use of reusable tableware or biodegradable material in the non-sedentary establishments, venues and activities in the food and drink sector.

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Recommendation	Basis for assessment/Information Requested/CA response
	ASAE presented two examples of Operational Supervision Reports (RAO): one from November 2018, on PL/368/18 targeting FCM (bisphenol A) and another of May 2022, on PL/105/22, on restaurants.
2018-6376-2 ESB-UCP's role as NRL should be enhanced, to ensure coordination of the activities of all other official laboratories responsible for the analysis of FCM samples in accordance with the requirements of Article 33 of Regulation (EC) No 882/2004. Recommendation based on conclusions:105 Associated findings: 96	**Closed due to action taken** In relation to its NRL duties, the laboratory has not undertaken coordination activities with the other official laboratories dealing with FCM, including organising comparative tests, which is detrimental to enhanced high quality and uniformity of the analytical results. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 5(1)(a) and (e) of Regulation (EU) 2017/625.* ***Assessment (May 2022):*** *The DGAV invites the official national laboratories to participate in the Joint Research Centre (JRC) schemes when these are not restricted to the NRL and when the work is within their scope; it also disseminates by email the information received from JRC meetings.* *In addition, the DGAV implemented a programme of annual meetings between the Portuguese NRL and the official control laboratories to discuss official control activities within their scope and to collect information about their performance in inter-laboratory tests. This annual meeting occurs typically in May/June at the NRL premises.* ***The actions taken address the recommendation.*** **Background** First response (25/10/2018) It is recognised that the national network has been not very active in the recent years. However, all listed laboratories participate in ILABs exercises in their specific scope of analyses: CTCOR in cork, CENCAL in ceramics; etc. Given the small size of the country and respective FCM market, the various laboratories do not overlap in extent, exception to the overall migration that is covered in most of the schemes where the laboratories participate. Proposed actions: - invite official national laboratories to participate in JRC schemes when this possibility is open to others than the NRL and when the work is under the capability of those laboratories; - disseminate by email, information received from JRC meetings. Second response (10/05/2019 and 25/05/2019)

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Recommendation	Basis for assessment/Information Requested/CA response
	It is foreseen to implement a programme of annual meetings between Portuguese NRL and the official control laboratories to discuss activities of the laboratories under the scope of official controls and collect information about their performance on inter-lab participations. This annual meeting will occur typically in May/June at the NRL premises. Information received from JRC will preferably be shared in these meetings, otherwise dissemination by email will be forward up to 1 month after the reception from the JRC (letter provided showing that the programme is already initiated for this year).

Audit 2018-6428 of 10 September 2018 in order to evaluate the official control system in place governing food improvement agents	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6428-1 The CA should, after completing the pilot project, and based on the results, implement a monitoring programme of food additive intake in line with the requirements of Article 27 of Regulation (EC) No 1333/2008. Recommendation based on conclusion: 51 Associated finding: 34	**Closed due to action taken** This recommendation is based on finding 34 and conclusion 51 of the audit report. that a monitoring programme of food additive intake was not in place, and in consequence it impeded efforts to update EU law on food additives in a proportionate and effective way. DGAV mitigated the absence of the programme by introducing a pilot project including evaluation of the intake of additives with acceptable daily intake in children and adolescents in Portuguese schools. ***Assessment (January 2024):*** *The competent authority (INSA) confirmed that the simplified food consumption assessment tool is in place to assess additives intake, is widely available and easy to use (MONITADITIVOS - a secure web application for building and managing online surveys and databases).* *INSA provided the 2021/2022 survey results, which show that 22 schools were contacted but only four schools participated actively. 1,616 responses to the survey were obtained from the group of adolescents aged 11 to 17 years. To monitor the consumption of food additives, the sample size representative for the country was established at 539 questionnaires answered. INSA analysed 545 completed questionnaires, where the valid response rate was 67%. INSA committed to taking further actions to improve this response (e.g. more schools per district to be contacted; creation, over time, of a network of schools that every year will carry out the process; improving information to schools on how to answer the questionnaire).*

Audit 2018-6428 of 10 September 2018 in order to evaluate the official control system in place governing food improvement agents	
Recommendation	Basis for assessment/Information Requested/CA response
	Sociodemographic and food consumption data obtained through the questionnaires is analysed in a newly created computer platform Access®, within the MONITADITIVOS tool. For the foods consumed, the additives present and/or allowed are identified in order to calculate the estimated daily intake from the maximum allowed limits. The estimated intake is compared with the admissible daily intake (ADI). Foodstuffs with additives whose consumption exceeds the ADI are proposed for further study and action with newly created networks of industry representatives and other competent authorities. *INSA provided evidence of the analysis of the data received in 2022 and the implementation of the next steps, namely for foodstuffs with additives whose consumption exceeds the ADI (28 additives identified) and the creation of networks with industry representatives and competent authorities.* *INSA also provided an update on the 2023 survey, where more schools had been contacted (43 public schools and 406 private schools). At the time of writing, the data as still being processed.* ***The actions taken address the recommendation.*** **<u>Background</u>** <u>First response (09/01/2019)</u> DGAV stated that following the exploratory study (the pilot project) it would undertake the following steps to implement the monitoring programme: a) Simplify and streamline the tool for the evaluation of food consumption. b) Create a representative network of public schools where food questionnaires will be periodically carried out. c) Create a network with food industry to collect the approximate "real" levels of additives added to each type of products to refine the estimate. d) Create a network with other competent authorities to collect and analyse samples contributing to intakes exceeding acceptable daily intakes. <u>In the context of the 2022 GFA</u>, the competent authority clarified: • "*Information on the progress on adjusting the food consumption evaluation tool.* The simplified food (containing additives) consumption assessment tool is already built. It was performed in the REDCap software (Research Electronic Data Capture) that is a secure web application for building and managing online surveys and databases. The food consumption questionnaire is easily completed online on any electronic

Audit 2018-6428 of 10 September 2018 in order to evaluate the official control system in place governing food improvement agents	
Recommendation	Basis for assessment/Information Requested/CA response
	device. Survey results are easily obtained through the possibility of REDCap to export automatically to different types of data files. • *Evidence of actions resulting in establishing school, industry and authority networks.* The school network is still under construction. To assess the intake of food additives by the population aged 4 to 17 years in Portugal, the sample size to be studied was estimated at around 420 individuals. To independently assess the 4-10 and 11-17 age groups, 420 individuals will be needed for each age group. Thus, from all Grouping of schools in Portugal, 22 were randomly selected in order to cover all districts in Portugal. From the selected schools in each Grouping of schools, two classes will also be chosen for students to answer the questionnaires. This selection will allow for a higher number of answered questionnaires than necessary. During the years 2020 and 2021, due to the COVID19 pandemic, it was very difficult for schools to participate in this type of activities, in addition to having been closed the challenges that the pandemic raised hindered them from collaborating in this activity. At the end of 2021, the 22 schools were again invited to collaborate in the "Evaluation of the Intake of Food Additives"-Monitaditivos. So far 4 schools have joined our network. In 2022, 156 adolescents (11-17 years old) have already answered the online questionnaire. With the situation of the covid19 pandemic, the entire process of evaluation of the Intake of Food Additives is delayed, so the network with the industry and competent authorities has not yet been developed. If the estimated intake of additives by adolescents evaluated through the questionnaires does not exceed the ADI, the real values will not be necessary and there are no collection and analyse of food samples that contribute to intakes exceeding the ADI. In this case, there will be no need to refine the study with the help of industry and competent authorities. In any case, Portugal has a food additive monitoring programme implemented by the competent authority and results are reported to EFSA". This programme checks on residues on food and not on consumption. In a further update in August 2022, INSA provided the results of the survey: • In the academic year 2021/2022, 22 schools were contacted, one per district and 3 in the most populated districts of Lisbon and Porto, the response rate was 18%. The schools involvement is voluntary and depends only on the goodwill of the responsible person at the school and the consent of the parents. This process is very time consuming and often without a positive result. From schools (11) that had answered affirmative in their participation, 2 reported that they would not be able to complete the food consumption questionnaires

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Recommendation	Basis for assessment/Information Requested/CA response
	until the end of the 2021/2022 school year, 5 did not participate and did not contact more. 4 schools had participated. • Of the 4 schools that participated, 1 616 responses to the 24 hours questionnaire were obtained from the group of adolescents aged 11 to 17 years. To monitor the consumption of food additives, the sample size was established in order to be able to estimate the expected prevalence taking into account the pilot test carried out, with an admissible margin of error of 5% and with a confidence of 95% (539 questionnaires answered) . This sample size is representative for the country, regardless of districts. • Therefore, in the academic year 2021/2022, the number of individuals with at least two questionnaires answered, for a representative sample (considering the effect of sample design) of Portugal, for the age group from 11 to 17 years old, was reached (545). However, due to incomplete responses and only one time 24 hours the valid response rate was only 67%. Some actions will have to be taken to improve this response. • Sociodemographic (age, sex, height, weight, body mass index, school year and district) and food consumption (chocolate milk, yogurts, chocolate powder, cereals, ham, cheese, bread, monthly sweeteners, soft drinks, cakes, pastilles, candies, among others) data obtained through the questionnaires will be analysed. For the foods consumed, the additives present and/or allowed will be identified in order to calculate the estimated daily intake from the maximum allowed limits. The estimated intake will be compared with the Admissible Daily Intake (ADI). Additives whose consumption exceeds the ADI will be the subject of a more refined study. • To overcome the problem of low school response, in the next school year, more schools per district will be contacted to increase the probability of positive responses and thus increase the response rate. The objective is to create, over time, a network of schools that every year will carry out the process of applying the questionnaires in at least two classes per year and per school. Reinforce information to schools on the need for each student to answer the questionnaire twice, as well as the importance of reporting the exact weight and height between the two questionnaires answered by the same student. The data for the pairing of the questionnaires are also very important, which should be reinforced in the instructions given to schools. • If the determination of the estimated intake of food additives reveals values for some food additives that are higher than the respective ADI, the responsible foods will be identified and the industries responsible for their

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Recommendation	Basis for assessment/Information Requested/CA response
	production will be contacted in order to request the real value of the additive in the foodstuff. This contact with industries can be direct and/or through FIPA (Federation of Portuguese Agro-Food Industries) and/or APED (Portuguese Association of Distribution Companies). After the contacts, we ask the industries for their future collaboration and thus creating the industry network. With regard to the competent authorities, inform which foodstuffs most contribute to the intake of food additives, so that they can more often be subject to official control. In this way, we are creating a network with these entities. In November 2023, in the reply to the draft Country Profile, INSA indicated that: The task of creating a network of schools that actively participate, annually, in monitoring of food additives intake is underway. More schools have been contacted in 2023 (43 public schools and 406 private schools). So far, only five schools, have participated in the assessment of food consumption by filling out around four hundred food consumption questionnaires (data not yet processed). All efforts are being made to increase the number of participating schools by the end of the year. However, currently teacher's availability in Portugal is compromised due to ongoing labour struggles. Information to schools was reinforced clarifying teachers on how to orient students in fulfilling the food consumption questionnaire. The questionnaire was improved to increase response rate validity. To calculate the estimated daily intake of food additives and compare it with the ADI, a computer platform access® was created, within the MONITADITIVOS tool. This platform allows to store all data on food additives (designation, E, additive class, among others, existing in legislation 1333/2008), their respective admissible daily intake (ADI), food categories where they are permitted and their maximum permitted levels (MPL). The platform also allows, i) receiving and storing sociodemographic, anthropometric and food consumption data resulting from the food consumption questionnaire, ii) storing food additive information collected from the labels of brands available for the 24 generic foods included in the food questionnaire. Based on all this information, the platform calculates, for each individual, the estimated intake of each food additive consumed and compares it with the respective ADI. The platform also allows a global analysis of sociodemographic and anthropometric data, as well as analysis of data regarding the intake of food additives by additive and by individual. It should be noted that the calculation that the platform performs is an overestimated value because on the one hand it uses the MPLs and on the other it considers all the additives present in the different brands for each food category of the questionnaire.

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Recommendation	Basis for assessment/Information Requested/CA response
	Based on the results from 2022, and according to the information on the labels, 164 food additives were identified, 113 with unspecified ADI and 49 with ADI (6 colourings, 8 preservatives, 3 antioxidants, 3 sweeteners and 29 others). Of the additives with a defined ADI, 21 do not require further evaluation (estimated daily intake is lower than the ADI) and 28 will be the subject of more precise studies (some individuals presented an estimated daily intake higher than the ADI). The results obtained allow us to identify which additives are the target of a more refined study. Contact with industries responsible for the production of the foods identified as most contributors is undergoing in order to perform the refined evaluation.The contacts have not yet been formalized in writing; to date, informal contacts have been established on a global basis during technical-scientific meetings organized by the Department of Food and Nutrition at INSA, covering the network of "stakeholders" of the PortFIR program. The results obtained from the monitoring carried out in 2022 were presented at the 10th National Symposium on the Promotion of Healthy and Safe Eating, in June 2023 (meeting program attached) and raising awareness with the food industry began on the need for collaboration with the monitoring system. The PortFIR network includes representatives from various sectors of the food industry.

2.B.8 Imports of food of plant origin

There are no recommendations currently open for follow-up.

2.B.9 Plant protection products

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
2012-6298-4 Ensure that formulation analysis is performed as part of the official controls to guarantee that PPPs placed on the market meet the requirements laid down in Article	**In Progress** This recommendation is based on the finding and related conclusions in Section 5.2.4 of the audit report. The formulation analysis of plant protection products (PPPs) is not performed as part of the PPPs marketing controls; this cannot guarantee that PPPs placed on the market in Portugal meet EU requirements. Moreover, the lack of quality control of PPPs prevents the detection of counterfeit or illegal pesticides. ***Assessment (January 2024)**:*

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
29(1)(a), (c), (d) and (h) of Regulation (EC) No 1107/2009.	*23 samples of PPPs placed on the market were collected for formulation analysis under the 2018/2019 control plans. The samples were sent (September 2019) and tested in an accredited laboratory in another Member State. Results were transmitted to DGAV only in July 2020 (due to the COVID-19 pandemic). DGAV provided evidence on the results of the formulation analysis carried out in 2020, on samples collected in 2018/2019 (22 samples – 3 non-compliant). ASAE did not carry out enforcement activities on the reported 3 non-complaint results due to the COVID-19 pandemic.* *DGAV indicated that the 2020 and 2021 control plans were not fully executed due to the COVID-19 pandemic and unavailability of ASAE to cooperate in the analysis of the samples.* *DGAV has continued with the collection of samples on its own initiative in 2022, having collected a total of 58 samples that were sent to a laboratory in another Member State, in July 2023. DGAV staff collected the samples from distributors and wholesalers. DGAV committed to sending any non-compliant results to ASAE who committed to taking follow-up enforcement measures upon receipt of the results. Depending on the severity of the non-compliance, DGAV may take administrative actions independent of the actions to be taken by ASAE.* *A Memorandum of Understanding on Agriculture and Rural Development was signed between the Ministry of Agriculture and Food of the Portuguese Republic and the Ministry of Agriculture, Fisheries and Food of the Kingdom of Spain, on 7 December 2022, which allowed the laboratory to continue analysing the samples collected in 2022. DGAV awaits the laboratory results of the physical and chemical analyses of the samples sent in July 2023. According to the laboratory, which reported a delay due to the volume of work and equipment failure, the analysis bulletins were to be sent by the end of December 2023.* *The Commission services urge the competent authorities to ensure samples are sent to the laboratory promptly and that standard turnaround times are met. It is important for enforcement actions to be taken in a timely manner, which requires laboratory results to come back in a reasonable time frame so that non-compliant PPPs can be removed from the market. Otherwise, the effectiveness of enforcement measures is compromised.* ***The recommendation is classified as "In Progress" until the competent authorities provide evidence of:*** • ***Laboratory results on formulation analysis testing carried out on the samples collected during the 2020-2022 control plan.***

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	• ***Enforcement measures taken when results were found to be non-compliant, the delay that elapsed from the collection of the sample to the result being available to the competent authorities, justification(s) for the delay and actions to prevent reoccurrence of such delay.*** **Background** During the 2014 GFA, DGAV stated that the formulation laboratory had been incorporated into INIAV but in further clarification, it stated that the INIAV laboratory for formulation analyses shut down. DGAV expressed intention to find an alternative solution by the second half of 2015. During the 2016 GFA, DGAV explained that it decided to outsource formulation analyses in another MS, has already identified such accredited laboratory and is in the process of signing a contract. Moreover DGAV had developed the 2016 National Control Plan according to which 49 samples (representing 5% of PPPs on the market) would be collected by the end of September 2016. DGAV presented: a) documents from the procurement process aimed on identification of suitable laboratory in another MS, b) copy of accreditation certificate of designated laboratory (MAGRAMA - Spain), and c) copy of the approved 2016 Plan including formulation analyses. In the context of the 2019 GFA, DGAV stated that the 2016 and 2017 National Control Plans were only executed during 2017/2018 and results of analyses were received in 2018. The 2016 Plan, despite being approved, was not completed. DGAV collected 15 samples out of 49 planned. Because of the difficulties with collection DGAV revised its procedures and involved ASAE in the collection of samples for 2017 and 2018. Due to the small number of samples collected (15) and difficulties in contracting adequate transportation of samples to the laboratory in another MS, samples were not analysed. In 2017, DGAV/ASAE collected 46 samples which, together with 15 samples collected in 2016, were dispatched for analyses in an accredited laboratory in Spain. In 2018 DGAV obtained results showing that out of 61 samples analysed, 26 samples were compliant and 35 samples were not (42,6% and 57,4% respectively). With respect to the sampling periods this represented: - out of 15 samples from 2016, 4 were compliant and 11 not (26,7% and 73,3% respectively), - out of 46 samples from 2017, 22 were compliant and 24 not (47,8% and 52,2% respectively).

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV explained that formulation analyses performed were to determine the active substances and impurities, and that obtained results were used to better target the 2018 sampling. Regarding the 2018 Sampling Plan, DGAV stated that the Plan required collection of 60 samples; however, at the time of the 2019 GFA, 16 samples in total had been collected, and none of those were sent for analyses. DGAV explained that it had difficulties in achieving the samples target as it is part of the ASAE enforcement procedures not to release samples if a non-compliance investigation is carried out. DGAV explained that since the 2018 Plan had not been completed, it did not initiate the 2019 Plan. Competent Authority reply of 07/05/2021 During July 2019, DGAV contacted a number of laboratories in the EU (ES, IE, EL, DE, FR) to seek availability for carrying out the formulation analysis for samples collected in the Portuguese market for the 2018/2019 Control Plans. Some of the responses were negative and or not satisfactory (FR laboratory not accredited) or did not represent the best economic choice (supporting documents provided). Samples were finally sent to the formulation analysis laboratory of the Ministry of Agriculture, Fisheries and Food (MAPA) in ES. A total of 23 samples were shipped to the MAPA laboratory for physical and chemical analytical control in September 2019. Results were received in July 2020. This late reply was reported as due to the COVID-19 pandemic situation and general shutdown of non-essential services (evidence that results were transmitted provided, but not the results). In 2020, it was not possible to collect samples from the market also due to the COVID-19 pandemic and unavailability of the ASAE for this task. For 2021, the Control Plan is under preparation and is expected to be agreed with ASAE (draft protocol provided). A protocol to ensure formulation analysis with the Laboratorio Arbitral Agroalimentario of the MAPA, Spain is also under preparation (draft protocol provided). During the 2022 GFA *DGAV response* A proposal for a protocol was prepared by DGAV and sent by e-mail on the 28/06/2021 to ASAE for consideration with a view to be agreed upon and signed. A first response with redactorial suggestions was sent for consideration by DGAV on the 12/10/2021 and a revised version submitted by DGAV followed shortly afterwards. To date, the Protocol has not been agreed upon or signed as DGAV is still waiting for final feedback from ASAE. Recently DGAV sent a reminder to ASAE for the purpose of finalising this procedure and received on 18/05/2022 the ASAE's revision of the protocol which has not been assessed yet.

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	In the frame of the 2018/2019 Plan, a total of 22 samples was collected by ASAE and sent to the laboratory for analysis. The laboratory was only able to provide the results in mid-2020 due to the COVID-19 situation. Results obtained were the following: 3 samples were non-compliant (active substance content above authorised) representing 13.4% of samples analysed (a copy of the 2018/2019 report, dated September 2021, was provided). Due to the COVID Pandemic ASAE did not engage in enforcement activities under Regulation 1107/2009 during 2020 or 2021 thus no samples were collected for the purpose of formulation controls. To overcome the constraints for 2022, DGAV has modified the Control Plan (includes a formulation analysis control plan) and procedure for sample collection for the purpose of analytical control and samples will be collected by DGAV staff from distributors and wholesalers (copy of the PCPF 2022, updated in March 2022 was provided). For this purpose, appropriate sample collection material was purchased and a communication to authorisation holders was issued for the purpose of informing the distribution channels that samples will be collected from selling points and distributors at the expense of authorisation holders. At this date DGAV is organizing the first visits to distributors for sample collection. Only logistic costs for DGAV - agreement with the Plant Health Association to make authorisation holders to pay to wholesalers and retailers for the samples. This control plan, for the period 2020-2022 has so far 20 samples collected. There is no example yet of the implementation of a full plan. The market dynamic is concentrating the PPPs' trade volume during certain periods of the year; spring time is the best to identify issues in relation to PPPs (professional users). DGAV finished the sampling in May 2022, but no vehicles were available to transport the samples. Hence no results are available yet, as DGAV will wait until June/July 2022 before sending them to the laboratory. On this, DGAV is waiting for the authorisation of the Spanish CA to use its laboratory. A protocol has been drafted in Spanish which does not include a mention to the turn-around time of the testing. There is no intention to make the plan available to the public because the information is on sensitive substances and would allow establishments to prevent/hinder the collection of certain product that could be on the market. DGAV will confirm if the reports are published. In August every year, DGAV requests for authorisation for financial support only. The results from 2022 are needed to assess the risk for planning the controls for 2023. DGAV staff will continue to collect samples, but the legal status of staff is not equivalent to the ASAE inspectors status, meaning that the legal value of the sample collection is solely to fulfill DGAV competences. This is important to understand follow-up enforcement measures, as DGAV can only

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Recommendation	Basis for assessment/Information Requested/CA response
	take administrative measures. Any non-compliant results from 2022 will be transmitted to ASAE for further enforcement. In ASAE actions, when collecting a sample to check the product label, a non-compliance can trigger an immediate seizure of the product and the sample is no longer sent for analysis. DGAV staff cannot do this. *ASAE response* ASAE had cooperated with DGAV, sampling in 2017 and 2019, those samplings were carried out in inspection actions for plant protection product distributors. The list of products to be sampled was communicated by DGAV, our collaboration was only requested until the year 2019. In 2020, DGAV did not request ASAE's collaboration in this matter. However, DGAV addressed this issue in February 2021 in a virtual meeting between ASAE/DGAV, on another matter, later, in June 2021, they sent a proposal for a protocol and a plan to control the formulations of Plant Protection Products (product samples). ASAE carries out 6 types of sampling for DGAV and acts in an holistic way with scarce resources, namely state budget dependent for all of ASAE's tasks. This has an impact on the actions that can be carried out for other institutions. Currently, ASAE is still evaluating the logistic costs and discussing with DGAV all current sample collections, as ASAE supports some costs: staff collecting samples, collection material, transport to laboratory. For PPPs tests, DGAV pays the transport to the laboratory and the analysis, under the same state budget. Regarding the operational performance of ASAE, it should be noted that in 2020, a cooperation action with EUROPOL was also initiated, called Operation SILVER AXE V, with the participation of several criminal police agencies from different Member States, but due to the development of the pandemic and resulting from the application of the measures imposed by the pandemic, with the consequent interruption of economic activities, ended on March 03, 2020. ASAE does not have implement a specific control plan on formulation analysis, like the DGAV one. ASAE's PNFA only targets the marketing of PPPs, namely the control of labelling, selling rules and safety and an example of an Operational order can be sent. Internal sampling procedures are not the same as using ASAE inspectors for sampling (exception in 2018, after DGAV request). ASAE welcomes that the DGAV control plan for 2022 is approved and that samples will be collected by DGAV. The follow-up enforcement measures are taken when DGAV informs ASAE of non-compliant results. In relation to the protocol, it will commit to it in 2023. In November 2023, in the reply to the draft Country Profile, DGAV indicated that:

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	The Protocol with ASAE had not been received as it was no longer relevant given that DGAV continued with the collection of samples on its own initiative, which it did in 2022, having collected a total of 58 samples that were sent to the laboratory. Instead of a Protocol with the laboratory, a Memorandum of Understanding was signed between the Ministry of Agriculture and Food of the Portuguese Republic and the Ministry of Agriculture, Fisheries and Food of the Kingdom of Spain, on Agriculture and Rural Development, on December 7, 2022 , which allowed the laboratory to continue analyzing the samples collected in 2022. The Control Plan for samples collected in 2022 was executed and the samples were sent to the laboratory in 2023. DGAV awaits the laboratory sending the results of the physical and chemical analyses of the samples sent in July 2023. According to the laboratory, the analysis bulletins will be sent by the end of December 2023. As indicated, DGAV is still awaiting the results of the analyzes as the laboratory reported a delay in its execution due to the volume of work and equipment failure. However, as provided for in the Plan, if non-conformities are detected, they will be notified to ASAE for follow-up. Depending on the severity of the non-compliance, DGAV may take administrative actions independent of the actions to be taken by ASAE.
2012-6298-5 Ensure that the official laboratory designated for formulation analysis of PPPs is assessed and accredited in accordance with the European standards, as required by Article 12(2) of Regulation (EC) No 882/2004.	**Closed due to action taken** This recommendation is based on the finding and related conclusion in Section 5.2.4 of the audit report. The official laboratory designated for formulation analysis was not accredited. ***Assessment (January 2024)****:* *There was no arrangement in place for carrying out formulation analyses in an accredited laboratory of samples collected in 2018 as no contract with an accredited laboratory capable of carrying out formulation analyses was in place.* *23 samples of PPPs placed on market were collected for formulation analysis under the 2018/2019 control plans. The samples were sent (September 2019) and tested in an accredited laboratory in another Member State. Results were transmitted to DGAV only in July 2020 (due to the COVID-19 pandemic).* *In December 2022, a Memorandum of Understanding on Agriculture and Rural Development was signed between the Ministry of Agriculture and Food of the Portuguese Republic and the Ministry of Agriculture, Fisheries and Food of the Kingdom of Spain, which allowed the laboratory to continue analysing in 2023, the samples DGAV collected in 2022. DGAV provided the accreditation certificate for the laboratory.*

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Recommendation	Basis for assessment/Information Requested/CA response
	DGAV awaits the laboratory sending the results of the physical and chemical analyses of the samples sent in July 2023. According to the laboratory, which reported a delay due to the volume of work and equipment failure, the analysis bulletins were to be sent by the end of December 2023. ***The actions taken address the recommendation.*** **Background** During the 2016 GFA INIAV stated that it lacked the laboratory capacity for these analyses in the country. As a consequence analyses would be outsourced in another MS (MAGRAMA - Spain) and DGAV is in the process of signing a contract (see answer to recommendation No. 2012-6298-4). DGAV presented a copy of the accreditation certificate of the MAGRAMA laboratory. In the context of the 2019 GFA DGAV stated that contracting outsourced services requires a public tender which can be initiated only if financial resources are guaranteed under the general budgetary rules. However, financial resources are usually known only at the beginning of a given year, thus delaying the administrative procedure for public tender. Also, for that reason, the duration of the contract cannot exceed one budgetary year. DGAV explained that while organising the previous tender it included in the tender the pre-requisite that laboratory submitting its offer must be accredited for carrying out formulation analyses Competent Authority reply of 07/05/2021 A total of 23 samples were shipped to the MAPA laboratory for physical and chemical analytical control in September 2019. Results were received in July 2020. This late reply was reported as due to the COVID-19 pandemic situation and general shutdown of non-essential services (evidence that results were transmitted provided, but not the results). A protocol to ensure formulation analysis with the Laboratorio Arbitral Agroalimentario of the MAPA, Spain is also under preparation (draft protocol provided). During the 2022 GFA *DGAV response* A proposal for a protocol was prepared by DGAV and sent by e-mail on the 28/06/2021 to ASAE for consideration with a view to be agreed upon and signed. A first response with redactorial suggestions was sent for consideration by DGAV on the 12/10/2021 and a revised version submitted by DGAV followed shortly afterwards. To date, the Protocol has not been agreed upon or signed as DGAV is still waiting for final feedback from ASAE. Recently DGAV

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	sent a reminder to ASAE for the purpose of finalising this procedure and received on 18/05/2022 the ASAE's revision of the protocol which has not been assessed yet. In the frame of the 2018/2019 Plan, a total of 22 samples was collected by ASAE and sent to the laboratory for analysis. The laboratory was only able to provide the results in mid-2020 due to the COVID-19 situation. Results obtained were the following: 3 samples were non-compliant (active substance content above authorised) representing 13.4% of samples analysed. Due to the COVID Pandemic ASAE did not engage in enforcement activities under Regulation 1107/2009 during 2020 or 2021 thus no samples were collected for the purpose of formulation controls. To overcome the constraints for 2022, DGAV has modified the Control Plan (includes a formulation analysis control plan) and procedure for sample collection for the purpose of analytical control and samples will be collected by DGAV staff from distributors and wholesalers. For this purpose, appropriate sample collection material was purchased and a communication to authorisation holders was issued for the purpose of informing the distribution channels that samples will be collected from selling points and distributors at the expense of authorisation holders. At this date DGAV is organizing the first visits to distributors for sample collection. Only logistic costs for DGAV - agreement with the Plant Health Association to make authorisation holders to pay to wholesalers and retailers for the samples. This control plan, for the period 2020-2022 has so far 20 samples collected. There is no example yet of the implementation of a full plan. The market dynamic is concentrating the PPPs' trade volume during certain periods of the year; spring time is the best to identify issues in relation to PPPs (professional users). DGAV finished the sampling in May 2022, but no vehicles were available to transport the samples. Hence no results are available yet, as DGAV will wait until June/July 2022 before sending them to the laboratory. On this, DGAV is waiting for the authorisation of the Spanish CA to use its laboratory. A protocol has been drafted in Spanish which does not include a mention to the turn-around time of the testing. There is no intention to make the plan available to the public because the information is on sensitive substances and would allow establishments to prevent/hinder the collection of certain product that could be on the market. DGAV will confirm if the reports are published. In August every year, DGAV requests for authorisation for financial support only. The results from 2022 are needed to assess the risk for planning the controls for 2023. DGAV staff will continue to collect samples, but the legal status of staff is not equivalent to the ASAE inspectors status, meaning that the legal value of the sample collection is solely

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	to fulfill DGAV competences. This is important to understand follow-up enforcement measures, as DGAV can only take administrative measures. Any non-compliant results from 2022 will be transmitted to ASAE for further enforcement. In ASAE actions, when collecting a sample to check the product label, a non-compliance can trigger an immediate seizure of the product and the sample is no longer sent for analysis. DGAV staff cannot do this. *ASAE response* ASAE had cooperated with DGAV, sampling in 2017 and 2019, those samplings were carried out in inspection actions for plant protection product distributors. The list of products to be sampled was communicated by DGAV, our collaboration was only requested until the year 2019. In 2020, DGAV did not request ASAE's collaboration in this matter. However, DGAV addressed this issue in February 2021 in a virtual meeting between ASAE/DGAV, on another matter, later, in June 2021, they sent a proposal for a protocol and a plan to control the formulations of Plant Protection Products (product samples). ASAE carries out 6 types of sampling for DGAV and acts in an holistic way with scarce resources, namely state budget dependent for all of ASAE's tasks. This has an impact on the actions that can be carried out for other institutions. Currently, ASAE is still evaluating the logistic costs and discussing with DGAV all current sample collections, as ASAE supports some costs: staff collecting samples, collection material, transport to laboratory. For PPPs tests, DGAV pays the transport to the laboratory and the analysis, under the same state budget. Regarding the operational performance of ASAE, it should be noted that in 2020, a cooperation action with EUROPOL was also initiated, called Operation SILVER AXE V, with the participation of several criminal police agencies from different Member States, but due to the development of the pandemic and resulting from the application of the measures imposed by the pandemic, with the consequent interruption of economic activities, ended on March 03, 2020. ASAE does not have implement a specific control plan on formulation analysis, like the DGAV one. ASAE's PNFA only targets the marketing of PPPs, namely the control of labelling, selling rules and safety and an example of an Operational order can be sent. Internal sampling procedures are not the same as using ASAE inspectors for sampling (exception in 2018, after DGAV request). ASAE welcomes that the DGAV control plan for 2022 is approved and that samples will be collected by DGAV. The follow-up enforcement measures are taken when DGAV informs ASAE of non-compliant results. In relation to the protocol, it will commit to it in 2023.

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	In November 2023, in the reply to the draft Country Profile, DGAV, as indicated in the response to Audit No. 2012-6298, instead of a Protocol with the laboratory, a Memorandum was signed between the Ministries of Agriculture of Portugal and Spain. However, DGAV has provided the relevant documents that attest to the laboratory's accreditation for carrying out physical and chemical analyses of plant protection product formulations.

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
2016-8792-6 Ensure that the system for processing applications for PTPs is reviewed, and the necessary changes implemented, so as to consistently meet the deadlines laid down in Article 52 of Regulation (EC) No 1107/2009. Conclusions upon which this recommendation is based: 66 Associated findings upon which this recommendation is based: 63	**Closed for other reasons** The system for granting Parallel Trade Permits (PTPs), which is purely an administrative task, is not effective or efficient (deadlines laid down in Article 52 of Regulation (EC) No 1107/2009 are not respected). This results in significant delays for operators in gaining access to the market and creates obstacles to the free movement of PPPs contrary to the objectives of Regulation (EC) No 1107/2009. ***Assessment (January 2024)**:* *DGAV's process to assess PTPs applications has two steps:* • *Period between date of PTP application and date of Request to Reference Member State (mainly administrative tasks).* • *Technical assessment and administrative procedures.* *Only the second step is taken into account when counting the days for completing the assessment in relation to meeting the regulatory deadline. One of the main reasons for not meeting the deadlines relates to unavailability of staff to carry the task.* *DGAV informed the GFA team that following improvements in procedural management and rearrangement of procedures, it was possible to significantly improve the evaluation times for PTP requests: up to July 2023, 47 applications for PTP were received, of which only 7 (3,29%) were processed after the regulatory requirement.* ***The recommendation is closed for other reasons. The situation will be further monitored by means of regular DG SANTE's surveys to monitor trends in Member States in compliance with the legal deadlines.*** **<u>Background</u>**

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
	First response (16/12/2016) DGAV stated that: a) In 2017 it would issue a call for tender for a process management software for managing Parallel Trade Permits (PTPs) applications that would allow the electronic management and on-line evaluation of applications and issuing authorisations without undue delay. b) In 2017 it would strengthen the application evaluation team. c) It would use the pool of experts provided for in Decree-Law No. 145/2015 to supplement the work of the DGAV experts in order to cover also issuing of PTPs. In the context of the 2019 GFA, DGAV stressed that granting PTPs is not purely an administrative task. DGAV explained that this process requires obtaining information on the composition of the product and verifying if the product from the reference MS is identical to the one traded in Portugal. If this is not the case, the staff processing the application must contact the relevant MS(s). DGAV presented data showing that in 2018 its staff processed more than 20 PTP applications and completed them all, while in 2019 there were only 2 such applications. However, the 2 applications received in 2019 are still not concluded as the relevant MSs had not provided the requested information. DGAV stressed that there is a significant variation in the response time as some MSs respond quickly (respecting tight deadlines for processing PTP application) and some not. As a consequence, the mitigating measures undertaken by an individual country to meet the deadline for processing applications may be simply jeopardised by external factors. During the 2022 GFA Since the 2019 GFA, DGAV has improved procedures with respect to PTP applications including rearrangement of the Unit responsible for the authorisation of Plant Protection Products and staff involved in the management and assessment of applications. As such, in 2020 the existing backlog from 2019 was authorised and all applications received in 2021 for PTP were assessed and decision on authorisations taken. Mean assessment duration of PTP in 2021 (excluding time for completeness of the requirement and of response of Reference Member State) was 70 days with a maximum of 151 days and minimum of 5 days. During 2022, 24 PTP applications have been received. For applications received until the 31st march, information has been requested to the Reference Member State. DGAV

<table>
<tr><th colspan="2">Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products</th></tr>
<tr><th>Recommendation</th><th>Basis for assessment/Information Requested/CA response</th></tr>
<tr><td></td><td>awaits response to proceed with the assessments. It is foreseen that new management of applications will improve further the time used for processing PTP applications.
Year Parallel Trade Permits art 52º
Applications PTP issued Non admissible applications
2018 13 25 12
2019 7 10 1
2020 9 19 3
2021 25 28 0
2022 25 1 1
Total 79 83 17
DGAV provided an update for the the PTP applications assessment for the period 2020-2022, up to 30/05/2022:
• 3 applications in 2020 - no assessment met the regulatory deadline
• 22 applications in 2021 - 3 assessments met the regulatory deadline
• 32 applications in 2022 - 28 assessments are pending and 1 did not meet the regulatory deadline.
The process to assess PTPs applications has two steps:
• Period between date of PTP application and date of Request to Reference Member State includes the following administrative steps:
o reception and registry in the head office in Lisbon;
o transport and logging in the DGAV services in Oeiras;
o Dispatch from Director to Head of Unit;
o file creation and registry in file management database;
o invoice preparation and submission to applicant;
o control of invoice settlement and preparation of request for communication to Reference Member State.
These activities are carried out within the DGAPF Unit and different staff (Administrative tasks) are involved in different steps.
2. Technical assessment and administrative procedures:
• composition, packaging material and capacity comparison,</td></tr>
</table>

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
	• conformity check between GAP and C&L of Reference product and PTP label proposal and prior hearing for authorisation content (publication), • Data Base registry and decision One of the main reasons for not meeting the deadlines relates to unavailability of staff to carry the task (e.g. "summer holidays; No alternate staff to proceed with application"; "Christmas holidays/COVID-19; No alternate staff to proceed with application"; "conflict with other tasks carried out by the same technical/admin staff"; "holidays of staff". In November 2023, in the reply to the draft Country Profile, DGAV informed that following improvements in procedural management and rearrangement of procedures, it was possible to significantly improve the evaluation times for PTP requests, as illustrated in the table provided. The table indicates that up to July 2023, 47 applications for PTP were received, of which 7 (3,29%) were processed after the regulatory requirement.

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6719-1 Ensure that (a) only pesticide application equipment that has successfully passed the required inspection is used, as required by Article 8(2) of Directive 2009/128/EC, (b) exemptions from mandatory inspections are allowed only for pesticide application equipment items listed in Article 8(3)(b) of the Directive and (c) any other derogations allowed for comply with the requirements laid	**Closed due to action taken** Although a system has been established for inspection of pesticide application equipment items in use, there is a significant delay in implementing the inspection activities. Thus, the CAs failed to comply with the requirements of Article 8(2) of Directive 2009/128/EC. Moreover, exemptions from mandatory inspections, allowed under national legislation, are not fully in line with the requirements of Article 8(3) of the Directive. As a result, no guarantees could be provided that pesticide application equipment items in use meet the technical requirements in place to ensure proper and safe plant protection products use, and to avoid unnecessary risks and negative impacts on human and animal health and the environment. ***Assessment (August 2021)**:* *Part (a) of the recommendation:* *The actions proposed (July 2019) were considered as measures facilitating the competent authorities in identifying the actual number of pesticide application equipment items in use and extending inspections to the ones used in non-agricultural areas. In October 2019 more specific measures aiming at speeding up the process of pesticide application*

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
down in Article 8(3)(a) of the Directive. Conclusion upon which this recommendation is based: 42 Associated findings upon which this recommendation is based: 31 and 32	*equipment testing as well as indications with regard to deadlines for achieving 100% compliance were provided. As for one of those measures, the deadline for completion was in June 2020, requiring more time for analysis and assessment.* *The update provided (August 2021) on the implementation of the actions to address this part of the recommendation provides guarantees that pesticide application equipment items in use (including the ones used in non-agricultural areas) will be inspected.* *Parts (b) and (c) of the recommendation:* *The amended Decree-Law No 86/2010, applicable from 29/10/2020, establishes in its Article 4(1) that exemptions from mandatory inspections are allowed only for pesticide application equipment items listed in Article 8(3)(b) of the Directive; and establishes in its Articles 3(3) and 18(5) different timetables and inspection intervals to pesticide application equipment not used for spraying pesticides and handheld pesticide application equipment or knapsack sprayers that comply with the requirements laid down in Article 8(3)(a) of the Directive.* ***The actions proposed for part (a) of the recommendation satisfactorily address this part of the recommendation.*** ***The action taken for part (b) and (c) of the recommendation satisfactorily address those parts of the recommendation.*** **<u>Background</u>** <u>First response (15/07/2019):</u> (a) The DGAV considers that the number of checks carried out on agricultural producers in relation to inspected equipment is satisfactory, bearing in mind that around 10% of plant producers (approx. 150) are inspected every year as well as 1% of producers (approx. 1,700) who benefit from financial aid under cross-compliance. In parallel, in order to improve our knowledge of the equipment in use, in 2018 it was agreed with the National Statistical Institute to incorporate into the survey for farms to be conducted as part of the Agricultural Census from October 2019 questions that would allow us to identify the main spraying equipment used. In addition, under PANUSPF 2018-2023, it is planned to set up a working group by the end of 2019, to be coordinated by the Directorate-General for Agriculture and Rural Development and involving different bodies from the Ministry of Agriculture, Forestry and Rural Development, the Ministry of the Economy and the Ministry of Employment,

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	Solidarity, and Social Security, to prepare a legal framework governing the compulsory registration of machinery and equipment, including that used for applying plant protection products. By the end of 2019, the DGAV will implement an Official Control Plan for the application of plant protection products in urban areas, recreation areas and alongside roads and railways, which will also include checks on the equipment used to apply plant protection products, thus strengthening the checks on the inspection of spraying equipment used in such non-agricultural areas. (b) The DGAV has already drafted an amendment to Decree-Law No 86/2010 to bring it into line with the new equipment inspection requirements laid down in EN ISO 16122 and to remove the inspection exemption for equipment not intended for spraying and all manual spraying equipment, except knapsack sprayers. At the time of this Recovery Plan, the above-mentioned legal instrument is going through the legislative process and is expected to be approved by the end of 2019. Second response (04/10/2019): (a) DGAV reiterates that due to lack of an obligatory register of machinery, including application equipment's, actual numbers of PAE that need inspection are not known. Nevertheless, at date, a total number of 21,409 PAE have been inspected. This is the reason why an extensive survey will be conducted from October 2019 to June 2020 under the 2019 Agriculture Census. For this reason it is also not possible to set a deadline for achieving 100% inspected equipment as the total number of PAE available for inspection is not fixed as new equipment come to use and substitution of old equipment is possible. It is also noteworthy that as from end of 2019, an additional number of PAE will be subject to inspection as all hand-held equipment will need also to be inspected introducing therefore an additional layer of uncertainty as to the number or possible timelines for all PAE to be inspected. Nevertheless, the DGAV has taken additional actions as follow: - The publication of additional warnings on the website as from 16.09.2019 at http://www.dgv.min-agricultura.pt/portal/page/portal/DGV: and also the publication of a Notice in specialized agriculture magazines was done; - Communication to representative Agriculture Organisations stressing the need to remind farmers to inspect their PAE (e-mail sent on the 16/09/2019);

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	- Communication to Control Authorities (National Republican Guard) as to reinforce controls on farmers with particular attention to PAE (e-mail sent on the 16/09/2019); The DGAV will also engage in additional public sessions at regional level for the promotion of the revised decree-law and reinforce awareness-raising for the need to inspect equipment during the 1st semester of 2020. (b) and (c) DGAV provided the draft amended Decree-Law No 86/2010. As of 04/10/2019, the legislative procedure is ongoing and will be part of the transition legislative package to be taken over by the new government as legislative elections will take place on 06/10/2019. Third response (27/11/2020) The DGAV informed the Commission on the publication of Decree-Law No 78/2020 transposing several directives and ensuring compliance with obligations arising from European regulations in the field of plant health, on 29/09/2020, which includes amendments to Decree-Law No 86/2010 (republished in Annex IX with the amendments). The amended Decree-Law No 86/2010 is applicable from 29/10/2020. Pesticide application equipment not used for spraying pesticides and handheld pesticide application equipment or knapsack sprayers, which were exempt from inspection, have a period of two years after the date of entry into force of Decree-Law No 78/2020 to be subject to the first mandatory inspection (by 29/10/2022). This type of pesticide application equipment must be inspected and approved every five years. Decree-Law No 78/2020 (Article 11-A) creates the Pesticide Application Equipment Inspection Management System (SIGECIPP), which constitutes the system for recording the inspection activity of pesticide application equipment. Fourth response (09/08/2021 - Ares(2021)3878160) (a) DGAV stated that according to the information provided by the National Statistics Institute, collected under the 2019 Agriculture Census, a total of 66,689 PAE were in use by 2019, and provided a table with the distribution of the different types of PAE in the national territory, including the autonomous regions of Azores and Madeira. DGAV indicated that as of 20/07/2021, the total number of PAE inspected was 25,735. This number is lower than anticipated and foreseen as from the last count in February 2019 (20,313) due most probably to the COVID-19 pandemic during 2020 and 2021 that also resulted in the closure of 3 inspection centres and general slow-down of activity. It is thus difficult to identify a deadline for having 100% of PAE inspected without improvement of the current situation, despite actions already taken regarding improving controls. In addition, as of 2020 with the

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	publication of the amendment to Decree-Law No 86/2010, an increased number of PAE, not necessarily identified in the table (annexed) will also be subject to inspection as from October 2022.
2019-6719-2 Ensure that (a) based on risk assessment, measures are introduced for minimising or prohibiting PPP use in certain specific areas, in particular, areas defined under Article 12(b) of Directive 2009/128/EC and (b) implementation of these measures is sufficiently verified during inspections at PPP professional users. Conclusion upon which this recommendation is based: 69 Associated findings upon which this recommendation is based: 59 and 61	**Closed due to action taken** Due to the lack of provisions and the limited specific measures for minimising or prohibiting PPP use in protected areas, as well as the weak verification of their implementation, no guarantees can be provided that the risks for wildlife and non-target organisms are minimised or eliminated. This is an aspect of significant relevance for Portugal taking account of the high scale of agricultural activities in Natura 2000 areas. ***Assessment (August 2021)**:* *A working group on sensitive areas was established and a first meeting was held on 12/11/2019 with the presence of the competent authorities of the Ministry of Agriculture (DGAV and DGADR) and Environment (Portuguese Environment Agency (APA)). The meeting focused mainly on the Water quality legislation implementation as ICNF was not present although invited to be part of the working group.* *As first actions from the meeting it was agreed to establish a pilot project to assess if the measures already in place in protected areas under the water quality for human consumption Directive 98/83/EC are being effectively implemented. For that purpose, four surface water reservoirs and four Counties were selected for critical overview by the regional services of the Ministry of Agriculture on soil occupation (major agricultural crops) and input from DGAV on the most likely pesticide usage in these areas. This information would be cross-referenced with the soil vulnerability charts so that, based on the results further measures would be possible to implement at farm level e.g., restriction of use of active substances of concern with respect to ground water contamination and to increase efficiency in the monitoring of most problematic pesticides in surface waters. Meanwhile additional information was received from APA with respect to the shapefiles of the surface and ground water bodies, catchment areas and protection perimeters for further analysis.* ***The implementation of the action, along with the actions implemented under recommendations 2019-6719-1 and 2019-6719-3, addresses the recommendation.*** **Background** First response (15/07/2019) The DGAV recognises the importance of introducing measures to restrict or ban PPP use in specific areas, in particular

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	in accordance with Directive 2000/60/EC and the Birds and Habitats Directive, in addition to those already provided for in Law No 26/2013, which transposes the Directive on the Sustainable Use of Pesticides into Portuguese law. However, the DGAV is not the competent authority for implementing the Directives. For this reason, it has proposed setting up a Working Group, which it will coordinate and in which it will work together with the competent authorities to assess and propose the measures to be implemented to reduce the risks related to PPP use in sensitive areas and to monitor the implementation of these measures by professional users. Deadline: 31.12.2019. Second response (04/10/2019) The DGAV informed that an invitation has been forwarded to the relevant CA for the setting of the envisaged Working group and a first meeting has been tentatively scheduled for 12/11/2019. Third response (09/08/2021 - Ares(2021)3878160) The DGAV informed that a WG on Sensitive areas was established and a 1st meeting was held on 12/11/2019 with the presence of the competent authorities of the Ministry of Agriculture (DGAV and DGADR) and Environment (APA, Portuguese Environment Agency). The meeting focused mainly on the Water quality legislation implementation as ICNF was not present although invited to be part of the WG (Minutes of the meeting provided). As first actions from the meeting it was agreed to establish a pilot project to assess if the measures already in place in protected areas under the water quality for human consumption Directive 98/83 are being effectively implemented. For that purpose, 4 surface water reservoirs and 4 Counties were selected for critical overview by the regional services of the Ministry of Agriculture on soil occupation (major agricultural crops) and input from DGAV on most likely pesticide usage in these areas. This information would be cross-referenced with the soil vulnerability charts so that, based on the results further measures would be possible to implement at farm level e.g., restriction of use of active substances of concern with respect to ground water contamination and to increase efficiency in the monitoring of most problematic pesticides in surface waters. Meanwhile additional information was received from APA with respect to the shapefiles of the surface and ground water bodies, catchment areas and protection perimeters for further analysis. Due to the COVID-19 pandemic and to several audits under the frame of the Sustainable Use Directive, Regulation 1107/2009, and Regulation 625/2017, hosted by the relevant services unit responsible for coordinating the work of the WG, conducted by IGAMAOT, during 2020/2021 it was not possible to take further action under this project. It is the intention to resume activities in the 4Q of 2021.

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Recommendation	Basis for assessment/Information Requested/CA response
2019-6719-3 Ensure that the general principles of IPM, as referred to in Article 14 of and Annex III to Directive 2009/128/EC are implemented by all PPP professional users, in accordance with Article 14 (4) of the Directive, in conjunction with 55 of Regulation (EC) No 1107/2009. Conclusion upon which this recommendation is based: 82 Associated findings upon which this recommendation is based: 72 and 73	**Closed due to action taken** Although implementation of integrated pest management (IPM) general principles is a legal obligation for professional PPP users, IPM aspects are not subject to control during inspections at farm level. Some elements are in place, which will support IPM implementation at farm level. However, there are no guarantees at present that IPM is systematically applied to reduce dependency on pesticides and the potential risks for human health and the environment, arising from PPP use. ***Assessment (August 2021)****:* *DGAV has provided the field book for farmers agreed by DGAV/DGADR, which as been adopted and published, accompanied by a short list of instructions for its completion.* *DGAV provided the checklist prepared for the inspection of IPM implementation at farm level under the Control Plan of Primary production, Hygiene and Sustainable use of PPP (PCPP-HUSPF). This checklist is supported by a Procedural Manual for the use of inspectors.* ***The implementation of the actions, along with the actions implemented under recommendation 2019-6719-1, addresses the recommendation.*** **<u>Background</u>** <u>First response (July 2019)</u> DGAV indicated its intention to: • continue develop the actions started during PANUSPF 2013-2018 aimed at producing and/ updating technical documentation to help all producers implement IPM; • during PANUSPF 2018-2023, continue with all the actions provided for in the plan to ensure the widespread adoption of IPM by all agricultural and forestry producers; • review the model field book and promote its widespread use by the end of 2019, and, during 2020, to incorporate checks on the implementation of IPM-compatible practices into the Official Control Plan on primary production and the sustainable use of plant protection products coordinated by the DGAV; • propose that, by the end of 2020, the DGADR review whether additional checks to be taken by private bodies that certify producers in IPM should be adopted. <u>Second response (October 2019)</u>

Audit 2019-6719 of 29 January 2019 in order to evaluate the implementation of measures to achieve the sustainable use of pesticides	
Recommendation	Basis for assessment/Information Requested/CA response
	DGAV informed that a first meeting of the working group (see recommendation 2019-6719-2) aiming at discussing the model field book and revising checks to be taken by private certifying bodies, has been scheduled for 24/11/2019. In parallel, the revision of the Official Control Plan for Primary production and sustainable use of PPP for 2020 to address the control of IPM-compatible practices will be done in order to adopt the plan until 31/12/2019. Third response (09/08/2021 - Ares(2021)3878160) DGAV provided the field book agreed by DGAV/DGADR (Directorate-General for Agriculture and Rural Development) that was prepared. To date, the official adoption and publication of the field book is dependent on the public presentation to the main farmers' organisations, accompanied by a short list of filling instructions that is under preparation by DGADR. It is envisaged that still during the 3Q of 2021 the field book will be publicly available. DGAV provided the checklist prepared for the inspection of IPM implementation at farm level under the Control Plan of Primary production, Hygiene and Sustainable use of PPP (PCPP-HUSPF). This Checklist is supported by a Procedural Manual for the use of inspectors.

2.B.10 Animal welfare

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6750-1 The competent authority should make additional provisions for pig producers to correctly identify all relevant risk factors for tail biting in order that they can ensure that those animals are not caused any unnecessary pain, suffering or injury, as required by Article 3 of Directive 98/58/EC.	**Closed due to action taken** There is a defined level of tail biting below which pig producers will have to start rearing some batches of pigs with full tails. However, the fact that producers are not yet correctly identifying all risk factors (for example relative humidity, gas (CO2 or NH3) concentrations, and/or active ventilation systems) for tail biting is likely to cause significant delays in rearing the first batches of full tail pigs or to result in major tail biting outbreaks in those batches. ***Assessment (July 2023)****:* *DGAV collaborated with relevant stakeholders (FPAS, SCS, UTAD) to implement clarification sessions/workshops on the theme of tail-docking and management of pig farms. DGAV provided evidence of relevant seminars and workshops organised in June and November 2019 and March 2022. No events took place in 2020-2021 due to the COVID-19 pandemic.*

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation based on conclusion 38. Associated findings: 29, 51, 53 and 54 and audit findings in Annex 2.	*DGAV amended the training curriculum for pig farmers in collaboration with DGADR. This is publicly available on the portal of DGADR. An increased level of trained farmers is expected when the eco-scheme intervention on Animal Welfare, included in the Portuguese CAP National Strategic Plan, is implemented due to the compulsory nature of the training.* *DGAV translated the Commission factsheets on the tail biting risk factors and distributed them to pig farmers and veterinarians and made them publicly available on its website, and drafted a code of good practices on pig welfare in collaboration with the farmers association (CAP) (2021), which is also publicly available on its website.* *The Commission services asked in July 2021, and DGAV replied in December 2021, wi th the first evaluation of the replies received during 2020 to the questionnaires (for assessment of risk factors related to tail biting outbreaks in pig farms) sent to the veterinarians and farmers. DGAV planned nonetheless to do a further evaluation to better support the adoption of further measures and scheduled for June 2022, a new meeting of the working group on pig tail docking for this purpose.* *1017 questionnaires were filled in (the last ones in 2022 from the main pig producing region) by farmers with 20 or more sows and 200 or more fattening pigs in intensive production systems. The analysis of 930 questionnaires (by May 2022) shows that most of the farmers presented an action plan that is being implemented. Main risk factors identified were: records, enrichment material, gases in environment, human resources, and training.* *DGAV sent, in August and September 2022, to the Commission services, updates on its national action plan on tail docking. DGAV provided detailed and complete answers to the assessment of the tail docking action plan's 16 concrete criteria (Annex II) concerning relevant requirements e.g. on enrichment materials, competition for food and space, recording of lesions etc. DGAV provided documented evidence in support of its response to the recommendation, namely the action plan for 2022-2024, the pig farm control manual and working instructions, the farmers flowchart to address tail biting, the farmers risk assessment questionnaire, and additional training sessions for official staff of the regional services (October 2019).* *The action plan for 2022-2024 reflects the actions considered necessary to reinforce the ongoing process to forbid routine pig tail docking and prevent tail biting in Portugal. This new plan had in consideration the assessment of the outcomes of the actions established in the plan for 2018-2021 and the evolution of the pig tail docking and tail biting situation in Portugal (results of the pig farmers questionnaires on tail biting risk factors and slaughterhouse*

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
	monitoring) and was discussed on 29 June 2022 with the working group, which involves representatives from the farm and industry sectors, private veterinarians and academia. *DGAV is proposing new actions in the action plan 2022-2024, based on the characterization of the national situation, the evolution of the tail docking ban process and the need to continuously improve the tools and instruments that support the monitoring and assessment of compliance with the legal requirements:* • *Development of a new IT tool to facilitate and allow a better monitoring of the tail biting records, results of experimental no-tail cutting trials, tail biting risk assessment, implementation of the action plans at the farm level.* • *Development of a new instrument to facilitate the farmers compliance with the tail docking requirements, based on the official control manual (requirements and indicators) - farm self-assessment checklist.* • *Meetings, workshops and training sessions with private veterinarians, official veterinarians and farmers - planned for 2022 and 2023.* • *In accordance with the operational objectives established in the plan, reinforcement of the controls on tail docking and enrichment materials requirements - Farmers' notification regarding the state of play; controls based on specific risk criteria, procedures in case of non-compliance.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (23/09/2019)</u> 1 - The DGAV will seek, in collaboration with the FPAS (Portuguese Federation of Pig's Association) and the "Sociedade Científica de Suinicultura" (Scientific Society of Pig Farming), to promote clarification sessions on the theme of tail-docking and management of pig farms. 2 - The training curricula of pig farmers will be reviewed within the framework of Animal Welfare, with the aim of consolidating the knowledge on risk factors of tail docking and their prevention. 3 - DGAV will seek to strengthen the need to implement the requirements regarding the competence, experience and training of the pigs' holders, with the FPAS and the "Sociedade Cientifica de Suinicultura" (Scientific Society of Pig Farming).

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
	The dissemination of the material prepared by the DGAV will be reinforced, within the scope of the reduction of tail-docking, prevention of tail docking and the use of manipulable materials. Second response (15/11/2019) 1 - It is intended that these clarification actions / Workshops take place between the last semester of 2019 and the 1st semester of 2020. Resulting of the information that has been conveyed by the DGAV and given the complexity of the theme, the Scientific Society of Pig Farming considered it appropriate to hold a Workshop (trainer - Emma Fabrega) on tail docking for its members - 14/11/2019. 2 - The DGAV, in collaboration with the competent authority for specialized sectorial training (DGADR), is amending the training curriculum for pig farmers - module 'Protection of animals kept for farming purposes - Pigs'. DGAV intends to finalize this work by the end of 2019, and the new curriculum will be added to Regulation No. 9 of 24/05/2016 on the "Protection of animals in the places of rearing - Pigs ", published on the portal of DGADR and disclosed in the portal of the DGAV. 3 - This measure will be carried out during 2019-2020. It is intended that when official controls are carried out on intensive pig farms and confined animals, Official Veterinarians should carry and disseminate information material concerning the prevention of tail-biting and reduction of tail-docking. The DGAV also intends to place, where possible, the aforementioned information material for events related to pig production - fairs, congresses, symposiums and clarification sessions organized by the FPAS, SCS, CAP and others. We will also request to these entities the direct disclosure (via e-mail or other) of this information to their associates, producers, veterinarians and other technical officers responsible for the farms. 4 - DGAV indicated that in this first phase, it is only after having sufficient and dealt with data that it will be able to conclude whether, in fact, the measures implemented are achieving the desired aim and what needs to be changed to improve the implementation of DGAV's Action Plan. DGAV intends to carry out data processing work and, by the end of the first quarter of 2020, obtain more objective conclusions. During the 2022 GFA: DGAV provided the following replies: • *confirmation that the Workshop of 14/11/2019 took place and if additional ones are planned.*

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
	This information was requested from SCS, the entity that organized the Congress in which this Workshop was integrated. Attached we send congress flyer and the information regarding the target public (Documents: WS taildockingportugal; WS M_IXCongresso148x210) DGAV participated in other events: • Workshop on "IX Congresso da Sociedade Científica de Suinicultura" - 14/11/2019 • (2020 and 2021 workshops were cancelled) • Seminar organised by the IAAS-University of Trás-os-Montes e Alto Douro, and presented the preliminary outcomes of the risk assessment questionnaires - 12/03/2022 • *updated version of the Regulation No. 9 of 24/05/2016 on the "Protection of animals in the places of rearing - Pigs" and if the new curriculum was implemented.* In accordance with information given above, Regulation No. 9 of 24/05/2016 on the "Protection of animals in the places of rearing - Pigs" and respective *curriculum* has been updated and amended to provide the updated and necessary knowledge concerning the handling of pigs, space allowance, mutilations, tail biting, tail docking procedures and risk factors that lead to these situations, etc. (Documents: Regulamento especifico No 9; Copia de Curriculo formação suinicultores.rev). Certification schemes and the Eco-schemes for Pig welfare included in the Portuguese CAP NSP – request for compulsory training of the farmers, as so far (May 2022) the number of farmers trained is low. DGAV translated the Commission factsheets on the tail biting risk factors and distributed them to pig farmers and veterinarians and made them publicly available on its website (https://www.dgav.pt/animais/conteudo/animais-de-producao/suinos/bem-estar-animal/suinos/fichas-tecnicas-relativas-a-caudofagia/). DGAV drafted a code of good practices on pig welfare in collaboration with the farmers association (CAP) (2021), which is publicly available on its website (https://www.dgav.pt/wp-content/uploads/2021/03/Manual_Suinos_BEA_CAP.pdf) • *results of the assessment planned for the 1st quarter of 2020.* In December 2021, as requested by the Commission services in July 2021 (Ares(2021)4821160), the results of the MS enforcement to ban the routine tail docking were sent to the Commission (Doc – "Data request from MS concerning enforcement of the ban on routine tail docking"). A first evaluation of the replies to the questionnaire sent to the Veterinarians and farms, on the assessment of the tail biting risk factors was done. Although it was considered

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Recommendation	Basis for assessment/Information Requested/CA response
	to do a finer evaluation to better support the adoption of further measures. Scheduled for June 2022, a new meeting of the working group on pig tail docking to present results of the risk factors questionnaire and discuss new initiatives. 1017 questionnaires filled in (last ones in 2022 from main region regarding pig production) by farmers with 20 or more sows and 200 or more fattening pigs in intensive production system. The analysis of 930 questionnaires shows that most of the farmers presented an action plan that is being implemented. Main risk factors identified were: Records, Enrichment material, Gases in environment, Human Resources, and Training. Official controls noticed an increase in the use of enrichment materials by farmers. Concerning the rate of tail docking, based on the questionnaires analysed, 93% of the farms practice routine tail docking. Monitoring at slaughterhouse level indicates 50% of pigs with the tail docked. Tail biting signs are monitored at slaughterhouse level and DGAV will send data. DGAV operational objectives are in the Animal Welfare Control Plan for official controls. A percentage to reduce tail docking has not been established but the expectation is to reduce routine tail docking year after year, in a consistent manner. For this, each holding that presents a rate of tail biting >2% must do trials, present an action plan and work to abandon tail docking. A new information system for Official Controls Management is in preparation (elaboration of specifications for public tender by end June 2022), with the aim to be ready and used by 2023. It will allow: • Online recording of tail biting episodes, • Action plans state of implementation, • Monitoring results of the trials where the tail of the pigs are not docked, • Echo schemes evaluation, • Integration of slaughterhouse monitoring, • Classification of holdings according to risk. At the CVO meeting of 12 May 2022, a summary of the MS national action plans on tail docking in pigs was presented and it was mentioned that Portugal was one of the 5 MS that didn't provide data for analysis, regarding this subject. Portugal asked the Commission on 19 May 2022 to clarify this point and to indicate which data was not provided by Portugal, regarding the state of play of the national action plan on tail docking (Ares(2022)3783861), as it had replied in December 2021 (Ares(2021)7725143) to the Commission services.

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Recommendation	Basis for assessment/Information Requested/CA response
	On 29 July 2022, the Commission services replied to Portugal (Ares(2022)5464475), indicating the Commission observations on the content of the Portuguese reply sent on 14 December 2021 to the previous Commission assessment of the Portuguese action plan (Ares(2021)4821160): • Although in its letter Portugal highlighted certain developments in the area of tail docking, it did not submit responses linked to the individual detailed recommendations, thus not enabling the assessment of the updated action plan. Consequently, Portugal could not be included in the overall analysis of the Member States action plans. A relevant statement was made during the CVO meeting, referring to Portugal and another four Member States in the same situation. • In addition, and as previously clarified by the Commission, the enforcement data required in Annex III should follow the common rules established in Annex IV. In particular, Annex IV required that data originates either from official controls activities or from other sources, such as a reliable database. In the latter case, an explanation is required on the methodology used to collect the data and the reliability of the chosen source for the information. • Three out of the nine quantitative data provided by Portugal in Annex III derive from a risk assessment questionnaire and the Commission decided not to further analyse these data since there was no explanation on the methodology used. It should be noted that neither Portugal nor other Member States were named in this respect. An update was provided by DGAV on 04 August 2022 (Ares(2022)5593200) to the Commission services concerning the evolution of the national action plan on tail docking. DGAV took note of all Commission services comments. Also, during the GFA 2022-7380, a series of new data, information and documentation was presented, regarding the recommendations of the audit mission on pig tail docking (Audit mission 2019-6750-1 to 2019-6750-4). • In relation to the recommendations for the sixteen criteria, DGAV enclosed the European Commission Annex II document, with updated information regarding each assessment criteria as well as the documentation that supports the information on Annex II, namely annual control plan (2022-2025), pig farm control manual and working instructions, farmers flowchart, farmers risk assessment questionnaire, training materials. The following documentation completes the updated information on the actions taken by Portugal, in view of forbidding the routine tail docking:

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Recommendation	Basis for assessment/Information Requested/CA response
	○ Country profile pre-questionnaire reply updated; ○ Information sent to the Commission in December 2021 regarding the assessment of the tail docking ban process. • Regarding the data required in Annex III, DGAV informed that it tried to send information as broad as possible, to give a better picture of the situation regarding tail docking in Portugal. The information was based on official control data, tail docking monitoring system at the slaughterhouses and the farmers' replies to the risk assessment questionnaires. ○ The data on the official controls is only related with the farms that were controlled, which is just a sample of the total pig farms. ○ The information from the slaughterhouses only concerns the observations by Veterinary Inspectors from DGAV (official veterinarians) of adult animals at slaughter, which is just part of the total pigs housed in Portugal. Official veterinarians insert this data in the slaughterhouse information system. • The risk assessment questionnaire data gives a picture of the information from the majority of the farms, since almost all the farmers and veterinarians replied to this questionnaire (the replies to the questionnaire were sent via online and on paper to the CA). The methodology was the following: ○ Several meetings with the producers associations and the pig sector veterinarian's association to develop the plan and to develop the questionnaire, within a working group that also involved 2 universities; ○ Development of an online platform for the introduction of certain elements of the questionnaire; ○ Assistant veterinarians, registered as responsible veterinarians in DGAV information system SISS, carried out the questionnaires at the holdings, along with the producers and introduced the data at the platform; official veterinarians follow up the process; 1018 questionnaires were received; ○ This data was subjected to a preliminary analysis by a university. With the complete database the data was also analyzed by the Portuguese Competent Authorities and further analysis is ongoing, as a base to define further controls at farm level and to have a general picture of the main risk factors identified, which is an important data source to define further actions under the National action plan. • Concerning question 4, it's possible to give information based on the results of the official controls, nevertheless this is just a sample of the information of all the farms.

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Recommendation	Basis for assessment/Information Requested/CA response

	• Regarding questions 7 and 8, its only possible to reply to them based on the replies to the risk assessment questionnaire.
	  o On question 7, it required the number of "farms that made a risk assessment", which in fact are the farms that practice the tail docking and sent us the risk assessment questionnaire.
	  o On the other hand, the number of farms with action plans (question 8), are the ones that identified an action plan on the risk assessment questionnaire.
	• In the future DGAV plans to develop a new database, to compile all the information from the pig farm official controls, slaughterhouse monitoring process and at farm level. Nevertheless, the information at farm level, namely the recording of animals with tail biting, the results of the risk assessment and the outcomes of the action plans, must be always introduced by the farmers and the veterinarians as it is not feasible to make controls to all the farms in one year. This information will be the support for the official controls and be validated during the farm's controls.
	On 29 September 2022, DGAV provided a copy of the updated national action plan on tail docking (Plano de ação - Prevenção de mordeduras e redução do corte de cauda por rotina 2022-2024). The new plan reflects the actions considered necessary to reinforce the ongoing process to forbid routine pig tail docking and prevent tail biting in Portugal. This new plan had in consideration the assessment of the outcomes of the actions established in the plan 2018-2021 and the evolution of the pig tail docking and tail biting situation in Portugal (results of the pig farmers questionnaire on tail biting risk factors and slaughterhouse monitoring) and was discussed with the working group especially created for this proposed, which involves representatives from the farm sectors, private veterinarians and academia.

2019-6750-2 The competent authority should ensure that official controls correctly report routine tail docking as non-compliance, in line with the second paragraph of point 8 of Chapter I of Annex I of Council Directive	**Closed due to action taken** Official controls correctly detect routine tail docking but they report it as being compliant (until 2019). This causes under reporting of non-compliances in pig farms in the annual report to the Commission (in connection with Commission Decision 2006/778/EC). *Commission Decision 2006/778/EC has been repealed. The relevant requirements are in Commission Implementing Regulation (EU) 2019/723.* ***Assessment (September 2023)**:*

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Recommendation	Basis for assessment/Information Requested/CA response
2008/120/EC; so that this is also correctly reported under Commission Decision 2006/778/EC. Recommendation based on conclusion 61. Associated findings: 43 and 44.	*Between October and November 2019, four training actions were carried out as planned at national level, covering all Regions including Madeira and the Azores. These actions strengthened the way in which the requirements for tail-docking and environmental enrichment and action in case of non-compliance should be assessed, as well as the procedures to be followed in monitoring this issue at slaughterhouse level.* *DGAV provided the revised Animal Welfare Control Manual - Pigs (DBEA/MP/2010 Revisão: 2 Data: 2022) and the Working Instruction - Criteria for the evaluation of Animal Welfare indicators subject to official control on pig holdings (02/DBEA/ IT/2020 Revisão: Rev 2 Data: 2022). This revision took into account the Commission services' assessment of, and observations on, the national action plan on tail docking (July 2021 and July 2022, respectively).* *DGAV provided evidence that official controls are correctly reporting routine tail docking as a non-compliance, notifying the operators, requesting for corrective measures (with deadlines) and include follow-up checks. DGAV inspectors, for each control to be carried out, cross-reference information between what they see on farm and the answers that the producer has entered into the pig farmers questionnaires on tail biting risk factors; this cross-checking reinforces the monitoring intended in the context of the national action plan on tail docking.* *DGAV sent, in August and September 2022, to the Commission services, updates on its national action plan on tail docking. DGAV provided detailed and complete answers to the assessment of the tail docking action plan's 16 concrete criteria (Annex II) concerning relevant requirements e.g. on enrichment materials, competition for food and space, recording of lesions etc. DGAV provided documented evidence in support of its response to the recommendation, namely the action plan for 2022-2024, the Animal Welfare Control Manual - Pigs and working instructions, the farmers flowchart to address tail biting, and the farmers risk assessment questionnaire.* *Of relevance to this recommendation, DGAV indicated in the updates above that:* • *Apart from the tool used to collect the farmers' replies to the risk assessment questionnaire, which included questions on the records of tail lesions in the last 6 months, a new IT tool is being prepared to allow a full monitoring of this process. This will include an online record of the animals with tail biting, farm tail biting risk assessments, action plans and results of non-tail docking trials. This tool will allow a simplification and a better monitoring of the all the process.* • *As part of official checks on pig farms, the Official Veterinarians control the producers mandatory records of tail bite outbreaks that have occurred in the last 6 months. The absence of these records requires corrective measures.*

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Recommendation	Basis for assessment/Information Requested/CA response
	• *The action plan (2022-2024) defines as one of the operational objectives the reinforcement of the evaluation of the requirement to report tail docking as a non-compliance. The annual control report (under Regulation (EU) 2019/723) has an evaluation of the compliance of this specific objective.* • *The requirements contained in Directive 2008/120/EC are assessed during official controls and it is mandatory to comply with them otherwise it will be considered a non-compliance and, in the case of the multiannual national control plan (Regulation (EU) 2017/625 and Regulation (EU) 2019/783) counted as such. Until 2019, the evaluation results of the controls per pigs sent to DG SANTE specified the number of non-compliances relating to those requirements. National legislation - DL 135/2003 of 28 June, has these provisions clearly defined in its Article 11. The annual report under Regulation (EU) 2019/723 includes an analysis of the main non-compliances verified during the controls. This analysis is made taking in consideration the main categories of non-compliances.* *DGAV sent additional information in September 2023 on:* • *the Cross-compliance Control Manual and the specific Technical Guidance relating to RLG 12 - Cross-compliance Animal Welfare - pigs.* • *The pig welfare control checklist within the scope of cross-compliance.* • *Proposals for further improvements to the same documents, already proposed for 2024, in order to make producers' obligations and official veterinarians' controls clearer, in relation to the requirements of tail docking and enrichment materials.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (23/09/2019)</u> 1 - DGAV indicated that the Animal Welfare Control Manual, used as a basis for official controls, will be revised with a view to reinforcing the need to register and consider non-compliant tail docking practice in line with the legislation (lack of tail docking records that justify tail docking and failure to take action on identified risk factors). 2 - In September/October 2019, targeted training actions for the technical staff of the Regional Directorates for Food and Veterinary (DSAVR) (training actions in different regions) are planned regarding the action plan for tail docking in pigs, where the need to improve the assessment of compliance with the legislation in this area will be reinforced.

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Recommendation	Basis for assessment/Information Requested/CA response
	3 - Within the context of cross-compliance controls, DGAV intends that from 2020 onwards, the legal criteria relating to the practice of routine tail docking will be assessed in more detail and taking into account the Action Plan and the replies to the producers' questionnaires. This matter will be discussed with the local veterinary services at the next follow-up meeting of the Action Plan. <u>Second response (15/11/2019)</u> 1 - DGAV is carrying out the proposed revision of the Animal Welfare Control Manual - Pigs, which it intends to finalize in the first quarter of 2020. As soon as the manual is finalized, DGAV will forward it. 2 - Between October and November 2019, 4 training actions were carried out as planned at national level, covering all Regions including Madeira and the Azores (see attached programme). These actions strengthened the way in which the requirements for tail-docking and environmental enrichment and action in case of non-compliance should be assessed, as well as the procedures to be followed in monitoring this issue at slaughterhouse level. The training session addressed the audit findings and the measures that need to be taken at official control level in a very forceful manner. 3 - Cross- compliance – The procedures will be changed as early as 2020. The Agenda as well as the conditionality report will be changed for next year's campaign, and these new procedures will be released by the FPAS. 4 - (to query below) The DGAV is monitoring controls during the end of the year, beginning of the first half of 2020. The data from the controls that are being carried out will be collected through a new compilation report on the intranet - 1 month, after which the monitoring work will be done. A new reporting format will be created to compile the data from the controls. <u>During the 2022 GFA</u>: DGAV provided the following replies: • *revised Animal Welfare Control Manual - Pigs to confirm that relevant changes were made* The revised Animal Welfare Control Manual - Pigs (DBEA/MP/2010 Revisão: 2 Data: 2022) and the Working Instruction - Criteria for the evaluation of Animal Welfare indicators subject to official control on pig holdings (02/DBEA/ IT/2020 Revisão: Rev 2 Data: 2022) are attached. • *update on if official controls are correctly reporting routine tail docking as a non-compliance and if this is confirmed by the monitoring put in place by DGAV.*

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Recommendation	Basis for assessment/Information Requested/CA response
	During official checks on pig farms, DGAV technicians assess legal requirements using the checklists stipulated for this purpose, where the possible non-compliance (NC) are well defined, namely points: D.4. line 6; D.5 lines 1,2,4 e5; F; H-H2 lines 3.4 and 5 of the "Relatório de Controlo Ciclo Completo". Thus, under the Animal Protection Plan and the Action Plan - Tail Docking, monitoring of farms is being carried out to highlight the NC and give them the follow-up deemed necessary. In addition to the official control reports, DGAV inspectors for each control to be carried out, cross-reference information between what they see on farm and the answers that the producer has entered into the "Questionário para Avaliação de Factores de Risco Relativos ao Aparecimento de Surtos de Caudofagia em Suiniculturas"; this data crossing reinforces the monitoring intended in the context of the Action Plan - Tail Docking. Attached are two examples of control reports reporting routine tail docking as a non-compliance and notifications relating to these checks, corrective measures to be implemented and follow-up checks to verify the correct application of these measures (Documents: CICLO COMPLETO NOVO_; Controlo DSAVRC - Example of a pig farm control documentation; Controlo DSAVRN - Example of a pig farm control documentation) The Commission factsheets on the tail biting risk factors were translated to Portuguese and distributed to pig farmers and veterinarians. This documentation as well as the code of good practices made in collaboration with the farmers' association are available on DGAV internet page at: https://www.dgav.pt/animais/conteudo/animais-de-producao/suinos/bem-estar-animal/suinos/fichas-tecnicas-relativas-a-caudofagia/ and https://www.dgav.pt/wp-content/uploads/2021/03/Manual_Suinos_BEA_CAP.pdf. DGAV provided updates to the Commission services in August and September 2022 on its national action plan on tail docking (see background for recommendation 2019-6750_1). The animal welfare pig control manual and instructions were updated to define mandatory criteria to the requirements presented in the Annex II. For each requirement, DGAV identified the pages of the Control manual and working instructions in which the criteria and assessing methodology are defined. The criteria support the evaluation of the legal requirements and are the basis for the official controls. The revised version of the annual control and the working instructions were sent to all the official veterinarians and discussed with the farmers and industry during the meeting held in June 2022 to revise the national control plan on tail docking. The results of the outcome of the controls to pig farms, namely the number of non-compliances per type of requirement is sent to the European Commission annually (Reg. 723/2019). This report includes an analysis of the

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Recommendation	Basis for assessment/Information Requested/CA response
	main non compliances verified during the controls. This analysis is made taking in consideration the main categories of non-compliances. On the pig farm controls all the requirements of the Directive 120/2008, including those mentioned in the Annex II, are checked and it is mandatory to comply with them otherwise it will be considered non-compliance and counted as such. Update on 18/08/2023: DGAV sent the revised Cross-compliance Control Manual and the specific Technical Guidance relating to RLG 12-BEA Cross-compliance - pigs, in order to make producers' obligations and official veterinarians' controls clearer, in relation to the requirements of tail docking and enrichment materials.Furthermore, DGAV sent the the pig welfare control checklist within the scope of cross-compliance. DGAV also sent their proposals for further improvements to the same documents, already proposed for 2024.
2019-6750-3 The competent authority should ensure that official controls correctly indicate as non-compliance; enrichment material such as chains, insufficient to fulfil the essential needs for proper investigation and manipulation, in line with point 4 of Chapter I of Annex I of Council Directive 2008/120/EC and Commission Recommendation (EU) 2016/336; and routine tail docking, in line with the second paragraph of point 8 of	**Closed due to action taken** Official controls correctly detect routine tail docking but they report it as being compliant (until 2019). This causes under reporting of non-compliances in pig farms in the annual report to the Commission (in connection with Commission Decision 2006/778/EC). The new reference criteria have only been recently added to the official controls instructions and verification of their implementation has not started yet. The narrow scope of compliance criteria will prevent inspectors from fully enforcing these requirements. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Article 12(3)(b) of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:* *DGAV provided the revised Animal Welfare Control Manual - Pigs (DBEA/MP/2010 Revisão: 2 Data: 2022) and the Working Instruction - Criteria for the evaluation of Animal Welfare indicators subject to official control on pig holdings (02/DBEA/ IT/2020 Revisão: Rev 2 Data: 2022). This revision took into account the Commission assessment of, and observations on, the national action plan on tail docking (July 2021 and July 2022, respectively).* *DGAV provided evidence that official controls are correctly reporting routine tail docking as a non-compliance, notifying the operators, requesting for corrective measures (with deadlines) and include follow-up checks. DGAV inspectors, for each control to be carried out, cross-reference information between what they see on farm and the*

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Chapter I of Annex I of Council Directive 2008/120/EC; in order for official controls to require operators to take corrective action, in line with Article 8, 3, (b) of Regulation (EC) No 882/2004 of the European Parliament and of the Council. Recommendation based on conclusions 61 and 62. Associated findings: 43, 50, 52 and 54 and audit findings in Annex 2.	*answers that the producer has entered into the pig farmers questionnaires on tail biting risk factors; this cross-checking reinforces the monitoring intended in the context of the national action plan on tail docking.* *DGAV sent, in August and September 2022, to the Commission services, updates on its national action plan on tail docking. DGAV provided detailed and complete answers to the assessment of the tail docking action plan's 16 concrete criteria (Annex II) concerning relevant requirements e.g. on enrichment materials, competition for food and space, recording of lesions etc. DGAV provided documented evidence in support of its response to the recommendation, namely the action plan for 2022-2024, the Animal Welfare Control Manual - Pigs and working instructions, the farmers flowchart to address tail biting, and the farmers risk assessment questionnaire.* *Of relevance to this recommendation, DGAV indicated in the updates above that:* • *The control manual and instructions had been updated to define criteria to assess the enrichment material requirement. The action plan (2022-2024) defines as one of the operational objectives the reinforcement of the evaluation of this requirement. There has been an increase in the number of non-compliances regarding this specific item (the analysis of compliance with the operational objectives is in the annual reports sent to the Commission services). Additionally, more precise indicators to measure if the enrichment materials used are capable of preventing tail biting were included in the control manual and instructions and DGAV is continuously assessing them.* • *The control manual and instructions had been updated to define criteria to also assess:* o *cleanliness.* o *thermal confort and air quality.* o *the ability, knowledge, and professional competence of the staff.* o *the presence of suitable accommodation for animals that were sick or injured.* o *early weaning, and special/adapted/suitable piglet accommodation.* o *the unobstructed floor area.* o *excessive fighting behaviour and competition for food, water and space.* o *the diet.* *In 2019, 2020 and 2021, there were no significant non-compliances on these items (as reported in the DGAV analysis in the annual reports sent to the Commission services).* ***The actions address the recommendation.***

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Recommendation	Basis for assessment/Information Requested/CA response
	Background First response (23/09/2019) 1 - DGAV indicated that the Animal Welfare Control Manual, used as a basis for official controls, will be revised with a view to reinforcing the need to register and consider non-compliant tail docking practice in line with the legislation (lack of tail docking records that justify tail docking and failure to take action on identified risk factors). 2 - In September/October 2019, targeted training actions for the technical staff of the Regional Directorates for Food and Veterinary (DSAVR) (training actions in different regions) are planned regarding the action plan for tail docking in pigs, where the need to improve the assessment of compliance with the legislation in this area will be reinforced. 3 - Within the context of cross-compliance controls, DGAV intends that from 2020 onwards, the legal criteria relating to the practice of routine tail docking will be assessed in more detail and taking into account the Action Plan and the replies to the producers' questionnaires. This matter will be discussed with the local veterinary services at the next follow-up meeting of the Action Plan. Second response (15/11/2019) 1 - DGAV is carrying out the proposed revision of the Animal Welfare Control Manual - Pigs, which it intends to finalize in the first quarter of 2020. As soon as the manual is finalized, DGAV will forward it. 2 - Between October and November 2019, 4 training actions were carried out as planned at national level, covering all Regions including Madeira and the Azores (see attached programme). These actions strengthened the way in which the requirements for tail-docking and environmental enrichment and action in case of non-compliance should be assessed, as well as the procedures to be followed in monitoring this issue at slaughterhouse level. The training session addressed the audit findings and the measures that need to be taken at official control level in a very forceful manner. 3 - Cross- compliance – The procedures will be changed as early as 2020. The Agenda as well as the conditionality report will be changed for next year's campaign, and these new procedures will be released by the FPAS. 4 - (to query below) The DGAV is monitoring controls during the end of the year, beginning of the first half of 2020. The data from the controls that are being carried out will be collected through a new compilation report on the intranet - 1 month, after which the monitoring work will be done. During the 2022 GFA:

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Recommendation	Basis for assessment/Information Requested/CA response
	DGAV sent two examples of control reports reporting routine tail docking as a non-compliance and notifications relating to these checks, corrective measures to be implemented and follow-up checks to verify the correct application of these measures (Documents: CICLO COMPLETO NOVO_; Controlo DSAVRC - Example of a pig farm control documentation; Controlo DSAVRN - Example of a pig farm control documentation). DGAV provided updates to the Commission services in August and September 2022 on its national action plan on tail docking (see background for recommendation 2019-6750_1). The animal welfare pig control manual and instructions were updated to define mandatory criteria to the requirements presented in the Annex II. For each requirement, DGAV identified the pages of the Control manual and working instructions in which the criteria and assessing methodology are defined. The criteria support the evaluation of the legal requirements and are the basis for the official controls. The revised version of the annual control and the working instructions were sent to all the official veterinarians and discussed with the farmers and industry during the meeting held in June 2022 to revise the national control plan on tail docking. The results of the outcome of the controls to pig farms, namely the number of non-compliances per type of requirement is sent to the European Commission annually (Reg. 723/2019). This report includes an analysis of the main non compliances verified during the controls. This analysis is made taking in consideration the main categories of non-compliances. On the pig farm controls all the requirements of the Directive 120/2008, including those mentioned in the Annex II, are checked and it is mandatory to comply with them otherwise it will be considered non-compliance and counted as such.
2019-6750-4 The competent authority should provide additional compliance criteria so that farmers have a clear indication of what is required and official controls can more effectively enforce the legal requirements of Council Directive	**Closed due to action taken** The competent authorities together with producers, veterinarians and scientific support produced comprehensive guidance and monitoring tools. The new reference criteria have only been recently added to the official controls instructions and verification of their implementation has not started yet. The authorities will have difficulties to enforce existing legislative requirements related to risk factors as the new criteria they set are mainly guidance instead of compliance criteria. In addition, the producers' lack of recognition and acceptance of several stress factors present for tail biting, combined with most additional criteria being only guidance, may cause major delays, or even refusal, from producers to act on official controls' indications of areas they should improve.

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Recommendation	Basis for assessment/Information Requested/CA response
2008/120/EC and Council Directive 98/58/EC that are related to risk factors for tail biting. Recommendation based on conclusions 37, 62 and 63. Associated findings: 12, 14, 45, 46, 51 and audit findings in Annex 2.	***Assessment (July 2023)**:* *The "Questionnaire for Assessment of Risk Factors related to Tail Biting Outbreaks in Pig Farms", provided by DGAV, includes the (farmers' self-) assessment of the relevant points mentioned in findings 12, 14 and 45 of the audit report. The farmers communicate their assessments to the competent authority via an online platform, which allows for the monitoring of the implementation of the Action Plans on reducing tail biting and docking in the concerned farms.* *DGAV sent, in August and September 2022, to the Commission services, updates on its national action plan on tail docking. DGAV provided detailed and complete answers to the assessment of the tail docking action plan's 16 concrete criteria (Annex II) concerning relevant requirements e.g. on enrichment materials, competition for food and space, recording of lesions etc. DGAV provided documented evidence in support of its response to the recommendation, namely the action plan for 2022-2024, the Animal Welfare Control Manual - Pigs and working instructions, the farmers flowchart to address tail biting, and the farmers risk assessment questionnaire.* *Of relevance to this recommendation, DGAV indicated in the updates above that:* • *The control manual and instructions had been updated to define criteria to assess the enrichment material requirement. The action plan (2022-2024) defines as one of the operational objectives the reinforcement of the evaluation of this requirement. There has been an increase in the number of non-compliances regarding this specific item (the analysis of compliance with the operational objectives is in the annual reports sent to the Commission services). Additionally, more precise indicators to measure if the enrichment materials used are capable of preventing tail biting were included in the control manual and instructions and DGAV is continuously assessing them.* • *The control manual and instructions had been updated to define criteria to also assess:* o *cleanliness.* o *thermal confort and air quality.* o *the ability, knowledge, and professional competence of the staff.* o *the presence of suitable accommodation for animals that were sick or injured.* o *early weaning, and special/adapted/suitable piglet accommodation.* o *the unobstructed floor area.* o *excessive fighting behaviour and competition for food, water and space.*

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Recommendation	Basis for assessment/Information Requested/CA response
	○ *the diet.* *In 2019, 2020 and 2021, there were no significant non-compliances on these items (as reported in the DGAV analysis in the annual reports sent to the Commission services).* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (23/09/2019)</u> 1 - DGAV indicated that the Animal Welfare Control Manual, used as a basis for official controls, will be revised, seeking to improve the way legal requirements are assessed (linked to risk factors for tail docking) and the indicators to determine their non-compliance (animal and resource based indicators). 2 - Instructions to producers will be drawn up on the basis of the criteria to be reviewed in the context of controls and found to be non-compliant. <u>Second response (15/11/2019)</u> 1 - DGAV is carrying out the proposed revision of the Animal Welfare Control Manual - Pigs, which it intends to finalize in the first quarter of 2020. As soon as the manual is finalized, DGAV will forward it. 2 - The instructions will be reviewed after the revision of the Control Manual in the first half of 2020. When the instructions are prepared they will be sent to the European Commission. <u>During the 2022 GFA</u>: DGAV provided the following reply: • *The competent authority is invited to provide evidence that the revised instructions to producers cover the relevant points (such as findings 12, 14, 45 of the audit report).* The document: ”instructions to fill the questionnaire - evaluation parameters annexed to the “QUESTIONNAIRE FOR ASSESSMENT OF RISK FACTORS RELATED TO TAIL BITING OUTBREAKS IN PIG FARMS” (QUESTIONÁRIO PARA AVALIAÇÃO DE FATORES DE RISCO (FR) RELATIVOS AO APARECIMENTO DE SURTOS DE CAUDOFAGIA EM SUÍNICULTURAS) was attached. These questionnaires, and the specific instructions on the assessment of tail biting risk factors, were sent to all farmers with 20 or more sows and 200 or more fattening pigs in intensive production system. The purpose of these instructions is to guide producers to make a

Audit 2019-6750 of 13 May 2019 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
	more careful assessment of their holdings and management systems and introduce the necessary corrective measures by establishing a farm Action Plan (Document: Questionario Produtores _CorteCaudas_Março2019_F (1)). DGAV provided updates to the Commission services in August and September 2022 on its national action plan on tail docking (see background for recommendation 2019-6750_1). The animal welfare pig control manual and instructions were updated to define mandatory criteria to the requirements presented in the Annex II. For each requirement, DGAV identified the pages of the Control manual and working instructions in which the criteria and assessing methodology are defined. The criteria support the evaluation of the legal requirements and are the basis for the official controls. The revised version of the annual control and the working instructions were sent to all the official veterinarians and discussed with the farmers and industry during the meeting held in June 2022 to revise the national control plan on tail docking. The results of the outcome of the controls to pig farms, namely the number of non-compliances per type of requirement is sent to the European Commission annually (Reg. 723/2019). This report includes an analysis of the main non compliances verified during the controls. This analysis is made taking in consideration the main categories of non-compliances. On the pig farm controls all the requirements of the Directive 120/2008, including those mentioned in the Annex II, are checked and it is mandatory to comply with them otherwise it will be considered non-compliance and counted as such.

2.B.11 Plant health

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
2017-6167-1 Ensure that all dead or declining trees are identified and sampled in the buffer zone as required by point	**Closed due to action taken** While the identification and sampling of dead or declining trees are largely performed in accordance with legislation, the identification, recording and sampling of all dead or declining trees had some delays due to shortage of staff. Delayed elimination of these trees leads to a risk of PWN spreading within the buffer zone.

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
3(b) of Annex II to Commission Decision 2012/535/EU. In particular human resources should be sufficient to enable timely identification and sampling throughout the buffer zone. Recommendation based on conclusions 19, 43 Associated findings 10, 39, 40, 41	This recommendation takes over the issue already identified by earlier DG SANTE audit 2014-7193 (recommendation No 11). ***Assessment (July 2023)**:* *This recommendation was followed-up by recommendation (1) of the 2018-6488 audit report. A comprehensive action plan in response to that recommendation was received and considered satisfactory.* *Subsequently, DG SANTE audit 2021-7281 followed-up recommendation 1 of the 2018-6488 audit report. The findings (25 and 29) and the conclusion (35) along with the comments provided by the ICNF to the report (footnote 9) demonstrate that the authorities took actions to address the recommendation.* ***Therefore, this recommendation (2017-6167-1) is also considered addressed.*** **<u>Background</u>** <u>First response (25/09/2017)</u> ICNF stated that intensive identification of trees with decline symptoms continuous in the Buffer Zone and in the area surrounding the Buffer Zone where presence of PWN has been detected. The speed of identification depends on the availability of the ICNF teams and priority is given to areas with the biggest risk. ICNF uses highly skilled technical staff, operations assistants and nature wardens from both regional departments and its central services. Out of 90 of ICNF employees involved, 56 dedicate more than 10 working days to the identification activity, i.e. region North 18 people, Centre 25 people, LVT 5 people, Alentejo 3 people, Algarve 1 person, Central Services/DGAPPF 4 people. ICNF expressed intention to form a specific organisational unit at regional level to increase the capacity for intervention. ICNF informed that a new computer platform adapted to the current situation is in development with a view to providing quick and effective responses that are coordinated among the various bodies involved. It is expected that this will become operational in January 2018; the aim is for that new platform to now include functionalities for risk management and support to decision-making. The extent and complexity of the matter at issue mean that development of the new platform will require the use of specialised services, particularly those specialised in information management systems and topics such as Business

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
	Intelligence, graphic design, web-based communications and spatial representation. Accordingly, a financial contribution from the Commission would be essential here too. Second response (08/01/2018) ICNF informed that a reorganization is being considered, based on the experience gained in the last 5 years, especially that resulting from the impact of last year's forest fires. It is expected that during March 2018 a new proposal of an organic law for the ICNF will emerge that looks for a reinforcement of the intervention capacity at the forest protection level. A single information system is intended to be developed that integrates, in a unique web-based platform, all functionalities required to increase both the efficiency and efficacy of the control measures (e.g. internal communication, decision making and planning support, reporting). A public procurement procedure with direct award has been carried out during the last trimester and a contract has already been signed with an IT company, which will develop the above mentioned system during eight months, from December 2017 on. A functional prototype will be delivered in June and tested during the remaining months for fine tuning. It is considered adequate to request an EU financial support, namely to support the costs of the work involved in its development and of an extended computational capacity for the collection and processing of data and information Outcome and reply to Audit 2021-7281 The audit team indicated in conclusion 35 of the final audit report that "*Annual surveys are carried out according to the multi annual action plan elaborated by the CAs for the control of the PWN. The increased number of samples taken, particularly when sampling in the crown and placing traps and baits whilst targeting high risk areas, provide additional assurance with respect to the stated absence of the PWN from the buffer zone. However, a substantial part of the activities of the forest rangers is allocated to tasks other than surveillance for trees showing early declining symptoms. This reduces the likelihood of the earliest possible detection of PWN spread in the buffer zone, particularly during the summer.*" In its response to the draft report, the ICNF stated that: "*the ICNF has endeavoured to constantly reinforce its staff responsible for carrying out surveys and has allocated teams exclusively to forest plant health, a commitment which it maintains, and which meets the recommendation made further to the previous audit (carried out in report DG (SANTE)/2018-6488 MR Final). In 2021, 13 senior technicians from among the ICNF staff were taken on as forest*

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
	plant health inspectors by the Single Authority, to which a further five will be added at the end of this year. A number of park rangers have also been hired and have been stepping up preventive surveillance activities in this area. Most of these rangers have already participated in a number of targeted training courses. It should also be noted that the ICNF has recently completed the training of 40 firefighters who will work on fire prevention and firefighting, an initial contingent with a target of 600 operations spread throughout the country, which should certainly make it possible to redirect preventive surveillance measures carried out by park rangers to other areas, including forest plant health. Their training is considered as a module to address this specific issue."
2017-6167-2 Ensure that dead or declining trees identified in the buffer zone are felled and disposed of in an effective way in line with point 3(b) of Annex II to Commission Decision 2012/535/EU. Recommendation based on conclusions 56 Associated findings 45, 47, 49, 50, 51, 52	**Closed due to action taken** The felling and disposal of identified trees was not achieved due to serious forest fires and drought as well as disruption in contracts with felling operators. This poses a risk of infested vectors emerging from these trees. This recommendation takes over issues already identified by earlier DG SANTE audit 2014-7193 (recommendations No 12 and 13). ***Assessment (May 2022):*** *This has been overtaken by changes in the EU emergency measure, which the CA referred to in their action plan. The changes have removed the previous deadline for felling (prior to the vector emerging) and also provided for the plan for the removal of fire-damaged trees, which was approved by the Standing Committee on Plants, Animals, Food and Feed and evaluated by the audit 2018-6488.* ***Therefore, this recommendation is addressed.*** **<u>Background</u>** <u>First response (25/09/2017)</u> ICNF stated that all trees from the Buffer Zone found susceptible to PWN and with symptoms of decline would be felled and properly disposed of but this operation requires contracting specialised services to fell and destroy the trees on the spot. ICNF pointed out that phenomena of decline is a dynamic and constant process and cannot be confined to a specific period, even though time limits are set for their destruction. E.g. abiotic phenomena such as those arising from drought, storms and in particular from forest fires often take place out of a season and are not expected. This causes situations in which it is impossible to implement the measures within the set time-limits.

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
	ICNF stressed that between 1 April 2016 and 31 March 2017, a severe drought and forest fires resulted in an unprecedented increase of dead and/or declining trees. Approximately 2.6 times more trees showed symptoms of decline in 2016/2017 than the average in last 5 years. To mitigate these harmful effects competent authorities felled approximately 1.5 times more trees than the average in previous years and set priorities for intervention in order to eliminate any potential associated risks. The authorities made an arrangement for destruction of trees identified for cutting in the period 1 April 2016 and 31 March 2017. Out of 350,000 identified trees, 159,000 were on public land and fall under two contracts for a total of EUR 200,000. It has also been included in two new procedures for acquisition of specialised services (one public call for tenders, also for a maximum of EUR 200,000 and scheduled for implementation by the end of 2017, and an international public call for tenders, multi-annual in nature (2017-2020), for a maximum of EUR 3,000,000). The trees would be destroyed before the start of the period of emergence of the PWN vector insect. The Portuguese authorities committed itself to comply with the deadlines set.
2017-6167-3 Ensure that all trees found infested with PWN which are situated in parts adjacent to the buffer zone, are disposed of with their logging remains, taking all necessary precautions to avoid spreading PWN and its vector, in line with point 2 of Annex II to Commission Decision 2012/535/EU. In particular the management of samples as well as the internal and external communication of positive results of samples taken in parts adjacent to the buffer zone should be done quickly enough to ensure that the	**Closed due to action taken** Despite the system for the control of PWN in continental Portugal being comprehensive and generally in line with Decision 2012/535/EU, it is not currently designed to ensure a timely felling and disposal of trees found infested by PWN. This poses a risk of incursion of PWN into the buffer zone by vector dispersal. This recommendation takes over the issue already identified by earlier DG SANTE audit 2014-7193 (recommendation No 14). ***Assessment (May 2022):*** *This has been overtaken by changes in the EU emergency measure, which the CA referred to in their action plan. The changes have removed the previous deadline for felling (prior to the vector emerging) and also provided for the plan for the removal of fire-damaged trees, which was approved by the PAFF and evaluated by the audit 2018-6488. The handling of samples, analytical capacity and the recording and distribution of results are appropriate.* ***Therefore, this recommendation is addressed.*** **<u>Background</u>** <u>First response (25/09/2017)</u>

Audit 2017-6167 of 08 May 2017 in order to evaluate the situation and controls for Bursaphelenchus Xylophilus (PWN)	
Recommendation	Basis for assessment/Information Requested/CA response
PWN-infested trees can de felled and disposed of in a timely manner. Recommendation based on conclusions 18, 36, 37 Associated findings 3, 14, 34, 35	ICNF stated that all PWN infested trees, from Intervention Zones adjacent to the Buffer Zone and including the 10 new adjacent parishes, have been correctly disposed of. To avoid further spread from areas adjacent to the Buffer Zone, ICNF ensures the felling and destruction of infected and declining trees. The new ongoing procedure – valued at EUR 200 000 – would enable to continue the work in the Buffer Zone and in the adjacent Infected Zone parishes. The new multi-annual competition (2017-2020) valued at EUR 3,000,000 would allow covering the Buffer Zone, adjacent parishes of Infected Zone, and all other parishes adjacent to the Buffer Zone. ICNF expects that a new IT platform for communication of laboratory analyses become operational in January 2018. The platform would allow for quicker communication and responses between the bodies involved in testing and eradication of with a view to making the PWN control process more efficient.

Audit 2018-6488 of 12 November 2018 in order to evaluate the situation and control for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6488-1 Ensure that the surveys and the activities for the identification and sampling of dead or declining trees in the Buffer Zone, required by points 3(a) and 3(b) of Annex II to Commission Decision 2012/535/EU, enable the early detection of the presence of pinewood nematode. In particular the level of sampling in the crown should be increased and there should be sufficient resources	**Closed due to action taken** The system of official controls is dependent on the resources available to perform them. While it is concluded that the system is in line with the requirements of EU legislation, the constraints on resources mean that the surveys are not all carried out at the optimal time for detecting PWN (see section 5.2) and the controls of heat treatment facilities were limited. While the survey plan has been strengthened in response to increased risks of PWN incursion in the buffer zone, ICNF human resources have not been adapted accordingly, which has resulted in delays in the implementation of the surveys and identification of declining trees in the Buffer Zone and surveys in the Adjacent Area. This reduces the likelihood of early detection of PWN in the Buffer Zone and the Adjacent Area, and the assurance that the status of PWN, and in particular its absence from the Buffer Zone, is established reliably. This is compounded by the sampling methods used, which are not optimal for detecting the presence of PWN, in particular in trees that did not decline because of PWN and were infested at oviposition. Sampling in the crown and close to the vector's pupal chamber, is considered to be the most sensitive technique for detecting the presence of PWN in trees, and would provide considerable additional assurance with respect to the stated absence of the PWN from the Buffer Zone.

Audit 2018-6488 of 12 November 2018 in order to evaluate the situation and control for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
to ensure that these activities are carried out at optimal times. Recommendation based on conclusions 25, 48 and 49 Associated findings 12, 31, 38, 39 and 44	***Assessment (July 2023)***: *This recommendation was followed up in a subsequent audit on the same subject (2021-7281). The audit report 2021-7281 found that annual surveys were carried out according to the multi annual action plan elaborated by the CAs for the control of PWN. The increased number of samples taken, particularly when sampling in the crown and placing traps and baits whilst targeting high risk areas, provide additional assurance with respect to the stated absence of PWN from the buffer zone.* *The ICNF has endeavoured to constantly reinforce its staff responsible for carrying out surveys and has allocated teams exclusively to forest plant health, a commitment which it maintains, and which meets the recommendation made further to previous audits. In 2021, 13 senior technicians from among the ICNF staff were taken on as forest plant health inspectors by the Single Authority, to which a further five will be added at the end of 2022. A number of park rangers have also been hired and have been stepping up preventive surveillance activities in this area. Most of these rangers have already participated in a number of targeted training courses. The ICNF also completed the training of 40 firefighters who will work on fire prevention and firefighting, an initial contingent with a target of 600 operations spread throughout the country, which should certainly make it possible to redirect preventive surveillance measures carried out by park rangers to other areas, including forest plant health.* ***The audit 2021-7281 (namely its findings 25 and 29 and conclusion 35) confirmed that this recommendation has been addressed.*** **<u>Background</u>** <u>First response (21/05/2019 - Ares(2019)3321113</u>. The Instituto da Conservação da Natureza e das Florestas, IP (ICNF, I.P.), as the national forestry agency and entity responsible for the implementation of containment and control activities with respect to the pinewood nematode (PWN), will promote and ensure compliance with the emergency measures established to combat the spread of PWN in the EU and the implementation of the measures within the scope of its authority, with a special focus on the buffer zone, also including adjacent territory, mainly with respect to: annual surveys of susceptible plants and the vector in the buffer zones by inspecting, sampling and testing those plants and the vector in order to detect the presence of PWN; and identifying and removing susceptible plants which are dead, in poor health or situated in fire- or storm-affected areas, taking all necessary precautions to avoid the spread of PWN and its vector. In order to respond fully,

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	effectively and efficiently to the requirements and levels of sampling needed, the ICNF, I.P. has stated that, by the end of this year, it will start the process of recruiting an additional 100 expert technicians, some of them in the area of forest plant health (probably around 20) and, in particular, for issues related to the implementation of the Action Plan for the Control of the PWN (PANCNMP), which is planned for 2018-2022 and will be reviewed every five years or whenever necessary. Moreover, in addition to shoring up its human resources by recruiting staff externally, the INCF, I.P. will train 15 new plant health inspectors for forestry, in collaboration with the national plant health authority, in this case the Directorate-General for Food and Veterinary Matters (DGAV), which will also reinforce its PWN inspection, monitoring and control work. With regard to the training of technicians and operators involved in identifying and sampling PWN host trees and monitoring the vector insect, we can inform you that new training activities are already planned for June of this year and will be targeted at all the approximately 90 persons involved in the implementation of these actions, with a particular focus on: identifying signs of the presence or activity of the PWN vector and taking appropriate samples, where possible from the crown of the tree; and installing traps to capture and monitor the vector insect. During the audit 2021-7281 (September 2021), the following findings are relevant for this recommendation: 25. Forest fires negatively affect the performance of surveillance. A significant part of rangers' activities from June to September, is allocated to forest fire prevention and to the management of areas affected by forest fires. Following a forest fire, the surveying teams have to reassess the situation and the condition of tree stands affected by forest fires in areas already surveyed prior to the forest fire events. Rangers met by the audit team stated that this fact results in substantial delays of routine surveillance activities covering the entire area under their competence. The ICNF considers that the main reason for the forest fires is the big number of privately owned plots reaching approximately 96% of forest areas in the buffer zone, which in many cases are badly managed or abandoned by their owners who are not known to the local municipal authorities. The tasks for fire prevention lead to delays with PWN surveillance. The ICNF stated that during the 2019-2021 period, there were no significant incidents of forest fires in the buffer zone and its adjacent area. (Comments by ICNF: "the ICNF has taken various steps to reinforce its staffing by taking on plant health inspectors (13 senior technicians from among the ICNF staff who completed their training in 2021 with a further five joining them at the end of the year), and setting up a more targeted workforce in the area of forest fire protection including

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	firefighters, for example. This will make it possible to redirect some of the fire-prevention surveillance measures carried out by park rangers to other areas, including forest plant health.") 29. During 2019-2020, there was a substantial increase in the average number (ca. 2 827) and proportion (32%) of samples taken in the crown, compared to those taken in 2018, which according to the previous audit report, accounted for 1 359 samples/year and 15%, of all samples taken in the buffer zone and adjacent area. This indicates that forest rangers have increased their efforts to be present during felling operations and improved their sampling method for the detection of PWN, particularly within the buffer zone and the adjacent area. Conclusion 35 is also relevant for this recommendation: 35. Annual surveys are carried out according to the multi annual action plan elaborated by the CAs for the control of the PWN. The increased number of samples taken, particularly when sampling in the crown and placing traps and baits whilst targeting high risk areas, provide additional assurance with respect to the stated absence of the PWN from the buffer zone. However, a substantial part of the activities of the forest rangers is allocated to tasks other than surveillance for trees showing early declining symptoms. This reduces the likelihood of the earliest possible detection of PWN spread in the buffer zone, particularly during the summer. (Comments by ICNF: "the ICNF has endeavoured to constantly reinforce its staff responsible for carrying out surveys and has allocated teams exclusively to forest plant health, a commitment which it maintains, and which meets the recommendation made further to the previous audit (carried out in report DG (SANTE)/2018-6488 MR Final). In 2021, 13 senior technicians from among the ICNF staff were taken on as forest plant health inspectors by the Single Authority, to which a further five will be added at the end of this year. A number of park rangers have also been hired and have been stepping up preventive surveillance activities in this area. Most of these rangers have already participated in a number of targeted training courses. It should also be noted that the ICNF has recently completed the training of 40 firefighters who will work on fire prevention and firefighting, an initial contingent with a target of 600 operations spread throughout the country, which should certainly make it possible to redirect preventive surveillance measures carried out by park rangers to other areas, including forest plant health. Their training is considered as a module to address this specific issue.").

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Recommendation	Basis for assessment/Information Requested/CA response
2020-7065-1 Ensure the consistency and effectiveness of official controls and other official activities for Xylella fastidiosa across the affected territory, as required by Article 4(2)(a) of Regulation (EU) 2017/625. The recommendation is based on conclusion No 34. Associated findings No 18 and 21.	**Closed due to action taken** Portugal is failing to ensure across the demarcated areas the consistency and effectiveness of the official controls and other official activities (separate IT systems, missing procedures/arrangements) necessary to ensure timely implementation of the measures following confirmed presence of *Xylella fastidiosa* by the competent authorities. ***Assessment (September 2023):*** *A subsequent plant health audit on* Xylella fastidiosa *was carried out in 2022 (2022-7400). The later audit confirmed that a complete set of detailed DGAV guidance documents and a recently introduced IT platform ensures that the CAs have updated information about the state of play of the controls in the demarcated areas and about the actions to be completed.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (10/05/2021)</u> DGAV informed that a geographical information platform has been developed in collaboration with an investigation body which is already operational, used for planning the sampling to be conducted in the demarcated area, in line with EFSA's territorial surveying guidelines based on statistical data. This allows the real-time monitoring of the samples carried out, their geographical localisation, recording of the laboratory results obtained, management of outbreaks with regard to forest survey activities, sampling and eradication and the drawing up of maps of the demarcated zone whenever changes occur. The various survey teams, using tablets already distributed with the application installed, can enter data in real time during the surveys in forest areas, the collection of samples in the field and eradication activities. This system, as well as compiling and processing information in a single, joint platform for all entities involved, facilitates management, coordination and support for decision-making by the competent authorities (picture of the geographical information platform provided). <u>Second response (30/07/2021)</u> The word "forest" is replaced by word "floristic" throughout the text. <u>Audit 2022-7400 (3 to 13/05/2022)</u> Findings 4 and 5 of the audit report:

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	4. To address the recommendation of the 2020 audit, the cooperation between CAs was significantly improved, mainly by the introduction and use of an IT platform and database, operated by DGAV. DRAPs, ICNF headquarters and regional offices and municipalities 6 in the Porto DA, including their staff assigned for Xf controls have access to the platform. The system displays on a map the boundaries of the IZs and BZs, the borders and identification number of grid squares used for the surveys. It displays the map of the area in question either as a satellite image or by type of land use (agriculture, urban, forest, semi natural according to the national soil occupation register). The exact location of the plants sampled during the surveys or identified for removal during the IZ inventories, together with the relevant information (sampling date, laboratory test results, whether the plant is removed or not) is duly recorded on the platform. Teams for plant inventory, plant removal and surveys upload the information about their activities with minimal delay to the platform (see further details in sections 5.4, 5.5 and 5.9). 5.The audit team checked the operation of the platform and noted that it provides nearly real-time information about the state of play of the implemented controls in the DA. The land use map layer clearly indicates which part of the area in question is under the responsibility of DRAP or ICNF. It facilitates the programming and implementation of the controls in IZs and surveys in the BZs in particular in those areas, where the responsibilities are shared. The audit team noted that the DGAV, DRAPs, ICNF and the municipalities affected by the Porto outbreak carry out their Xf related activities with the assistance of the platform and the related database.
2020-7065-2 Ensure that all competent authorities who carry out official controls for Xylella fastidiosa have been designated in line with the requirements of Article 4 (1) of Regulation (EU) 2017/625 or official control tasks have been delegated to them in line with the requirements of Article 28 of the same Regulation.	**Closed due to action taken** The lack of official designation of some competent authorities responsible for the official controls of *Xylella fastidiosa* or delegation of official control tasks to them, as required by Article 4(1) and Article 28 of Regulation (EU) 2017/625, could affect the legal status of official controls performed by them. ***Assessment (September 2023):*** *A subsequent plant health audit on* Xylella fastidiosa *was carried out in 2022 (2022-7400). The later audit confirmed that the surveys carried out by six municipalities of the Porto area are regulated by written contracts with the DGAV.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (10/05/2021)</u>

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Recommendation	Basis for assessment/Information Requested/CA response
The recommendation is based on conclusion No 33. Associated finding No 8.	DGAV indicated that the municipalities within the demarcated area that are working with the competent authorities will be formally designated as delegated bodies with surveying tasks formally delegated to them (tasks associated with other official activities) pursuant to Article 31 of Regulation (EU) 2017/625, to be concluded by the end of 2021. During the 2022 GFA The formal delegation is assigned with 5 municipalities, CMSM Feira, CM Espinho, CM Gondomar, CM Matosinhos and CMVN Gaia (copies of the delegations were provided). For the remaining municipality, CM Porto, we are only waiting for the final signature of the protocol, as the procedure was agreed. Audit 2022-7400 (3 to 13/05/2022) Finding 1, last bullet point: The only change since the 2020 audit was that based on the cooperation agreements with DGAV, six municipalities in the Porto outbreak carry out annual surveys in the BZ in the public territories owned by them (see section 5.5.3). Finding 45: In the Porto BZ the surveillance was carried out by inspectors of DRAP North, of the ICNF regional directorate (in forest areas) and by workers of six municipalities (in publicly owned parts of their territory), based on written agreements with DGAV. In the Lisbon and Tavira BZs the work was carried out by DRAP Lisbon and DRAP Algarve, respectively. Finding 49, third bullet point: The personnel of DRAP, ICNF and municipalities carried out the surveys in line with DGAV rules. They used the necessary equipment and knowledge for that. The plants were selected for sampling in accordance with DGAV priorities, and the activity was duly registered including the proper recording of GPS coordinates of the sampled plants.
2020-7065-3 Ensure that competent authorities have access to sufficient number of suitably qualified staff and adequate laboratory capacity for timely implementation of official controls and other official activities for	**In Progress** Insufficient resources allocated for the implementation of measures following confirmed presence of *Xylella fastidiosa* in Portugal, have contributed to the delays in official control and other official activities for *Xylella fastidiosa*, in particular in the areas where immediate action is required to be undertaken, such as the removal of plants from the infected zone as per Article 7(1) of the Regulation (EU) 2020/1201. ***Assessment (January 2024):***

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Xylella fastidiosa as required by Article 5(1) (d) and (e) of Regulation (EU) 2017/625. The recommendation is based on conclusion No 35. Associated findings Nos. 9, 28, 52 and 53	*A subsequent plant health audit on* Xylella fastidiosa *was carried out in 2022 (2022-7400). The later audit confirmed that, since the audit 2020-7065, new staff have been allocated to DRAPs and ICNF regional offices. The transfer of the buffer zone surveys in the Porto outbreak to municipalities has been considered by the audit team as reinforcement of capacity. The audit team also noted that the DRAP, ICNF and municipality staff involved in the controls are highly qualified and possess the knowledge and experience necessary for the activities.* *ICNF, DRAPN, and DGAV are working on actions that will help with the implementation of eradication measures, namely for the removal of plants from the infected zones. Likewise, these authorities and DRAPLVT have secured additional laboratory capacity for testing plant samples and insects until the end of 2023. INIAV initiated a recruitment procedure for additional staff for laboratory analysis.* ***This recommendation will remain in progress until the competent authority provides the evidence to address recommendation 1 of the audit 2022-7400, which can also address this recommendation if implemented:*** • ***Completion by ICNF of the tendering procedure to outsource implementation of plant removal services and confirmation that the multi-annual contract for the work to be done was signed.*** • ***Completion by DRAPN of the procedure for a multi-annual contract for the removal of plants within the demarcated area and confirmation that a service contract for the work to be done was signed.*** • ***Additional recruitment of staff by INIAV for laboratory analysis*** **Background** First response (10/05/2021) The ICNF (Institute for Nature Conservation and Forests) is currently reinforcing its team of plant health inspectors at national level and technicians in the plant health field, both by training new inspectors (to be completed in June 2021), four of whom will be linked to the demarcated area, and by means of new tender procedures for taking on senior technicians in the area of plant health, to be concluded over 2021. In addition to the above, the multi-annual tender procedure for the procurement of specialist services for the disposal of vegetation in the context of the plant health measures associated with the control of *Xylella fastidiosa* is being developed and is due to be concluded by the end of September 2021. The DRAPN (Regional Directorate for Agriculture and Fisheries in the North Region) is reinforcing its staffing in order to be able to carry out timely plant surveys, sampling and eradication, with on-site monitoring, including the

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	application of vector treatments, and has already published in the Diário da República a tendering procedure for three senior technicians to be assigned to surveying and sampling in the demarcated area. This increase in human resources is expected within a month and half. In order to speed up the eradication of *Xylella fastidiosa* hosts within the demarcated area and on-site monitoring, including the application of vector treatments, the DRAPN has already earmarked budget for opening the procedure for contracting a service company. This should be concluded by mid-June 2021. Despite the constraints resulting from the pandemic, the INIAV (National Institute for Agricultural and Veterinary Research) has already increased its weekly capacity by 25%. During sampling peaks, specifically when a new positive is detected, weekly laboratory capacity will be stepped up (in particular, through the use of private laboratories), using the two designated laboratories simultaneously. An administrative procedure to facilitate the contracting of private laboratories for analyses is currently being developed, in addition to the contract already covered by the DGAV. <u>During the 2022 GFA</u> The ICNF reinforced their team with 4 new inspectors being one of them dedicated to Xf DA. The multi-annual tender procedure for the disposal of vegetation is waiting for governmental approval. The DRAPN has already a new inspector in place and is under administrative procedure the allocation of an extra inspector. The procedure for contracting a service company is ongoing. In what concerns the laboratory capacity, in 2021, two contracts with a private laboratory were accomplished, for the demarcated areas, taking into account the new demarcated areas. In 2022, one contract with the private laboratory is already in force, and another one is about to be signed shortly. <u>Audit 2022-7400 (3 to 13/05/2022)</u> Finding 11: • In 2020 and 2021 there were significant delays in the completion of the Xf tests by the NRL due to the lack of human resources and the limited availability of PCR reagents. In 2021, the NRL analysed 8,096 plant and insect samples for Xf, 79 of them tested positive. At the time of the audit the laboratory had a weekly capacity for 250 samples with an average response time of 7-15 days, which were significantly longer in the main sampling periods in 2021;

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	• The designation of Fitolab provided additional capacities, however the response time for samples from the DA averages 28 days due to the available laboratory capacities and other technical aspects; • The delays in the completion of the laboratory tests contributed to the delays in the implementation of the eradication measures (see section 5.5.1). Due to the reasons above it is considered by the audit team that the laboratory capacity issues present at the time of the 2020 audit have not been fully addressed. Finding 34: In relation to the inventory of the plants to be removed in the IZs, the audit team noted during the site visits that: • The work is carried out by DRAP or ICNF inspectors. This activity is particularly difficult and time consuming in the Porto DA, due to the very high number of plant species/genera tested positive for Xf subspecies multiplex; • CA inspectors possessed the necessary botanical knowledge. For the identification of unknown species, a publicly accessible internet application was used. The number and geographical location of the identified plants is duly recorded on the IT platform; • Access issues in steep or inaccessible parts of the IZs and legal access rights to some private properties significantly hindered or made it impossible to complete the inventories. Finding 37: In the Lisbon IZ the positive tested plants were destroyed about one month after the confirmation of the positive results, while in the Tavira IZ the destruction of the entire lot of *Salvia rosmarinus* plants together with their mother plants was completed within 14 days. In addition, plants of the same species found at a site of the nursery outside the DA were also destroyed as a precaution. Finding 51: In relation to the implementation of the 2021 surveys in the BZs of the Porto outbreak the audit team noted that: • In the urban areas significantly more sites were checked and more samples were collected than provided by RIBESS+ due to the involvement of the municipalities. However, as the municipal workers have no right of access to private properties their findings do not represent the entire area of the inspected squares;

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	• DGAL North concentrated on the agricultural areas but due to capacity issues could not complete the planned sampling and inspections there. The remaining capacities for the semi-natural areas resulted in even lower completion rates. In the case of semi-natural sites, issues with accessibility also played a certain role; • The low survey performance of ICNF in the forest parts of the BZs is the combined result of the lack of capacity and site access issues; • Due to the reasons listed above during the implementation of the surveys the minimum requirements of Article 10 of Regulation (EU) 2020/1201 were not met. Finding 52: In the urban part of the Lisbon BZ DRAP Lisbon collected three times more samples than required by RIBESS+. However, due to capacity issues the checks of the agricultural and forest parts of the BZ were not finished, consequently the EU requirements were not met. In November 2023, in the reply to the draft Country Profile (namely to recommendation 2022-7400_1), the competent authorities provided the following information: • ICNF, I.P. • The multi-annual procedure that will cover the elimination of trees and plants as part of the eradication of *Xylella fastidiosa* (in the amount of 0.3 million Euros) and *Bursaphelenchus xylophilus* (in the amount of 3 million Euros) will be common. As it is expected to be carried out over a period of 3 years requires the existence of an Interministerial order which is in the process of being analysed and subsequently ratified. • The contract between ICNF, I.P. and the FITOLAB laboratory, for laboratory testing of 2000 samples, as well as the respective technical specifications was provided. The contract will end at the end of the year, with 100% execution. • DRAPN • Under the contract, the entreprise partially provided the services foreseen, which expired on 13 November 2023. A new procedure for a multi-annual contract is currently being prepared, that will be submitted to the Minister of Agriculture and Food for authorising the expenditure. • DRAPLVT • DRAPLVT has signed a contract for external recruitment of one Technician, until the end of the current year, developing several activities related to the management of the demarcated areas (contract attached).

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	• The reinforcement of laboratory capacity was achieved, with a contract with the laboratory for 625 samples (contract attached). • DGAV • The budgetary reinforcement for the performance of contracts for analysis was achieved, and an international tender was launched in 3 lots, which resulted in contracts with 2 labs, for a total of 14 180 plant samples. Another contract was signed for 605 insect samples and 393 samples for subspecies determination. The 3 contracts are in annex. Also, additional 50 weekly samples are being analysed in a Spanish lab all year round. • INIAV, I.P. • Related with the process of recruitment that started in 2022, where INIAV asked to hire 60 human resources to the NRL the Minister of Finance only authorized the recruitment of 4 researchers in 2023 (in the hiring phase). • INIAV already initiate a new process of recruitment in order to hire the 60 human resources needed for the NRL (in evaluation on the Ministry of Agriculture and Food).
2020-7065-4 Ensure that competent authorities responsible for the official controls and other official activities for Xylella fastidiosa in Portugal have control verification procedures in place as required by Article 12(2) of Regulation (EU) 2017/625. The recommendation is based on conclusion No. 36 Associated finding No. 19	**Closed due to action taken** The lack of control verification procedures further reduces the effectiveness of the official controls and other official activities necessary to ensure timely implementation of the measures following confirmed presence of *Xylella fastidiosa* by the competent authorities. ***Assessment (September 2023):*** *DGAV has a Manual of Procedures for the Supervisory Actions of the DRAP/ICNF/Municipalities related to the implementation of the Action Plan for the eradication of* Xylella fastidiosa *since January 2022.* *A subsequent plant health audit on* Xylella fastidiosa *was carried out in 2022 (2022-7400). The later audit confirmed that the application of the verification procedures had started in the Porto demarcated areas. DGAV staff, in the form of regular site visits and continuous communication with the staff involved verifies the* Xylella fastidiosa *controls by DRAPs, ICNF and municipalities. The audit team observed the supervision of the plant inventory in an infected zone by ICNF and survey with sampling in the buffer zone by a municipality, which were carried out in line with the relevant provisions of the EU legislation.* ***The actions address the recommendation.***

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Recommendation	Basis for assessment/Information Requested/CA response
	Background First response (10/05/2021) DGAV informed that the geographical information platform, now produced and already in use, allows the real-time monitoring of sampling carried out, geographical localisation, the recording of laboratory results obtained, the management of outbreaks in the context of forest survey, sampling and eradication activities. This is an essential tool for the competent authorities – the DGAV, the ICNF and the DRAP – to ensure that official controls and other official activities in this area are consistent and effective, specifically by means of the timely implementation of measures following confirmation of the presence of *Xylella fastidiosa*. Physical monitoring will be implemented next year (2022), given the current restrictions resulting from the COVID-19 pandemic. A monitoring manual for the documentary and physical checks will be drawn up by the end of this year (2021). Second response (30/07/2021) The word "forest" is replaced by word "floristic" throughout the text. During the 2022 GFA The procedures for supervision are established and a first act of supervision is scheduled to be performed in the next days. The supervision manual was provided. Audit 2022-7400 (3 to 13/05/2022) Finding 33: DGAV guidelines regulate the identification, removal and destruction of plants, either tested positive or to be removed in line with provisions of Article 7(1) points (b) to (e) of Regulation (EU) 2020/1201. The procedures demonstrated to the audit team by DRAP North, municipality Porto and ICNF North, including the official supervision of the plant removals, was in line with provisions of Regulation (EU) 2020/1201.
2020-7065-5 Ensure that outbreaks of Xylella fastidiosa in Portugal are notified to	**Closed due to action taken** Notification to the European Commission and Member States of the outbreaks of *Xylella fastidiosa* in Portugal is not in compliance with the deadlines (no later than 8 working days after the date of official confirmation of the presence

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the Commission as required by Article 11 of Regulation (EU) 2016/2031, within the deadline established by Article 32(1) of Regulation (EU) 2019/1715. The recommendation is based on conclusion No. 64. Associated finding No. 48.	of the pest) established for notification in Article 32(1) of Regulation (EU) 2019/1715, and affects any possible actions by the EU or other Member States. ***Assessment (September 2023):*** *The DGAV indicated that it would submit EUROPHYT notifications no later than 8 working days after the date of the official confirmation of new findings of* Xylella fastidiosa *that lead to changes and expansion of the demarcated area. A subsequent plant health audit on Xylella fastidiosa was carried out in 2022 (2022-7400). In the preparation for that audit, the audit team confirmed that the new reporting procedures and practice had addressed the shortcoming identified with regard to the reporting deadline of the outbreaks via EUROPHYT-Outbreaks.* ***The actions address the recommendation.*** **Background** First response (10/05/2021) The DGAV will continue to update notifications in EUROPHYT whenever required, in line with Article 32(4) of Regulation (EU) 2019/1715. Second response (30/07/2021) The DGAV will submit EUROPHYT notifications no later than eight working days after the date of the official confirmation of new findings of *Xylella fastidiosa* that lead to changes and expansion of the demarcated area. During the 2022 GFA No reply received at pre-draft Audit 2022-7400 (3 to 13/05/2022) In the preparation for the audit, the audit team verified by using EUROPHYT-Outbreaks application, that notifications (including "updates") on outbreaks, that lead to changes and expansion of the demarcated area wee submitted to the Commission within 8 working days from the date of official confirmation of the pest as required by the Regulation (EU) 2019/1715.
2020-7065-6 Ensure the proper implementation of the requirements of the Article 23(d)	**Closed due to action taken** The interpretation of the requirements of Article 23(d) of Regulation (EU) 2020/1201 by the competent authorities with regard to the phytosanitary treatments against vector population (only enforced against professional operators

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Recommendation	Basis for assessment/Information Requested/CA response
of Regulation (EU) 2020/1201 with regard to the phytosanitary treatments against the vector population. The recommendation is based on conclusion No. 81. Associated finding No. 72.	producing specified plants and garden centres) does not enable the correct implementation of the above-mentioned requirements. ***Assessment (September 2023):*** *A subsequent plant health audit on* Xylella fastidiosa *was carried out in 2022 (2022-7400). The later audit confirmed the correct implementation of the application of vector treatments during the visit to a garden centre in the Porto area.* ***The actions address the recommendation.*** **Background** First response (10/05/2021) Professional operators will continue to be notified to ensure that they apply phytosanitary treatments as required by Article 23(d) of Implementing Regulation (EU) 2020/1201. Fulfilment of this obligation is verified by the checks conducted on professional operators, this requirement being included specifically on the control sheet (no longer registered with additional notes). To remain authorised to sell plant species susceptible to the multiplex subspecies in the demarcated area, operators will have to apply phytosanitary treatments against the vector population at appropriate times of the year, where susceptible plants are actually grown for part of their life cycle in that location (for more than four weeks) Second response (30/07/2021) Professional operators will continue to be notified to ensure that they apply phytosanitary treatments as required by Article 23(d) of Implementing Regulation (EU) 2020/1201. Fulfilment of this obligation is verified by the checks conducted on professional operators, including primarily retail, this requirement being included specifically on the control sheet (no longer registered with additional notes). To remain authorised to sell plant species susceptible to the multiplex subspecies in the demarcated area, operators, including primarily retail, will have to apply phytosanitary treatments against the vector population at appropriate times of the year, where susceptible plants are actually grown for part of their life cycle in that location (for more than four weeks). Audit 2022-7400 (3 to 13/05/2022)

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Recommendation	Basis for assessment/Information Requested/CA response
	Section 5.5.4: 56. Before any plant removal starts in the IZ, phytosanitary treatment with authorised pesticides against the vector population is applied, as required by Article 8(1) of Regulation (EU) 2020/1201. 57. In accordance with Article 8(2) of Regulation (EU) 2020/1201 a DGAV guidance document requests that field cleaning should be carried out in the DAs from January to April to reduce the juvenile vector population and from September to December to eliminate herbaceous plants used by adult vectors for egg laying. The measures shall be applied in the areas surrounding the agricultural plots, on the roadsides and on the undergrowth of areas covered by trees. Depending on the area, manual or mechanical methods of cutting, shredding or burial shall be used on the spontaneously grown vegetation. Treatment with authorised plant protection products is also allowed against the juvenile vector population, but it is practically used in nurseries only. No official controls are carried out in the DAs for the implementation of the measures against juveniles.

Audit 2021-7281 of 17 September 2021 in order to evaluate the situation and controls for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
2021-7281-1 Ensure that the surveillance carried out for the identification of dead or declining trees in the buffer zone will be increased and dead or declining trees identified during the flight season of the vector will be immediately felled and destroyed as required by point 3(b)(ii) of Annex II to Decision 2012/535/EU. Recommendation based on conclusions 35 and 50	**In Progress** A substantial part of the activities of the forest rangers is allocated to tasks other than surveillance for trees showing early declining symptoms. This reduces the likelihood of the earliest possible detection of PWN spread in the buffer zone, particularly during the summer. The delays in the identification and immediate elimination of dead and declining trees, in particular during the summer, do not adequately address the associated plant health risk against further spread of PWN, if it would be identified in the buffer zone. ***Assessment (January 2024):*** *The Commission recognises the increased efforts undertaken by the ICNF, I.P., namely resorting to signing a multi-annual contract (3 years) to work in areas not maintained or cleaned by landowners taking into account a highly fragmented rural landscape and landowners that are absent (moved abroad for example) or are too old and therefore cannot clean the land themselves. This contract is the same as for fighting* Xylella Fastidiosa*, as mentioned in the actions to address recommendation 2022-7400_1.*

Audit 2021-7281 of 17 September 2021 in order to evaluate the situation and controls for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings 24, 46 and 47	*ICNF, I.P. has confirmed the availability of additional logistical resources for the immediate felling and destruction of dead and declining trees including during the period of flight of the insect vector, namely:* • *Between the 2-year period of 2019/2020 and of 2021/2022, an increase of 10 technicians (on average).* • *Since 2021, 18 senior technicians from the ICNF, I.P. have been invested as phytosanitary inspectors in the forestry area by DGAV and one more as plant health inspector, who previously worked in a regional agricultural directorate. Although they are not full-time dedicated to the PWN Action Plan, they respond to all requests in the area of plant health inspection, namely those related to the obligations arising from the Commission Implementing Decision 2012/535/EU.* *ICNF, I.P. demonstrated the progress made in the collaboration with Information Technology Development (ITD) entities and projects for the identification of dead or declining trees.* ***The recommendation status remains "In Progress", until the ICNF, I.P. provides confirmation that it has completed the tendering procedure to outsource implementation of plant removal services and that the multi-annual contract has been signed.*** **<u>Background</u>** <u>First response (23/05/2022)</u> The identification of susceptible trees in decline and dead trees has been carried out on the basis of a 100 ha grid of operational squares, established throughout the buffer zone and a 5 km buffer adjacent to it. The monitoring of the squares with susceptible trees is planned and carried out, although, naturally, there is a greater concentration of work in areas with more pine forest and in areas with more decline, as well as in those with higher risk. Given the large size of the area in question (3.1 million hectares and 34,458 operational plots), extensive and continuous monitoring throughout the area, based on human resources, is obviously not permanent: • The annual Survey and Monitoring Plan foresees the carrying out of at least two decline survey actions, per year, especially in the quadrats located in the areas of greatest risk; • The ICNF, I.P. has been collaborating with I&DT entities in order to search for remote solutions for the identification of susceptible specimens, which are easy to implement and use, to complement the work carried out. It should also be stressed that, although this action is developed continuously, with teams permanently

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Recommendation	Basis for assessment/Information Requested/CA response
	dedicated to matters related to forest health, the focus of the actions is necessarily on the autumn-winter season, as it is at this time that the symptoms of decline are most apparent. In any case, and with regard to the elimination of specimens, ICNF, I.P. has been making multi-annual contracts with a view to reducing the decline (due to cutting pressure, contributing to a reduced availability of material suitable for oviposition by the insect vector) and the possibility of action throughout the year, including during the period of flight of the insect vector. The increase in the number of crown samples, collected when felling is carried out, reflects this reality. We take advantage of this reference to highlight that, since 2018, this increase has been substantial [see Table 2 (28) of the draft report] and responded to the recommendation made following the previous audit, carried out in report DG(SANTE)/2018-6488 MR Final. We also believe it is appropriate to note that the disposal and destruction of woody material, as well as the movement in forest areas, is subject to constraints arising from prerogatives of the Forest Fire Protection, and is not possible in situations of maximum and very high rural fire danger index, which occurs especially during the summer period. Finally, it should be noted that ICNF, I.P. has been continuously reinforcing its staff responsible for the implementation of survey actions and allocating teams exclusively to forest plant health, a commitment that it maintains and which is in line with the recommendation made following the previous audit (carried out in report DG(SANTE)/2018-6488 MR Final). Since the audit, 13 Senior Technicians from the ICNF, I.P. staff map have been invested as phytosanitary inspectors in the forestry area by the Single Authority, who completed their training in 2021, and will be joined by a further 5 at the end of the year, who are currently undergoing training. The practice of deploying experienced teams and having each of their members be accompanied by less trained elements (training in a real work context) has also proved to be fruitful. Also of note is the capacity building of the private sector, through specific training for forest producers' organizations, which under the National Monitoring Programme (2019-2022) have also been surveying plots with decline and promoting the detection of the presence of PWN in private property areas, essentially upstream of the Buffer Zone. It is also planned to allocate teams of forest sappers, from ICNF, I.P., and contracted mobile teams (under multi-annual contracts for the elimination of woody material) to the work of elimination and destruction of the woody material identified, in order to respond to immediate and short-term needs. A greater allocation of logistical resources to this area is also foreseen for 2022-2023, namely by providing the competent units with off-road vehicles. It should also be noted that ICNF, I.P. has recently concluded the training of 40 forest firefighters who will work in the prevention

Audit 2021-7281 of 17 September 2021 in order to evaluate the situation and controls for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
	and fighting of fires, an initial contingent of a process whose target is 600 operatives distributed throughout the country, and which will certainly make it possible to redirect preventive surveillance actions developed by the Nature Wardens to other areas, including forest plant health, as their training has considered a module aimed at this specific issue. On the other hand, in the winter season, this structure will contribute to making the territory more resilient. In November 2023, in the reply to the draft Country Profile, ICNF informed that the immediate felling and destruction of dead and declining trees, including during the period of flight of the insect vector, has been carried out mainly by landowners and by the action of the State, in the areas under its management or when and where possible and most necessary by action of specialized ICNF teams (CNAF, Forest Sappers). Less State intervention is the result of years of awareness-raising, a reduction in the dead and declining trees, in recent years, due to continued intervention (by ICNF contractors) and a greater awareness among the population of the importance of active management and compliance with forest fire protection rules, bearing in mind the enormous impacts of the 2017 extensive wildfires which even resulted in the loss of human lives. In any case, ICNF has resorted to signing multi-annual contracts to work in areas not intervened in by landowners taking into account a highly fragmented rural landscape and an absent or ageing population that is unable to provide a full and effective response. This process requires the existence of an Interministerial order and at this very moment we are waiting for it to be ratified and issued so that we can proceed with new contracting procedures, in the total amount of 3 million euros and 3 year period. As soon as it is signed, ICNF will provide a copy. As previously stated ICNF, I.P. has been continuously reinforcing its staff responsible for the implementation of survey actions and tree elimination monitoring allocating teams exclusively to forest plant health. Between the 2019/2020 and 2021/2022 biennia there was an increase of 10 technicians (average for the biennium) assigned to those actions. The list of technicians and hours allocated can be made available if necessary. In addition, since 2021, 18 senior Technicians from the ICNF, I.P. staff map have been invested as phytosanitary inspectors in the forestry area by the Single Authority; to these adds one more plant health inspector, previously working in a regional agricultural directorate. Although they are not full-time dedicated to the PWN Action Plan, they respond to all requests in the area of PH Inspection, namely those related to the obligations arising from the 2012/535/EU Commission Implementing Decision of 26 September 2012.

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Recommendation	Basis for assessment/Information Requested/CA response
	Also mentioned before was the training of sapper forest firefighters to support plant health actions. Previously, several elements were allocated to PWN survey and control, mainly in the North and Centre, allocated to this subject in specific periods and areas, depending on the need for human resources. The same goes for the "Corpo Nacional de Agentes Florestais", sapper forest firefighters allocated to forest areas under ICNF management, in closer liaison with the forest managers of those areas, but that can also work in private areas. ICNF, I.P. actively participated in the Project GI(PiN) - Integrated Pine Forest Management/Pine Wood Nematode, a Rural Development Program 2014-2020 funded project (Feader) whose main objective was to develop operational strategies that overcome the constraints associated with pine wilt disease (PWD), making the management of maritime pine forests more efficient, more specifically: • Define, plan and promote appropriate forest management practices with the aim of improving the health of the pine forest; • Develop, evaluate and validate methods for the early detection of potentially infected trees that can provide faster and more effective intervention in controlling the spread of PWN; • Adjust procedures to control the natural dispersal of vectors infected with PWN. The final report is not yet available but the preliminary conclusions are: • The confirmation that the development of the pine longicorn is closely dependent on the temperature variations that occur in its environment, so both the emergence period and the flight period will have different patterns depending on the year and for the same year depending on the climatic regions of Portugal. • The confirmation that scolitids (Coleoptera: Scolytidae) are an agent of pine forest mortality in Portugal. The surveys carried out on the pine trees showed that they were colonised by borers (*Orthotomicus erosus* and *Ips sexdentatus*) and also the pine weevil (*Pissodes castaneus*). Given the size of the pine trees in question, any of these insects is a probable causal agent of the mortality. • The confirmation that cultural operations in the pine forest are safe during the winter/spring period, with minimal risk of the wood being colonised by *M. galloprovincialis*; as seen in other regions of the country, it is the scolitids that are the first to colonise the wood in decline and in greater density. • The identification of the need for in-depth studies on the use of drones to locate infected trees, which could not be confirmed within the scope of the work carried out.

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Recommendation	Basis for assessment/Information Requested/CA response
	• As for the effectiveness of sampling at breast height diameter, the studies carried out showed that PWN was detected at DBH level in only 85 % of infected trees, resulting in 15 % false negatives, which emphasises the importance of sampling during felling operations, especially larger trees. The hypothesis of increasing the number of samples, especially at the crown level, with several limitations and high costs, may not increase the effectiveness of detecting trees with PWN, since false negatives have also been found in other sections of the trees, due to the gregarious and heterogeneous distribution of PWN within an infected pine tree. The most effective solution will always be to cut down trees showing symptoms of decline and destroy all material with a diameter of less than 20 cm. • The confirmation that the incidence rate of the disease was not constant across DBH classes; once again an association between Pinewilt disease and larger trees (DBH > 20 cm) was noted. ICNF, I.P. has been following other projects dedicated to this issue as closely as possible, although there is still a need to find a means of communication that will dynamically and periodically translate the results of the scientific activity carried out. At the moment, these aspects are not specifically provided for in specific action plans, but in a forest plant health awareness plan that is expected to cover the various forest pests of importance in the national context, whether they are priority pests or not. Some of the projects ICNF followed / has been following are:https://projects.iniav.pt/pineenemy/ • Pine ENEMY - Exploring the NEmatode-MYcobiota interactions in Pine Wilt Disease, whose purpose was to deepen knowledge about the dynamics of the disease caused by the pine wood nematode with a view to controlling it; • PINASTER-PWN – which aimed to develop molecular markers for resistance to wilt disease in *Pinus pinaster*; • FOCUS - Forest Operational monitoring using Copernicus and UAV hyperSpectral data which was launched as a project funded by Horizon 2020 aimed at demonstrating an innovative extension of an existing forest service monitoring service (www.silvisense.com) using a combination of multispectral and hyperspectral data acquired from satellite imagery (Sentinel-2, Landsat, and commercial high resolution), remotely Piloted Aerial Platforms (RPAS) and Airborne surveys with the purpose of detecting and characterize stands of Maritime Pine.

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Recommendation	Basis for assessment/Information Requested/CA response
	• NemaWAARS - The motif – whose purpose is to unravel the mechanisms of regulation of parasitism genes in the pine wood nematode in order to control the disease and develop resistant plants. Of all projects targeting Remote Sensing in support of Plant Health Measures, findings from the Canopy Health Monitoring (CanHeMon; JRC) project seemed the most promising. Despite the JRC's work in this area, supported by ICNF, additional work might be necessary to allow a more practical and accessible application, bearing in mind the specificity of these methodologies. ICNF believes it is very important to apply this type of technique to the monitoring and early detection of declining specimens, but the practical cases in PT have been developed by the academies, and ICNF does not have any practical experience of application per se at this time. Furthermore, ICNF is faced with the need to survey/monitor various pests and, as the diversity of methods may be necessary, it poses additional challenges from the point of view of managing financial and human resources. ICNF believes that this issue, as well as the training of staff in the use of remote detection methodologies, could perhaps be addressed in more detail by the Commission.
2021-7281-2 Ensure that frequent random checks concerning the movement of wood packaging material in the buffer zone are carried out in line with point 1 of Article 11 of Decision 2012/535/EU and the measures taken for non-compliant wood packaging material are in line with the requirements of the same point and Article 12 of the same Decision. Recommendation based on conclusion 60	**Closed due to action taken** The controls of retailers in the buffer zone are not adequate to identify the movement of potentially non-compliant wood packaging material. ***Assessment (January 2024):*** *DGAV and ICNF, I.P. provided training sessions to ASAE inspectors in December 2022 (16 inspectors attended) followed by 3 practical sessions in situ held at retailers located in 3 different regions of the Buffer Zone: in the North (Valença - 6 inspectors), in the Center (Castelo Branco - 6 inspectors) and at Alentejo (Elvas - 9 inspectors) on March and April 2023.* ***The actions address the recommendation.*** **Background** First response (23/05/2022) During 2022, DGAV will promote actions for knowledge improving to the inspectors of ASAE, towards an adequate application of procedures in force, in line with the established in with point 1 of Article 11 and Article 12 of Decision 2012/535/EU.

Audit 2021-7281 of 17 September 2021 in order to evaluate the situation and controls for Bursaphelenchus xylophilus	
Recommendation	Basis for assessment/Information Requested/CA response
Associated finding 58	In November 2023, in the reply to the draft Country Profile, DGAV and ICNF indicated that they have promoted training sessions to ASAE inspectors with a theoretical module in December 2022 (16 inspectors attended) followed by 3 practical sessions *in situ* held on retailers located in 3 different regions of the Buffer Zone: in the North (Valença - 6 inspectors), in the Center (Castelo Branco - 6 inspectors) and at Alentejo (Elvas - 9 inspectors) on March and April 2023. The lists of participants were provided.

Audit 2021-7284 of 08 November 2021 in order to evaluate the situation and controls for Trioza erytrea and citrus greening	
Recommendation	Basis for assessment/Information Requested/CA response
2021-7284-1 Ensure that the CA has the information necessary regarding all orchards in a DA, in order to be able to control that these are subject to phytosanitary measures necessary to eradicate a Union quarantine pest from the areas concerned, as required under Article 17(1) of Regulation (EU) 2016/2031. Recommendation based on conclusion No 41 and associated finding Nos 25, 26 and 30.	**In Progress** The competent authority does not have access to information about active orchards in demarcated areas or elsewhere, and therefore cannot check that phytosanitary measures are carried out in orchards, as required. This potentially undermines the measures for eradication taken in a demarcated area. ***Assessment (January 2024):*** *The competent authority (DGAV) indicated that the legal act Portaria nº 273/2022 introduced a registration system based on a web platform, and establishes the obligation of the farmers to register their crops in this system. This act also provides for the DGAV, the Regional Directorates of Agriculture and Fisheries and ASAE to have direct and permanent access to the data included in the register.* ***This recommendation remains "In Progress" until the competent authority provides evidence that a crop register has been established and is operational, and that it has direct and permanent access to the data included in the register.*** **Background** First response (02/06/2022) The information required may be obtained by establishing the obligation to register parcels (plots) for all crops planted. The legal basis for the mandatory production of such a general crop register will be obtained by means of legislation to be published, the proposal for which is being evaluated by the Ministry of Agriculture, and which is expected to be published. This general crop register shall provide all necessary information on orchards located in

Audit 2021-7284 of 08 November 2021 in order to evaluate the situation and controls for Trioza erytrea and citrus greening	
Recommendation	Basis for assessment/Information Requested/CA response
	demarcated areas. 29.09.2022: The legal basis for the mandatory crop register was approved by the Ministers of Agriculture and Economy and it's expected to be published in next weeks. The legislation provides for a rule that the DGAV, the Regional Directorates of Agriculture and Fisheries and ASAE have direct and permanent access to the data included in the register. Second response (29.09.2022) The legal basis for the mandatory crop register was approved by the Ministers of Agriculture and Economy and it's expected to be published in next weeks. The legislation provides for a rule that the DGAV, the Regional Directorates of Agriculture and Fisheries and ASAE have direct and permanent access to the data included in the register. In November 2023, in the reply to the draft Country Profile, DGAV indicated that the legal act, Portaria nº 273/2022, published on 10 November, introduced a registration system based on a web platform, and establishes the obligation of the farmers to register their crops in this system and foresees that official services, namely DGAV, will have access to the platform.
2021-7284-2 Ensure that eradication measures can be applied immediately to host plants in private gardens, as required under Article 17 of Regulation (EU) 2016/2031, where the owners do not cooperate voluntarily. Recommendation based on conclusion No 42 and associated finding No 34.	**Closed for other reasons** The competent authority cannot immediately take measures to eradicate *Trioza erytreae* in private gardens unless the owners cooperate voluntarily. Given the large number of host plants present in private gardens, this situation potentially risks undermining efforts made by the competent authority and professional operators to eradicate the pest and increases the risk for its further spread. ***Assessment (January 2024):*** *The Commission notes the communication from Portugal on the control strategy for the containment of* Trioza erytreae*, with biological control measures to be taken in private gardens.* *DGAV confirmed that the legislation in force provides the proper basis for any intervention and the legislation (Article 18(3) of Decree-Law nº67/2020) is being applied whenever necessary, whether in public or private property; the lack of cooperation can happen with any public or private person or entity and the legal mechanisms (including requesting police intervention) are followed in both cases.* *DGAV also informed that the last update of the demarcated area for* Trioza erytrea*, in the Despacho n.º 23/G/2023, was published on its website on 15 March 2023, and since then no new findings of the pest have occurred.* *The effective implementation of the eradication measures may be verified in the context of a future Commission audit.*

Audit 2021-7284 of 08 November 2021 in order to evaluate the situation and controls for Trioza erytrea and citrus greening	
Recommendation	Basis for assessment/Information Requested/CA response
	Taking into account that the spread of* Trioza erytreae *has slowed down in Portugal since March 2023, the recommendation is closed for other reasons. **Background** First response (02/06/2022) Private gardens are places that meet the most appropriate conditions for shooting the *Tamarixia dryi* parasitoid, which is a more effective strategy to mitigate the risk of the pest, with a better collaboration of individuals when surveyed by inspectors. These counts are also used to raise awareness. Second response (29.09.2022) The national legislation on plant health already provides the legal basis for action in private areas, including gardens in private homes, as well as the sanctions that can be applied to them. However, the level of dispersion of *T. erytrea* in the territory and its major host plants, no longer allows its total eradication. All our efforts are focused on reducing the population level of the pest, applying all the phytosanitary measures available, including biological control, both in private and public areas. Considering that eradication in some areas is not feasible anymore, we have sent DG SANTE a letter on containment measures for *T. erytreae*. In November 2023, in the reply to the draft Country Profile, DGAV indicated that, as already explained, the legislation in force provides the proper basis for any intervention and the legislation is being applied whenever necessary, whether in public or private property; the lack of cooperation can happen with any public or private person or entity and the legal mechanisms are followed in both cases. National legislation, namely the Decree-Law nº67/2020, foresees, in its art. 18(3), the legal possibility to intervene, namely in private property, and in case of difficulties to do so, the intervention of the police authorities is also foreseen. Difficulties on the implementation of phytosanitary measures arrive in various circumstances and may occur in any pest. Considering that the last update of the demarcated area for Trioza, the "Despacho n.º 23/G/2023", was published on our website on 15 March, https://www.dgav.pt/wp-content/uploads/2023/03/Despacho23-ZD-Trioza_MAR2023.pdf, and since then no new findings of the pest occurred, it provides the necessary evidence that the measures in place are being able to prevent the spread of the pest.

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
2022-7400-1 Ensure that competent authorities have access to a sufficient number of suitably qualified staff and adequate laboratory capacity for timely implementation of official controls and other official activities for Xylella fastidiosa as required by Article 5(1) (d) and (e) of Regulation (EU) 2017/625. The recommendation is based on conclusions Nos 14, 61 and 63. Associated findings Nos 11, 34 to 37, 51 and 52.	**In Progress** Although the designated laboratories have initiated procedures for accreditation to EN ISO/IEC 17025, this process was not finalised and therefore the required guarantees for the analytical performance are not provided. Delays in completing the laboratory tests can compromise the timely implementation of the eradication measures. In the infected zones of the Porto outbreaks there are very long delays in the identification and removal of plants, specified by the EU legislation, due to lack of inspection, administrative and plant removal capacities, difficulties in identifying and notifying the landowner and in accessing sites. Consequently, the eradication of *Xylella fastidiosa* is very unlikely and there is a considerable risk of spread of the disease within the demarcated areas and to other parts of the country. The 2021 statistically based surveys in the buffer zones were planned fully in line with the provisions of the EU legislation. Due to staff shortages, many of the selected sites were not checked in the Porto and Lisbon buffer zones. In addition, and in particular in the Porto buffer zones, the territory of the selected sites could not be inspected entirely due to access issues. Therefore, the minimum requirements of the EU legislation for the surveys were not met and the actual extent of the outbreak is not known in those areas. This prevents the proper implementation of the eradication measures. ***Assessment (January 2024):*** *ICNF, DRAPN and DRAPLVT plan to outsource the removal of the plants in demarcated areas. With regard to the activities planned:* • *The ICNF's tendering procedure (a common multi-annual (3 years) procedure that will cover the elimination of trees and plants as part of the eradication of* Xylella fastidiosa *and* Bursaphelenchus xylophilus*) is waiting for the approval of an Interministerial order.* • *After the current contract expired on 13 November 2023, DRAPN is preparing a new procedure for a multi-annual contract, that will be submitted to the Minister of Agriculture and Food for authorising the expenditure.* • *DRAPLVT signed a contract for external recruitment of one technician, until the end of 2023, to develop several activities related to the management of the demarcated areas.* *With regard to access to the adequate laboratory resources as indicated in their action plan by ICNF, DRAPLVT, DGAV and INIAV:* • *In August 2023, ICNF signed a contract with FITOLAB laboratory, for laboratory testing of 2 000 plant samples until the end of 2023.*

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
	• *In June 2023, DRAPLVT signed a contract with FITOLAB for the reinforcement of laboratory capacity for testing 625 plant samples to detect* Xylella fastidiosa. • *In July 2023, DGAV signed contracts with* o *INIAV for testing a total of 5 770 plant samples and for 605 insect samples and 393 samples for subspecies determination.* o *FITOLAB for testing a total of 8410 plant samples.* *Also, an additional 50 weekly plant samples are being analysed in a Spanish laboratory all year round.* • *In 2023, INIAV was authorised to recruit 4 researchers (out of 60 requested). INIAV initiated a new process of recruitment in order to hire the 60 human resources needed for the NRL.* ***The recommendation remains "In Progress" until the competent authorities provide the following evidence (which will also help address recommendation 2020-7065_3):*** • ***Completion by ICNF of the tendering procedure to outsource implementation of plant removal services and confirmation that the multi-annual contract for the work to be done was signed.*** • ***Completion by DRAPN of the procedure for a multi-annual contract for the removal of plants within the demarcated area and confirmation that a service contract for the work to be done was signed.*** • ***Additional recruitment of staff by INIAV for laboratory analysis.*** **<u>Background</u>** <u>First response (03/09/2022)</u> In order to comply with this recommendation, the ICNF, I.P.: • Is currently developing a tendering procedure for the purchase of specialised services for the elimination of vegetation under the plant protection measures associated with the control of *Xylella fastidios*a for the year 2022 in the demarcated area; • It will maintain the allocation of existing human resources, with reinforced action/prioritisation, depending on the risk. DRAPN intends to procure external services (2 teams: 4 technicians and 2 cars). DRAPLVT intends to carry out external recruitment of suitably qualified staff using the available recruitment bursary of the last external competition.

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
	DRAPALG already contracted 2 Senior Technicians — Phytosanitary Inspectors at DRAP Algarve in 2022 to comply with the requirements (official controls and other official activities related to *Xylella fastidiosa*). As regards laboratory capacity, the ICNF, I.P. and the DGAV have already contracted for 2022 purchases of specialised services for carrying out laboratory analyses to detect *Xylella fastidiosa* of samples collected in the LFA, as a reinforcement of the previous year. For 2023, this reinforcement is planned to be stepped up, with several purchases of services contracted by DGAV, ICNF and DRAPLVT. INIAV indicated that in January 2022 a request was made to the government to authorise the opening of an external call for tender for new human resources for the National Reference Laboratory. This request was issued in favour of the Minister for Agriculture and Food in July 2022 and is now for consideration by the Minister of Finance Second response (25/01/2023) ICNF - Due to budgetary unavailability the tendering procedure for the purchase could not be accomplished in 2022 and is foreseen in 2023, as an international tendering procedure. Nevertheless, the actions were developed with ICNF own means and also with the cooperation of the forest rangers, in the framework of the service they provide to ICNF. ICNF also wants to state that the procedure foreseen for 2023 is a multiannual model, that has a wider scope for the control of quarantine pests, such as *Bursaphelenchus xylophilus* and *Xylella fastidiosa*, with a total amount of 3,3 million euros, distributed for 3 years, and in this way assuring the continuity of the work, without interruption, until 2025. This procedure depends of the authorization of the Government, in the form of an ordinance extending charges. For laboratory capacity, ICNF intends to make a contract of at least 2000 samples. In the case of DRAPN, as a follow up of the information previously reported, has already signed a contract with one company for the treatments against the vectors, before the destruction of the plants, and their subsequent destruction and removal, in infected zones, in private areas. Contract will be in force all year round. DRAPLVT intends to carry out external recruitment of suitably qualified staff using the available recruitment bursary of the last external competition. For 2023, also the reinforcement of laboratory capacity is planned to be stepped up, with the purchase of services contracted by DRAPLVT, for at least 760 samples. For DGAV budgetary reinforcement will be requested for the performance of contracts to perform analysis, with an official lab and with NRL, for 15 000 samples. Also, additional 50 weekly samples will be analyzed in a Spanish lab. INIAV: in progress, with positive feedback from the General Directorate responsible for the national budget. Waiting the final decision by the Minister of Finance.

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
	In November 2023, in the reply to the draft Country Profile, the competent authorities provided the following information: • ICNF, I.P. • The multi-annual procedure that will cover the elimination of trees and plants as part of the eradication of *Xylella fastidiosa* (in the amount of 0.3 million Euros) and *Bursaphelenchus xylophilus* (in the amount of 3 million Euros) will be common. As it is expected to be carried out over a period of 3 years requires the existence of an Interministerial order which is in the process of being analysed and subsequently ratified. • The contract between ICNF, I.P. and the FITOLAB laboratory, for laboratory testing of 2000 samples, as well as the respective technical specifications was provided. The contract will end at the end of the year, with 100% execution. • DRAPN • Under the contract, the entreprise partially provided the services foreseen, which expired on 13 November 2023. A new procedure for a multi-annual contract is currently being prepared, that will be submitted to the Minister of Agriculture and Food for authorising the expenditure. • DRAPLVT • DRAPLVT has signed a contract for external recruitment of one Technician, until the end of the current year, developing several activities related to the management of the demarcated areas (contract attached). • The reinforcement of laboratory capacity was achieved, with a contract with the laboratory for 625 samples (contract attached). • DGAV • The budgetary reinforcement for the performance of contracts for analysis was achieved, and an international tender was launched in 3 lots, which resulted in contracts with 2 labs, for a total of 14 180 plant samples. Another contract was signed for 605 insect samples and 393 samples for subspecies determination. The 3 contracts are in annex. Also, additional 50 weekly samples are being analysed in a Spanish lab all year round. • INIAV, I.P. • Related with the process of recruitment that started in 2022, where INIAV asked to hire 60 human resources to the NRL the Minister of Finance only authorized the recruitment of 4 researchers in 2023 (in the hiring phase).

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
	• INIAV already initiate a new process of recruitment in order to hire the 60 human resources needed for the NRL (in evaluation on the Ministry of Agriculture and Food).
2022-7400-2 Ensure that official plant and insect vector samples are tested for Xylella fastidiosa in laboratories which are accredited in accordance with standard EN ISO/IEC 17025 as required by Article 37(4)(e) of Regulation(EU) 2017/625. The recommendation is based on conclusions No 14. Associated findings No 10.	**In Progress** Although the designated laboratories have initiated procedures for accreditation to EN ISO/IEC 17025, this process was not finalised and therefore the required guarantees for the analytical performance are not provided. ***Assessment (January 2024):*** *The action proposed (expand the scope of accreditation of INIAV, as the National Reference Laboratory, to include the test method for the detection of* Xylella fastidiosa*), if implemented will address the recommendation.* ***The competent authority (INIAV) is invited to provide evidence that the accreditation procedure (including the test method for the detection of* Xylella fastidiosa*) of the National Reference Laboratory was completed.*** **Background** First response (03/09/2022) INIAV, as the National Reference Laboratory, has been accredited since 2008 and has always been working in a quality environment and working closely with EURL. This is a process of continuous improvement and the scope of accreditation has been expanded over the years (https://www.iniav.pt/acreditacao). In the plant health area, including *Xylella fastidiosa*, it is expected that this process will be completed in the 1st half of 2023. As regards the private laboratory, FITOLAB, it has already been designated as an official laboratory and is already accredited according to EN ISO/IEC 17025 standard as required by Article 37(4)(e) of Regulation (EU) 2017/625, as well as for the test method for the detection of *Xylella fastidiosa* (Supporting documents were provided) Second response (25/01/2023) INIAV: In progress. We expect to have an IPAC (Portuguese Institute of Accreditation) audit in the first half of 2023. In November 2023, in the reply to the draft Country Profile, INIAV indicated that in relation to the process of recruitment that started in 2022, where INIAV asked to hire 60 human resources to the NRL, the Minister of Finance only authorized the recruitment of 4 researchers in 2023 (in the hiring phase). INIAV already initiate a new process of recruitment in order to hire the 60 human resources needed for the NRL (in evaluation on the Ministry of Agriculture and Food).

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
2022-7400-3 Ensure that the Portuguese contingency plan for Xylella fastidiosa identifies the minimum resources to be made available in case of a confirmed presence of the pest, and specifies effective procedures for making those additional resources available swiftly, in line with Article 3(2)(a) of Regulation (EU) 2020/1201. The recommendation is based on conclusion No 23. Associated finding No 20.	**Closed due to action taken** The structure and information content of the national *Xylella fastidiosa* contingency plan of Portugal and the action plans are largely in line with provisions of the EU legislation. However, as there are no clear procedures on how to make available the minimum resources necessary for the controls, the timely implementation of the actions necessary for the eradication is not guaranteed. ***Assessment (September 2023):*** *DGAV amended, at the end of 2022, the appropriate chapter of the contingency plan by mentioning the resources needed to comply with the action plans.* ***The action addresses the recommendation.*** **Background** First response (03/09/2022) DGAV will amend the appropriate chapter of the contingency plan by mentioning the resources needed to comply with the action plans by the end of 2022. Second response (25/01/2023) The contingency plan was revised at the end of 2022, to be aligned with your remarks and is annexed to this answer.
2022-7400-4 Ensure that all plants, listed in Article 7(1) (a) to (e) of Regulation (EU) 2020/1201, are immediately removed in each infected zone for Xylella fastidiosa. In particular, ensure that measures are taken to address any issues that hinder or delay the plant removal, such as laboratory capacities, administrative procedures and accessibility of the	**In Progress** In the infected zones of the Porto outbreaks there are very long delays in the identification and removal of plants, specified by the EU legislation, due to lack of inspection, administrative and plant removal capacities, difficulties in identifying and notifying the landowner and in accessing sites. Consequently, the eradication of *Xylella fastidiosa* is very unlikely and there is a considerable risk of spread of the disease within the demarcated areas and to other parts of the country ***Assessment (January 2024):*** *DGAV informed on the progress made in removal of plants by providing the actual state of play as of 1 January 2023 for each individual infected zones indicating the date of confirmation of the pest, the date of the completion of inventory and the date of the completion of the removal of plants.*

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
locations, as requested by Article 11 of that Regulation. The recommendation is based on conclusion No 61. Associated findings Nos 34 to 37.	*The actions proposed (additional resources for the removal of plants within the demarcated areas - as already provided in response to recommendation 2022-7400_1), if implemented, can address the recommendation.* ***This recommendation remains "In Progress" until the competent authorities provide confirmation that additional resources have been made available for the removal of plants, as per recommendation 2022-7400_1.*** **Background** First response (03/09/2022) The ICNF is currently developing a tendering procedure for the acquisition of specialised services for the elimination of vegetation under the plant protection measures associated with the control of Xylella fastidiosa for the year 2022, in order to comply with the procedures laid down for the demarcated area. The ICNF will maintain the notification procedure for all owners located in the LFA, by means of an official notice, with a view to speeding up the implementation of eradication measures. According to Article 15 of Decree-Law No 67/2020, the State may, in the event of failure to act by the owners, take the place of the owners. The DRAPN is in the process of contracting a plant start-up company, the process of which is already being examined by the selection board for the removal of infected plants and all those identified infected from the LFA list. DRAPLVT will carry out a service contract in 2023 to support this activity. Second response (25/01/2023) In the case of DRAPN, please see answer to recommendation 1. For ICNF, it was not possible to conclude the contracting of services in 2022 for the foreseen intervention in the infected zones in forest areas. It is under preparation the pluriannual international tendering procedure to ensure the work to be carried out until 2025, as soon as authorizations of the Ministers of Environment and of the Finances are obtained. The intervention in infected zones is being held with ICNF own resources and also the forest rangers, while waiting for the reinforcement of action with the contracting services. DRAPLVT will also carry out a service contract in 2023 to support this activity. In November 2023, in the reply to the draft Country Profile, DGAV indicated: Please see answer to recommendation 2022-7400-1 and the progress made in removal of plants is presented in the excel file in annex, reported as to 1 January of 2023.
2022-7400-5	**In Progress**

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
Ensure that the statistically based surveys are fully implemented in the buffer zones to guarantee the identification of infected plants present with the level required by Article 10 of Regulation (EU)2020/1201. The recommendation is based on conclusion No. 63. Associated findings Nos 50 to 52.	Due to staff shortages, many of the selected sites in the statistically based surveys were not checked in the Porto and Lisbon buffer zones. In addition, and in particular in the Porto buffer zones, the territory of the selected sites could not be inspected entirely due to access issues. Therefore, the minimum requirements of the EU legislation for the surveys were not met and the actual extent of the outbreak is not known in those areas. This prevents the proper implementation of the eradication measures. ***Assessment (January 2024):*** The proposed actions (which are the same as the ones proposed to address recommendation 2022-7400_1) satisfactorily address the recommendation, if implemented. ***This recommendation remains "In Progress" until the competent authorities provide confirmation that additional resources have been made available for the removal of plants, as per recommendation 2022-7400_1.*** **Background** First response (03/09/2022) The actions proposed in recommendation 1, with regard to the commitments made by the DRAP and ICNF, also make it possible to ensure that this recommendation is addressed. Second response (25/01/2023) In the buffer zone, each square is assigned to one single entity, considering the class of soil provided by Corine Land Cover. In this sense, there are no squares with a shared responsibility, acting each entity in an individual manner. In case the entity to which the square was assigned considers it was not properly assigned, the square is given back to DGAV, to reassign it to the correct entity. So, considering the additional information provided now in recommendation 1, the tasks will be performed by each entity using the means at their disposal. In November 2023, in the reply to the draft Country Profile, the competent authorities provided the following information: • ICNF, I.P. 1. The multi-annual procedure that will cover the elimination of trees and plants as part of the eradication of *Xylella fastidiosa* (in the amount of 0.3 million Euros) and *Bursaphelenchus xylophilus* (in the amount of 3 million Euros) will be common. As it is expected to be carried out over a period of 3 years requires the existence of an Interministerial order which is in the process of being analysed and subsequently ratified.

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
	2. The contract between ICNF, I.P. and the FITOLAB laboratory, for laboratory testing of 2000 samples, as well as the respective technical specifications was provided. The contract will end at the end of the year, with 100% execution. • DRAPN 1. Under the contract, the entreprise partially provided the services foreseen, which expired on 13 November 2023. A new procedure for a multi-annual contract is currently being prepared, that will be submitted to the Minister of Agriculture and Food for authorising the expenditure. • DRAPLVT 1. DRAPLVT has signed a contract for external recruitment of one Technician, until the end of the current year, developing several activities related to the management of the demarcated areas (contract attached). 2. The reinforcement of laboratory capacity was achieved, with a contract with the laboratory for 625 samples (contract attached). • DGAV 1. The budgetary reinforcement for the performance of contracts for analysis was achieved, and an international tender was launched in 3 lots, which resulted in contracts with 2 labs, for a total of 14 180 plant samples. Another contract was signed for 605 insect samples and 393 samples for subspecies determination. The 3 contracts are in annex. Also, additional 50 weekly samples are being analysed in a Spanish lab all year round. • INIAV, I.P. 1. Related with the process of recruitment that started in 2022, where INIAV asked to hire 60 human resources to the NRL the Minister of Finance only authorized the recruitment of 4 researchers in 2023 (in the hiring phase). 2. INIAV already initiate a new process of recruitment in order to hire the 60 human resources needed for the NRL (in evaluation on the Ministry of Agriculture and Food).
2022-7400-6 Ensure that agricultural practices in the demarcated areas in Portugal are applied at the most appropriate	**Closed due to action taken** The application of the agricultural practices to control all stages of the vector population in the demarcated areas is not checked by the competent authorities. Therefore, the implementation of these measures, which play an important role in the reduction of the risk of *Xylella fastidiosa* spread, is not ensured.

Audit 2022-7400 of 03 May 2022 in order to evaluate the situation and controls for Xylella fastidiosa	
Recommendation	Basis for assessment/Information Requested/CA response
times of the year for the control of the vector population of Xylella fastidiosa in all its stages, regardless of the removal of plants concerned, in line with provisions of Article 8(2) of Regulation (EU) 2020/1201. The recommendation is based on conclusion No 64. Associated findings Nos 54 and 55.	***Assessment (September 2023):*** *The inspection sheet, drawn up based on the DGAV guidance document, to check and register the compliance with the agricultural practices includes the following fields:* • *period of execution of agricultural practices,* • *the type of locations subject to the intervention, and* • *the agricultural practices methods applied.* *These fields are checked and recorded in the sheet by the inspector. This approach is followed in the same manner for agricultural and forestry areas and was disseminated for immediate implementation, in the same way, by DRAP and ICNF.* *In case of detection on non-compliances, according to article 17 of Decree Law 67/2020, they are subject to the respective regime of administrative offences set out in the same Decree law.* ***The action addresses the recommendation.*** **Background** First response (03/09/2022) On the basis of the DGAV guidance document in force, an inspection sheet is being drawn up to carry out and record the official controls carried out in the demarcated area, which will soon make these actions measurable and thus assess their degree of compliance, to be carried out by the end of 2022. Second response (25/01/2023) The inspection sheet, to check and register the compliance with the agricultural practices is in annex to this answer. In this sheet, it has to be registered the period of execution of those practices, the type of locations subject to the intervention, and the methods applied for it. These items are checked by the inspector and registered by him in the sheet. This approach is followed the same manner for agricultural and forestry areas and will be disseminated for immediate implementation, in the same way, by DRAP and ICNF. The percentage of inspections on agriculture, forest and seminatural areas is indicated. In case of detection on non-compliances, and considering that these measures were previously informed through a notification procedure, and being considered plant health measures, according to article 17 of Decree Law 67/2020, non-compliance is subject to the respective regime of administrative offences set out in the same Decree law.

2.B.12 Quality Labelling

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
2016-8749-2 Ensure that audits or inspections of CBs are organised as necessary, as required by Article 5(3) of Regulation (EC) No 882/2004, to verify that CBs carry out properly the tasks delegated to them, and in particular that: Control plans are submitted by CBs as required by Article 3.3.(e) of the Ministerial Order No 22522/2006, and that the conditions under which controls take place are described by CBs and evaluated by IVV. The results of controls are adequately reported by CBs, as required by Article 5(2)(e) of Regulation (EC) No 882/2004; All CBs are adequately staffed to carry out effective controls, as required by Article 5(2)(b) of Regulation (EC) No 882/2004;	**Closed due to action taken** There is no system in place to verify if CBs carry out properly the tasks delegated to them. In particular, IVV neither carries out audits/inspections on the CBs nor verifies how control plans are designed and implemented by CBs. In consequence, the control measures applied by CBs are not harmonised at national level. Moreover, since the CBs do not report adequately results of their controls to IVV this may inhibit taking enforcement measures by IVV. *Regulation (EC) No 882/2004 has been repealed. The relevant requirements are in Articles 29, 32 and 33 of Regulation (EU) 2017/625.* ***Assessment (July 2023)**:* *IVV provided copies of the national legal acts concerning:* • *the institutional organisation of the wine sector, as well as the recognition, protection and control of the designations of origin (DO) and geographical indications (IG) of wines, vinegars, spirits of wine origin and aromatized wine products (Decree-Law nº 61/2020).* • *the principles and duties of the Managing Entities of PDO/PGI for the wine sector products, rules applicable to product specifications and traditional terms, as well as rules and procedures applicable for their use and marketing (Ordinance nº 142/2021).* • *the designation of all the Certification Bodies responsible for executing the official controls of PDO/PGI wine sector products (Order nº 175/2022).* *IVV provided a copy of the Technical Guidance nº 01/2019 on the Control Plan for certified PDO/PGI products. Due to the COVID-19 pandemic, the implementation of this guidance covered the period 1 July 2020 to 31 December 2021. The IVV also provided a copy of the guidance issued to CBs on how to present their execution reports, including the contribution to the MS annual report under Article 113(1) of Regulation (EU) 2017/625.* *The IVV provided evidence of the satisfactory assessment of two CBs control plans for 2020 and of the qualitative supervision of the implementation of the CBs control plans carried out on three CBs in October, November and December 2021. The outcome of this supervision was satisfactory.*

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation is based on conclusions No 18, 49 and 55 Associated findings No 16, 17, 32, 45 and 54	*The IVV assessment of the results from the CBs first execution period according to the new harmonized rules occurred in December 2022.* ***The actions address the recommendation.*** **<u>Background</u>** <u>First response (20/03/2017)</u> IVV stated that it would revise national legislation with the aim to harmonise the procedures hold by CBs. In brief, harmonisation would cover technical guidelines defining procedures for official controls, provisions for the Control Plans to be submitted to IVV for validation and a single model for reporting on the controls and their outcome. <u>Additional response (July and September 2017)</u> IVV informed that it had carried out the assessment of the 2016 control plans and controls reports on PDO/PGI wines by CBs. The assessment revealed the need of making changes in the existing legislation. IVV expects the amended legislation to be in force by the end of 2017 and presented drafts of the two pieces of legislation to be amended. Moreover IVV was in process of drafting a set of Technical Guidelines - OTE concerning controls on PDO and PGI products to be carried out by CBs and also meeting requirements for official controls lay down in Regulation (EC) No 882/2004. <u>In the context of the 2019 GFA,</u> IVV stated that: - it expects the amended Decree to be published and adopted by the end of June 2019, - all the CBs must be accredited following the ISO standards 17025 and for testing of collected samples use only accredited laboratories, - audit by IPAC is the form in which IVV verifies the CBs' activities. IVV inspectors join the IPAC audit teams and while participating in audits have direct insight into CBs' operations. In case of audits in an area requiring special knowledge, IPAC invites also technical experts to join the audit team. These audits are part of the regular arrangement and are included in the IPAC annual audit programme. - IVV decided to up-date the agreement with IPAC to ensure clarity in responsibilities and roles of IVV and IPAC when carrying audits on CBs.

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
	In its response to the Draft Country profile (June 2019), IVV presented evidence that it had carried out supervision on the CBs control activities, namely copies of the IVV audit/inspection reports on official controls by CBs. During the 2022 GFA IVV confirmed that from 2020 to 2022, 3 legislative acts were published related with the control systems of PDO/PGI for the wine sector products: • Decreto-Lei nº 61/2020 was published in August 2020 and it reviews the institutional organization of the wine sector, as well as recognizes, protects, and controls the designations of origin (DO) and geographical indications (IG) of wines, vinegars, spirits of wine origin and aromatized wine products. (ANNEX 1 - Anexo01_DL61_2020_NOVO). • Portaria nº 142/2021 was published in July 2021, and it defines the principles and duties of the Managing Entities of PDO/PGI for the wine sector products, rules applicable to product specifications and traditional terms, as well as rules and procedures applicable for their use and marketing. (ANNEX 2 - Anexo02_Portaria_142_2021). • Aviso nº 175/2022 was published in January 2022 and it designates all the Certification Bodies responsible for executing the official controls of PDO/PGI wine sector products. (ANNEX 3 - Anexo03_Aviso_175-2022). In December 2019, IVV published the first version of the Technical Guidance, OTE nº 1/2019 (ANNEX 4 - 04_OTE 2019 – PlanosControlo; 04a_Tabela I_OTE_1-2019; 04b_Tabela II_OTE_1-2019; 04c_Tabela III_OTE_1-2019). The adoption of the technical guidance rules was foreseen for March 2020 but, as a direct consequence of the COVID-19 pandemic situation, its implementation was delayed until 1st July 2020. For this reason, the first period for the implementation of the new harmonized rules was extended until 31th December 2021 (ANNEX 5 - Anexo05_mail_PControlos_2020-2021). Since Portaria nº 142/2021 establishes the 30th April as the deadline for the presentation to IVV of the annual Execution Report for the previous period, the assessment of the results from the CBs first execution period according to the new harmonized rules (defined in the 2nd version of the OTE nº 1/2019, dated May 2022) occurred in December 2022. For the preparation of this Execution Report, IVV sent guidelines for the harmonized reporting structure to all CBs (ANNEX 6 - Anexo06_Guidelines_Relat_Exec_PC2021).

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
	IVV assessed the Control Plans for 2020 presented by the CBs and presented 2 examples (ANNEX 7 - Avaliacao_CheckList_CVA; Avaliacao_PC2020_CVA; Avaliacao_CheckList_CVRTEJO; Avaliacao_PC2020_CVRTEJO). Although the initial implementation period was extended to December 2021, IVV performed a qualitative assessment in 2021. Supervision reports were made for the 2020 period based on information sent by a sample of 3 CBs (ANNEX 8 - RelSupervisao_CVA; RelSupervisao_CVRT; RelSupervisao_CVRVV). Simultaneously, it was developed in the SIvv (IVV's Information System online platform) a specific structure that will be available very soon to the CBs for the periodical submission of information regarding the execution of their annual control plan (screenshot provided). It was also created a specific IVV email address (planodecontrolos@ivv.gov.pt) to ensure a better and easier communication between IVV and CBs in what official control plans of PDO/PGI is concerned (two examples of emails exchanged were provided).
2016-8749-3 Ensure that a minimum number of operators to be subjected to the annual verification is selected, as required by Article 25(1) of Regulation (EC) No 607/2009, and that such verification includes bottlers of PDO/PGI wines located outside Portugal. Recommendation is based on conclusion No 29 Associated finding No 21	**Closed due to action taken** The frequency of official controls by CBs is not harmonised at national level as the minimum number of operators for annual verification has not been yet established. Moreover, bottlers of Portuguese wines located outside Portugal should also be included in the verification. Regulation (EC) No 607/2009 has been repealed. The relevant requirements are in Article 19(1) and (7) of Regulation (EU) 2019/34. ***Assessment (July 2023)**:* *IVV provided copies of the national legal acts concerning:* • *the institutional organisation of the wine sector, as well as the recognition, protection and control of the designations of origin (DO) and geographical indications (IG) of wines, vinegars, spirits of wine origin and aromatized wine products (Decree-Law nº 61/2020).* • *the principles and duties of the Managing Entities of PDO/PGI for the wine sector products, rules applicable to product specifications and traditional terms, as well as rules and procedures applicable for their use and marketing (Ordinance nº 142/2021).*

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
	• *the designation of all the Certification Bodies responsible for executing the official controls of PDO/PGI wine sector products (Order nº 175/2022).* *IVV provided a copy of the Technical Guidance nº 01/2019 on the Control Plan for certified PDO/PGI products, which includes a methodology to establish a minimum number of operators for annual verification.* *IVV approved in July 2022, the Technical Guidance OTE nº 01/2022 establishing the general rules for situations in which bottling of DO/GI wine products will take place outside Portugal.* ***The actions address the recommendation.*** **Background** First response (15/03/2017) IVV stated that the Technical Guidelines - OTE - proposed as one of the corrective actions to address recommendation 2016-8749-2 would address also this recommendation by setting up solutions covering the entire wine production chain 'from the vine to the bottle'. Second response (July and September 2017) IVV stated that the Technical Guidelines would indicate the minimum frequency of the CBs controls and define the register of data and information on products. In the context of the 2019 GFA IVV stated the following: - Once the Decree law is adopted/published IVV would have legal basis to disseminate and request the use of the Technical Guidance, which is now completed. Despite the Guidance being ready, IVV does not apply it, since it may require some slight amendments depending on the final version of the Decree. - Azores and Madeira have not developed procedures/rules similar to those from the Guidance but IVV expects they would use the Guidance. Nonetheless, an official agreement with the Azores and Madeira would be necessary. - Concerning verification on bottlers outside Portugal, IVV confirmed that such activity takes place in some Nordic Countries. The wine traded from Portugal is sealed in the presence of CBs and in the bottling country unsealing and bottling take place also in the presence of the CBs. This practice, however, is not included in the Guideline. IVV expects that this aspect would be cover by the Decree, thus it waits for the adopted version to make these changes. During the 2022 GFA

Audit 2016-8749 of 11 October 2016 in order to Evaluate the control systems related to Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) for wine sector products	
Recommendation	Basis for assessment/Information Requested/CA response
	IVV confirmed that from 2020 to 2022, 3 legislative acts were published related with the control systems of PDO/PGI for the wine sector products: • Decreto-Lei nº 61/2020 was published in August 2020 and it reviews the institutional organization of the wine sector, as well as recognizes, protects, and controls the designations of origin (DO) and geographical indications (IG) of wines, vinegars, spirits of wine origin and aromatized wine products. (ANNEX 1 - Anexo01_DL61_2020_NOVO). • Portaria nº 142/2021 was published in July 2021, and it defines the principles and duties of the Managing Entities of PDO/PGI for the wine sector products, rules applicable to product specifications and traditional terms, as well as rules and procedures applicable for their use and marketing. (ANNEX 2 - Anexo02_Portaria_142_2021). • Aviso nº 175/2022 was published in January 2022 and it designates all the Certification Bodies responsible for executing the official controls of PDO/PGI wine sector products. (ANNEX 3 - Anexo03_Aviso_175-2022). In December 2019, IVV published the first version of the Technical Guidance, OTE nº 1/2019 (ANNEX 4 - 04_OTE 2019 – PlanosControlo; 04a_Tabela I_OTE_1-2019; 04b_Tabela II_OTE_1-2019; 04c_Tabela III_OTE_1-2019). The adoption of the technical guidance rules was foreseen for March 2020 but, as a direct consequence of the COVID-19 pandemic situation, its implementation was delayed until 1st July 2020. For this reason, the first period for the implementation of the new harmonized rules was extended until 31th December 2021 (ANNEX 5 - Anexo05_mail_PControlos_2020-2021). Since Portaria nº 142/2021 establishes the 30th April as the deadline for the presentation to IVV of the annual Execution Report for the previous period, the assessment of the results from the CBs first execution period according to the new harmonized rules (defined in the 2nd version of the OTE nº 1/2019, dated May 2022) occurred in December 2022. For the preparation of this Execution Report, IVV sent guidelines for the harmonized reporting structure to all CBs (ANNEX 6 - Anexo06_Guidelines_Relat_Exec_PC2021). In July 2022, IVV approved and provided a copy of the Technical Guidance OTE nº 01/2022 establishing the general rules for situations in which bottling of DO/GI wine products will take place outside Portugal.

3. OVERVIEW OF MORE RECENT AUDITS NOT COVERED IN THIS COUNTRY PROFILE

3.A PUBLISHED REPORTS

In addition to the recommendations dealt with in chapters 2.B.1 to 2.B.12, the reports of a further three audits carried out by DG Health and Food Safety in Portugal have now been published. The follow-up of the recommendations in these reports will be published in future country profile updates.

Audit number	*Topic*	*Date*
2022-7421	Evaluate the implementation of official controls on animal by-products (ABP) and derived products (DP)	October 2022
2023-7739	Evaluate the system of official controls relating to microbial safety of food of non-animal origin	March 2023
2023-7692	Evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria	April 2023

3.B ONGOING AND PLANNED AUDITS

In addition to the published reports, there are a further five audits ongoing or planned:

Audit number	*Topic*	*Date*
2023-7781	Evaluate the system of official controls on animals and goods entering the European Union and verification of compliance of border control posts with European Union requirements	October 2023
2023-7680	Evaluate the implementation of official controls on Genetically Modified Organisms, including their deliberate release into the environment	November 2023
2024-8019	Evaluate the food safety control systems in place governing the production and placing on the market of fishery products	February – March 2024
2024-7995	Animal Health - Avian influenza	April 2024

Audit number	*Topic*	*Date*
2024-8009	Evaluate the official controls related to the safety of milk and dairy products	May 2024

ANNEX I – ACRONYMS, ABBREVIATIONS, SPECIAL TERMS

ACRONYM	DESCRIPTION
AAC-FF	Administrative Assistance and Cooperation System for Food Fraud
ABP	Animal by-products
ADI	Admissable daily intake
APA	*Agência Portuguesa do Ambiente* - Portuguese Environment Agency
ARAE	*Autoridade Regional das Atividades Económicas* - Regional Authority of Economic Activities (Madeira)
ASAE	*Autoridade de Segurança Alimentar e Económica* - Economic and Food Safety Authority
ASF	African Swine Fever
AT	*Autoridade Tributária e Aduaneira* – Tax and Customs Authority
BAC	Bacterial artificial chromosome
BCP	Border control post(s) (replaced BIPs as from 14 December 2019)
BIP	Border Inspection Post(s)
BSE	Bovine spongiform encephalopathy
BTSF	Better Training for Safer Food
CA	Competent authority(ies)
CAA	*Plano de Controlo de Alimentação Animal* - Official Feed Control Plan
CB	Control body(ies)
CCA	Central competent authority
CSF	Classical Swine Fever
DA	Demarcated area
DAA	*Divisão de Alimentação Animal* – Animal Feed Unit
DAH	*Divisão de Alimentação Humana* - Food Unit
DAV	*Divisão(ões) de Alimentação e Veterinária* - Food and Veterinary Unit(s)
DBEA	*Divisão de Bem Estar Animal* - Animal Welfare Unit
DCCA	*Divisão de Controlo da Cadeia Alimentar* - Food Chain Control Unit
DESA	*Divisão de Epidemiologia e Saúde Animal* - Epidemiology and Animal Health Unit
DGADR	*Direção-Geral de Agricultura e Desenvolvimento Rural* - Directorate-General for Agriculture and Rural Development
DGAE	*Direção-Geral das Atividades Económicas* – Directorate-General of Economic Activities
DGAMV	*Divisão de Gestão e Autorização de Medicamentos Veterinários* - Management and Authorisation of Veterinary Medicines Unit
DGAPF	*Divisão de Gestão e Autorização de Produtos Fitofarmacêuticos* - Plant Protection Products Management and Authorisation Unit
DGAV	*Direção-Geral de Alimentação e Veterinária* – Directorate-General for Food and Veterinary
DGEG	*Direção-Geral de Energia e Geologia* - Directorate- General for Energy and Geology

ACRONYM	DESCRIPTION
DGRM	*Direção-Geral de Recursos Naturais, Segurança e Serviços Marítimos* - Directorate-General for Natural Resources, Safety and Maritime Services
DGS	*Direção-Geral da Saúde* – Directorate-General for Health
DIFMPV	*Divisão de Inspeção de Fitosanitária e de Materiais de Propagação Vegetativa* - Plant Health Inspection and Propagation Material Unit
DIM	*Divisão de Internacionalização e Mercados* - Internationalisation and Markets Unit
DIRMA	*Divisão de Identificação, Registo e Movimentação Animal* - Identification, Registration and Animal Movement Unit
DoC	Declaration of compliance
DP	Derived products
DPEC	*Divisão de Planeamento, Estratégia e Comunicação* - Planning, Strategy and Communication Unit
DRA	*Divisão de Riscos Alimentares* – Division of Food Risks
DRAg, Açores	*Direção Regional de Agricultura (Açores)* - Regional Directorate of Agriculture of Azores
DRAL	*Departamento de Riscos Alimentares e Laboratórios* - Department of Food Risks and Laboratories
DRA-Madeira	*Direção Regional de Agricultura e Desenvolvimento Rural* - Regional Directorate for Agriculture and Rural Development
DRAP	*Direção Regional de Agricultura e Pescas* - Regional Directorate(s) for Agriculture and Fisheries
DSAVR	*Direção de Serviços de Alimentação e Veterinária Regional* – Regional Directorate(s) for Food and Veterinary
DSECI	*Direção de Serviços de Estratégia, Comunicação e Internacionalização* - Directorate for Strategy, Communication, and Internationalisation
DSMDS	*Direção de Serviços de Meios de Defesa Sanitária* - Directorate for Health Protection Means
DSNA	*Direção de Serviços de Nutrição e Alimentação* - Directorate for Nutrition, Food and Feed
DSP	*Divisão de Saúde Pública* - Public Health Unit
DSPA	*Direção de Serviços de Proteção Animal* – Directorate for Animal Protection
DSSA	*Direção de Serviços de Segurança Alimentar* - Directorate for Food Safety
DSSV	*Direção de Serviços de Sanidade Vegetal* - Directorate for Plant Health
DVS	*Divisão de Variedades e Sementes* - Varieties and Seeds Unit
EC	European Community
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
EURL	European Union Reference Laboratory
FCM	Food contact materials
FMD	Foot and Mouth Disease

ACRONYM	DESCRIPTION
FNAO	Food of non-animal origin
FVO	Food and Veterinary Office (Directorate F – Health and Food Audits and Analysis - of DG Health and Food Safety (DG SANTE), with effect from 1 February 2016)
GFA	General follow-up audit
GMO	Genetically modified organism(s)
GNR	*Guarda Nacional Republicana* – National Republican Guard
HACCP	Hazard Analysis and Critical Control Points
IAMA	*Instituto De Alimentação e Mercados Agrícolas* - Institute for Food and Agricultural Markets
ICNF, I.P.	*Instituto da Conservação da Natureza e das Florestas, I.P.* - Institute for Nature Conservation and Forests
IFAP, I.P.	*Instituto de Financiamento da Agricultura e Pescas, I.P.* - Financing Institute for Agriculture and Fisheries
IGAMAOT	*Inspeção-Geral da Agricultura, do Mar, do Ambiente e do Ordenamento do Território* - General Inspection for Agriculture, Sea, Environment and Spatial Planning
INIAV, I.P.	*Instituto Nacional de Investigação Agrária e Veterinária, I.P.* - National Institute for Agrarian and Veterinary Investigation
IPAC, I.P.	*Instituto Português de Acreditação, I.P.* - Portuguese Institute of Accreditation
IPM	Integrated pest management
IPMA, I.P.	*Instituto Português do Mar e da Atmosfera, I. P.* - Portuguese Institute for Sea and Atmosphere
IRAE	*Inspeção Regional das Atividades Económicas* (Azores) - Regional Inspectorate of Economic Activities
ISO	International Organization for Standardization
IVDP, I.P.	*Instituto dos Vinhos do Douro e do Porto, I.P.* - Porto and Douro Wines Institute
IVV, I.P.	*Instituto da Vinha e do Vinho, I.P.* - Vine and Wine Institute
LBM	Live bivalve molluscs
LC-MS/MS	Liquid Chromatography with tandem mass spectrometry
MAA	*Ministério da Agricultura e Alimentação* - Ministry of Agriculture and Food
MAAC	*Ministério do Ambiente e Ação Climática* - Ministry of Environment and Climate Action
MAI	*Ministério da Administração Interna* - Ministry of Home Affairs
MANCP	Multi-annual national control plan
MDN	*Ministério da Defesa Nacional* - Ministry of National Defence
MEM	*Ministério da Economia e do Mar* - Ministry of Economy and Maritime Affairs
MF	*Ministério das Finanças* - Ministry of Finance
MRL	Maximum Residue Level

ACRONYM	DESCRIPTION
MS	*Ministério da Saúde* - Ministry of Health
NAS	National Audit System
NRL	National reference laboratory(ies)
NRMP	National Residues Monitoring Plan
OF/SI	Organic fertilisers and soil improvers
OPP	*Organizações de Produtores Pecuários* - Livestock Producer's Organisations
PACE	*Plano de Controlo de Estabelecimentos Aprovados de Géneros Alimentícios* - Control Plan for Approved Foodstuffs Establishments
PAP	Processed animal proteins
PC	*Ponto de Controlo* – Control Point
PCAI	*Plano de Controlo Agro-Industrial* - Control Plan on Agro-Industry
PCGE	*Plano de Controlo dos Alimentos para Grupos específicos* - Control Plan for Foodstuffs for Specific Groups
PCMC	*Plano de Controlo dos Materiais em Contacto* - Control Plan on Food Contact Materials
PCPP	*Plano de Controlo da Produção Primária* - Control Plan on Primary Production
PCR	Polymerase Chain Reaction
PCSA	*Plano de Controlo de Suplementos Alimentares* - Control Plan on Food Supplements
PDO	Protected Designation of Origin
PGI	Protected Geographical Indication
PNCA	*Plano Nacional de Colheita de Amostras* - National Sampling Plan
PNFA	*Plano Nacional de Fiscalização Alimentar* - Food and Feed Inspection National Plan
PNPR	*Plano Nacional de Pesquisa de Resíduos* - National Residues Control Plan
PPP	Plant protection product(s)
PTP	Parallel trade permit(s)
PWN	Pine Wood Nematode
RASFF	Rapid Alert System for Food and Feed
SIPACE	Information System for PACE
SNIRA	*Sistema Nacional de Informação e Registo Animal* - National Animal Identification and Registration System
SRA	*Secretaria Regional de Agricultura e Desenvolvimento Rural* - Regional Secretariat for Agriculture and Rural Development of Madeira
SRADR	*Secretaria Regional da Agricultura e do Desenvolvimento Rural* – Regional Secretariat for Agriculture and Rural Development of Azores
SRM	Specified risk material
TB	Bovine tuberculosis
TRACES	Trade control and expert system

ACRONYM	DESCRIPTION
TSE	Transmissible spongiform encephalopathy
TSG	Traditional speciality guaranteed
UNO	*Unidade Nacional de Operações* - National Control and Enforcement Unit
UR	*Unidade Regional* – Regional Unit(s)
VMP	Veterinary medicinal products