



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 for Health and Food Safety of the European Commission works to ensure effective control systems for food and feed safety, animal health, animal welfare, plant health and food quality labelling and to evaluate compliance with EU standards. It does this mainly by carrying out audits in Member States and Non-EU countries.

It 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 45 (5) (a) of Regulation (EC) No 882/2004 requires that Member States take appropriate follow-up action in the light of recommendations resulting from EU 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.

The instrument of general follow-up audits to review progress on the implementation of recommendations made was introduced in 2005. This process follows the Commission services' "package meeting" approach whereby these audits provide an opportunity to discuss open issues with the competent national authorities. In the intervening period, Member States may provide additional information on progress and, following assessment by the Commission, this may result in an update of the follow-up status of recommendations.

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

The information in this part of the country profile has been compiled in the context of a general follow-up audit which was carried out by our services in March 2019.

Administrative follow-up and general follow-up audits are regularly conducted in order to monitor progress in relation to open 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 information and documentation received from the competent authorities and reviewed in the course of the 2018 general follow-up audit and on subsequent information provided by the authorities in Portugal.

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 finalised 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 2011-2018

Control system	Total number of finalised audits 2011 - 2018	Recommendations 2011 - 2018				
		Total	Closed because action taken	Closed for other reasons	In progress	Action still required
Horizontal issues	1	3	2	0	1	0
Animal Health	3	20	17	1	2	0
Food of animal origin	4	28	26	0	2	0
Imports of animals and food of animal origin	4	11	8	3	0	0
Feedingstuffs and animal nutrition	1	8	8	0	0	0
TSE/ABP	3	10	7	3	0	0
Veterinary medicines and residues	1	5	4	1	0	0
Foodstuffs and food hygiene	4	33	28	3	2	0
Imports of food of plant origin	2	16	16	0	0	0
Plant protection products	3	25	19	3	1	2
Animal welfare	2	7	7	0	0	0
Plant health	8	62	23	39	0	0
Quality Labelling	2	24	15	7	2	0
Total:	38	252	180	60	10	2
General follow-up audits/ Administrative follow-up	2					

1. MAIN ISSUES

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

Sector specific issues

Controls on pesticides (plant protection products)

- Formulation analysis of Plant Protection Products (PPPs) is not being carried out to verify that PPPs placed on the market in Portugal meet EU requirements (2012-6298-4).
- An accredited laboratory had not been designated to carry out formulation analyses of PPPs (2012-6298-5).

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": Appropriate measures to address the recommendation have been implemented by the competent authority. The recommendation is therefore closed.

"In progress": Appropriate measures to address the recommendation have been initiated by the competent authority 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. The recommendation therefore remains open.

Given the nature and scope of the general follow-up audit, no verification through audit on-the-spot was carried out. The assessment undertaken through the general follow-up audit is considered complementary to other follow-up actions and verifications that may be necessary and carried out as part of future sectoral audits by our services. Recommendations classified as "In progress" or "Action still required" are not necessarily considered to require any immediate specific legal or administrative action on the part of Commission services. These recommendations will remain the subject of monitoring by 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 problems. Some recommendations may be related to minor technical aspects while others may refer to more problematic, systemic, issues.

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	Current Status
<p>2017-6027-1</p> <p>To ensure that the audit process is subject to independent scrutiny as required by Article 4(6) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusion 18.</p> <p>Associated finding: 16.</p>	<p>This recommendation is based on finding No: 16 and associated conclusion No: 18 of the audit report that 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.</p> <p>In its original response IGAMAOT stated that it asked the Minister of Agriculture, Forests and Rural Development to implement regular independent scrutiny, and proposed some solutions.</p> <p>In its further correspondence (May 2018) IGAMAOT clarified that the solution chosen was for regular external scrutiny of the IGAMAOT audit system to be based on:</p> <p>a) A review of the audit process, regularly carried out by the IGAMAOT internal audit service; and</p> <p>b) An approval of the audit universe and the analysis of a risk-based planning carried out by the Panel of Experts of the National Audit System on Regulation (EC) No 882/2004.</p> <p>IGAMAOT clarified that the independent scrutiny would take place approximately every three years starting beginning from 2020.</p> <p><u>In the context of the 2019 GFA</u>, IGAMAOT stated that Dispatch No.: I/00028/DIR/18 endorsed proposed solution.</p> <p>Section G of the Dispatch defines competences and tasks of the Experts Panel for regulatory systems and official control systems for food security, and in points (f) and (g) indicated that EMAS is responsible for:</p> <p>(f) assessing the audit systems of the bodies referred to in (d), in particular within the</p>	<p>In Progress</p>

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	Current Status
	<p>framework of the official control systems for food safety, in complying with the same Regulation;</p> <p>(g) conducting studies, investigations, surveys, analysis of exposures or claims, or other actions in its area of intervention;</p> <p>Moreover, Section I defines competences and tasks of the Management and Information Control Team, stipulates point (e) and (f) that the Team is responsible for:</p> <p>e) evaluating internal control procedures in the IGAMAOT areas of activity, contributing to its continuous improvement;</p> <p>f) carrying out analyses of recommendations of the revised activities to improve the internal functioning of the services;”</p> <p>IGAMAOT stated that, in accordance with the endorsed Management Plan and Information Control Team Plan, the review of the audit process will take place in 2020.</p> <p>IGAMAOT presented copy of the Dispatch No.: I/00028/DIR/18.</p> <p><i>Assessment: In progress</i></p> <p><i>To demonstrate that actions for this recommendation are completed IGAMAOT should present evidence that independent scrutiny effectively took place, for example present the summary of the scrutiny.</i></p>	
<p>2017-6027-2</p> <p>To implement a documented risk-based approach in the development</p>	<p>This recommendation is based on findings No: 29, 30 and 31 and associated conclusion No: 33 of the audit report that despite some arrangements in place for audit programming, the process for developing the programme is not properly documented. It affects transparency of the development process, the clarity of risk-based prioritisation and establishing the audit</p>	<p>Closed due to action taken</p>

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	Current Status
<p>of the audit programme and to cover all relevant areas of activity in sufficient detail.</p> <p>Recommendation based on conclusion: 33.</p> <p>Associated findings: 29, 30 and 31.</p>	<p>frequency in specific selected areas.</p> <p>In its response (December 2017) IGAMAOT and DGAV stated that they continue to work on applying the risk analysis methodology developed by IGAMAOT to the Multi-annual Audit Programme. The authorities expect this work to be finished by January 2018 and, as a result, a new five-year audit cycle (2019-2023) would be established. Adjustment of the five-year audit programme would take place every year.</p> <p>Concerning the 2014-2018 audit cycle, planned audits will continue. These could be topped-up by ad-hoc audits (on specific field or topic) requested by the authorities.</p> <p>IGAMAOT and DGAV presented copy of the methodology/instruction/procedure demonstrating how the risk-based approach results in selection of relevant areas and the audit frequency.</p> <p><u>In the context of the 2019 GFA</u> the competent authorities stated the following:</p> <p>IGAMAOT has implemented the Multi-annual Audit Programme that had been developed in collaboration with DGAV. Moreover, IGAMAOT has applied the risk analysis methodology to all of the 58 thematic sub-domains of official controls.</p> <p>At the end of the risk evaluation work, joint planning of the audits was reflected in the new Multi-annual Audit Programme 2019-2023, the next five-year audits cycle, based on a suitable frequency established under the risk analysis, in order to prevent omissions and overlaps in the coverage of the audit universe. All the sub-domains of the official control systems were included in the Plan.</p> <p>The Multi-annual Audit Programme 2019-2023 was submitted to the National Audit System' representatives in June 2018. The Programme would be revised every year, based on updating of the risk analysis of the audited areas, through the results of the audits or of the follow-up</p>	

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	Current Status
	<p>actions.</p> <p>IGAMAOT presented the Multi-annual Audit Programme 2019-2023.</p> <p><i>Assessment: Closed due to action taken</i></p>	
<p>2017-6027-3</p> <p>To put arrangements in place in Madeira to ensure compliance with Article 4(6) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusion 9.</p> <p>Associated findings: 5 and 7.</p>	<p>This recommendation is based on findings No: 5 and 7 and associated conclusion No: 9 of the audit report that in the absence of an audit system in Madeira the official controls in that region are not subject to a systematic and independent examination. As a result there are no guarantees on the extent to which the official controls systems comply with the relevant EU legislation and meet the objectives of Regulation (EC) No 882/2004.</p> <p>In its original response DGAV stated that the competent authority of the Autonomous Region of Madeira would put in place an audit system as required by Article 4(6) of Regulation (EC) No 882/2004. The DGAV Audit Office would carry out these audits. The competent authority of Madeira and DGAV would sign respective written agreement.</p> <p>In its further correspondence (May 2018) DGAV stated that:</p> <p>a) The competent authority of Madeira and DGAV signed the audit agreement.</p> <p>b) Audits in Madeira would begin from October 2018.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated the following:</p> <ul style="list-style-type: none"> - DGAV signed a cooperation agreement with authorities of the autonomous region Madeira, - Areas included in the scope of the audit plan for the Autonomous Region of Madeira reflect these from the Portugal MANCP if are relevant/exist in Madeira. Moreover, the areas of import controls and RASFF are included in the audit plan. 	<p>Closed due to action taken</p>

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	Current Status
	<p>- In 2018 the DGAV Internal Audit Unit carried out in Madeira an audit on approval and controls of food establishments. In June 2019 DGAV scheduled an audit on eradication programmes for bovine tuberculosis, bovine brucellosis and brucellosis of small ruminants.</p> <p>The Madeira services have the intention to set up its own Audit Unit and prepare auditors for the region in order to be able to start performing audits by 2020, with the collaboration of the DGAV Internal Audit Unit. Until it's done DGAV would carry out audits in the Region.</p> <p>DGAV presented the protocol agreement between DGAV and the Madeira Autonomous Region, the DGAV Audit Programme covering also Madeira, a copy of the audit report from the 2018 audit in Madeira by the DGAV Internal Audit Unit (Approval and Control of Food Establishments).</p> <p><i>Assessment: Closed due to action taken</i></p>	

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	Current Status
2012-6402-8	This recommendation is based on the conclusion from Section 5.4 and related findings of the	In Progress

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	Current Status
<p>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 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.</p>	<p>audit report that 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 CP, 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.</p> <p>In its response INIAV stated that:</p> <p>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,</p> <p>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.</p> <p>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).</p> <p>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.</p>	

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	Current Status
	<p><u>During the 2016 GFA</u> 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 accreditation audit from IPAC. Expected deadline for accreditation process to be completed is the first quarter of 2017.</p> <p>Despite of the above INIAV stated that some departments of the laboratory already works according to the quality system established in the ISO 17025, and regularly participates in proficiency testing. Reference materials are ensured by access to certified reference materials provided by the EURL or available in the market.</p> <p>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.</p> <p>INIAV stated that analytical laboratory procedures for these diseases are in place but some have not been validated yet.</p> <p>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 for Rift valley fever and epizootic haemorrhagic disease of the deer are validated, while validation of analytical methods for remaining diseases is ongoing.</p> <p><u>In the context of the 2019 GFA</u> INIAV stated as regards the three diseases, the status of validation and accreditation is the following:</p> <p>- for peste des petits ruminants, control materials and laboratory techniques (PCR and ELISA)</p>	

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	Current Status
	<p>are validated, and accreditation of the laboratory would take place by June 2020;</p> <p>- 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;</p> <p>- 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.</p> <p>INIAV underlined that the NRL for epizootic diseases participated in proficiency tests by EURL and succeeded with satisfactory results.</p> <p>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.</p> <p>In addition the INIAV presented information on the <i>status quo</i> of other validations and accreditations for other epizootic diseases; in brief:</p> <p>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.</p> <p>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).</p> <p>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.</p> <p><u>Assessment:</u> <i>In progress</i></p>	

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	Current Status
	<p><i>To demonstrate that actions to address this recommendation are completed DGAV should present evidence that laboratories for peste des petits ruminants, sheep and goat pox and lumpy skin disease received accreditation.</i></p>	

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	Current Status
<p>2016-8773-1</p> <p>To ensure that, when used, the derogation for testing males for tuberculosis is applied in accordance with Annex A (I)(2)(c) to Directive 64/432/EEC, and in particular that derogations for testing male animals for fattening are only applied to those coming from officially tuberculosis-free herds, located within an isolated epidemiological unit and that will go directly for slaughter, for regions where the average — determined on 31 December of each year — of the annual percentages of bovine herds confirmed as infected with</p>	<p>This recommendation is based on conclusion No: 100 and related findings No: 71 and 72 of the audit report that eradication system for bovine tuberculosis (TBC) lacks efficiency due to exclusion of: a) male animals from testing (this concerns some areas of the mainland), and b) 25% of herds from testing (this concerns the mainland). In consequence the system loses its ability to detect and eliminate infected animals timely.</p> <p>In its response DGAV stated that breeding males have been included in the 2016 TBC monitoring and eradication programme. DGAV submitted this correction to the Commission.</p> <p>DGAV presented correspondence accompanying the corrected TBC 2016 programme.</p> <p>DGAV stated that the 2017 TBC programme excludes from TBC testing only bovine males kept for fattening and present in officially tuberculosis free (OTF) herds located in regions where the average breeding herds prevalence is not more than 1% (in accordance with Annex A (I)(2)(c) to Directive 64/432/EEC).</p> <p>Every year, DGAV carries out a risk assessment for areas where the testing derogation applies. Results of the assessment are available to the Livestock Producers Organisation (OPP) which submits sanitary programmes submitted for DGAV approved. PISA.Net system allows DGAV</p>	<p>Closed due to action taken</p>

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	Current Status
<p>tuberculosis is not more than 1 % of all herds within the defined area during the two most recent annual supervisory periods.</p> <p>Recommendation based on conclusion No.:100.</p> <p>Associated findings No.:71, 72.</p>	<p>to validate the OPP activities only if these follow the programme.</p> <p>SNIRA system receives information on the health status of farms and the pre-movement tests of animals, in order to allow or to block the issuing of transit permits; in consequence herds without TBC free status receive the movement restrictions.</p> <p>In its additional correspondence (November 2016) DGAV informed that it had revised the 2017 TBC programme and submitted revised version to the Commission. In brief, with the exception of animals sent for slaughter, TBC testing applies to all bovine animals (males and females) from 6 weeks of age that leave breeding officially tuberculosis-free herds to all destinations, regardless the TBC prevalence of the district of origin. Post-movement tests are also allowed.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that it revised the TBC monitoring programme accordingly and presented the revised 2017 TBC monitoring programme approved by the Commission.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2016-8773-3</p> <p>To ensure that the ELISA test is used on a sample of milk taken from the milk collected from a farm with at least 30% of dairy cows in milk, as required in Annex (C)(2.2.3.4) to Directive 64/432/EEC.</p>	<p>This recommendation is based on conclusion No: 109 and related finding No: 79 of the audit report that the competent authority did not verify if milk polled samples destined for indirect ELISA test (Enzyme-linked immunosorbent assay), collected at dairy farms, had been collected when at least 30% of cows were in lactation period. This undermines the representativeness of the polled samples, and in consequence cannot ensure the quality / reliability of testing for determining the status of a disease free herd.</p> <p>In its correspondence DGAV informed that in Acores, an appointed service samples milk for testing with indirect ELISA. Sampling takes place quarterly to ensure that in the sum of</p>	<p>Closed due to action taken</p>

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	Current Status
<p>Recommendation based on conclusion No.:109. Associated finding No.:79.</p>	<p>samples from each farm is more than 30% of dairy cows in lactation period.</p> <p>Beside ELISA test applied to cows in lactation the service collects blood samples from all cows present in the farm for a complementary screening test (serological test) under the programme. As a consequence each cow is individually tested.</p> <p>On the mainland the list of farms selected for testing with indirect ELISA test (screening of brucellosis) is cross-checked with the data available in PCOL (the official milk control plan) on the farms supplying the dairy industry. This list is also cross-checked with the one presented in the sanitary programme of OPP.</p> <p>Local veterinary services and OPP regularly exchange information concerning the farm status to avoid sampling at farms not complying with the sampling requirements.</p> <p>If OPP or official veterinarian identifies at least one of the following situation, the farm is excluded from the list:</p> <ul style="list-style-type: none"> a) changes in the animals present in the farm, b) detection of non-compliance of the rules for the introduction of animals in the farm, c) presence of brucellosis outbreaks in the neighbouring farms, d) lack of conditions for the collection of milk samples in all the milk tanks of the farm, and e) difficulties in the individual identification of all the milk cows related with each milk container. <p>If the farm is excluded from the list, thus excluded from screening by ELISA, all animals at farms are subject to serological blood tests, and OPP reports to the Regional Veterinary Services the reason for the blood sampling methodology.</p> <p><u>In the context of the 2019 GFA, DSPA (DGAV) confirmed that the sampling procedure described above still is in place and is followed, and sampling and testing applies quarterly to</u></p>	

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	Current Status
	<p>all eligible herds.</p> <p>DSPA added that in the first quarter sampling covers all cows in lactation (for ELISA) and all cows present at the farm (for serology test). During the three remaining quarters the service samples milk from all cows that at the moment of sampling are in lactation. For each sampled cow, the service inserts the information whether the cow is in lactation or not. This data is held in the database (SNIRA). Following each sampling period DSPA verifies the data inserted and calculates the percentage of cows in lactation.</p> <p><i>Assessment: Closed due to action taken.</i></p> <p><i>DSPA presented data demonstrating that the percentage of cows sampled per quarter exceeded 30%, therefore providing assurance that the annual average also exceeded the required 30%.</i></p>	
<p>2016-8773-4</p> <p>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.</p> <p>Recommendation based on conclusion No.:119.</p> <p>Associated finding No.:111.</p>	<p>This recommendation is based on conclusion No: 119 and related finding No: 111 of the audit report that the NRL is not accredited; this puts in questions the quality and reliability of obtained test results.</p> <p>In its response DGAV clarified that only one of the laboratories carrying out laboratory tests for bovine brucellosis is not accredited. Nonetheless, the laboratory is under the accreditation process that should be completed by the end of 2016. DGAV presented the list of the approved laboratories, also available at:</p> <p>http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=18550&_afz=18550&_afz=18472&_afz=18472</p> <p>http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=19058&_afz=19058&_afz=19058</p>	In Progress

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	Current Status
<p>2013-6667-5</p> <p>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.</p>	<p>This recommendation is based on findings from Section 5.3.2 and related conclusion of the audit report that 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.</p> <p>In its response (March 2014) 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.</p> <p>In its further clarification (June 2014) 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.</p> <p><u>During the 2016 GFA</u>, IPMA provided a copy of the up-dated 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.</p> <p><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.</p> <p>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.</p>	<p>In Progress</p>

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	Current Status
	<p><i>Assessment: In progress.</i></p> <p><i>To demonstrate that actions for this recommendation are completed IPMA should provide evidence that it concluded the sanitary surveys in the remaining 10 areas.</i></p>	
<p>2013-6667-10</p> <p>To ensure that food business operators comply with the requirements for the production and placing on the market of bivalve molluscs as required in Article 4 of Regulation (EC) No 854/2004, in particular that molluscs are continuously purified for a period sufficient to achieve compliance with microbiological criteria, as required in Point A.3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004 and that molluscs from class "C" production areas are relayed over a long period or undergo treatment to eliminate pathogenic micro-organisms, as required in Points A.4 and 5 of the same Regulation.</p>	<p>This recommendation is based on findings from Section 5.5.4 and 5.5.2 (molluscs of class "C" areas) and related conclusion of the audit report that despite of the satisfactory reduction microbiological contamination even with high initial levels of E.coli, there are deficiencies in the way operators run the purification of LBM. These are: mixing of different species in the same tank, not respecting the purification times following the introduction of new lots of molluscs to be purified in tanks with already purified molluscs and molluscs not fully immersed in water during the purification process. The competent authority only recently started to investigate if operators evaluate the parameters applied during the purification process in order to demonstrate that these are sufficient to ensure a reduction in the microbiological level of contamination below the EU limits. This evaluation had only started at the time of the audit and therefore results were not available.</p> <p>In addition, authorities could not ensure that requirements for molluscs harvested in class "C" production areas, established in Point A.4 and 5 of Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004, are met)</p> <p>In its response (March 2014) DGAV stated that it had already took measures to increase the effectiveness of the official controls, with a special focus in purification systems. In particular in November 2013 DGAV organised training in this respect for official staff 2013 and initiated work on Guidelines on LBM official controls. Moreover, DGAV prepared a booklet that is available to the public and to consumers.</p>	Closed due to action taken

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Recommendation	Basis for assessment	Current Status
	<p>DGRM stated that until the end of 2014 it will implement a control scheme to certify that LBM from production areas classified as "C" are effectively destined to processing establishments or relaying areas.</p> <p>In its further clarification (June 2014) DGRM stated that it issues the licenses for capture only if the destination for LBM from production area class "C" is a processing establishment or a relaying area and after the verification if destination is included in the documents register. Non-conformities detected during such controls result in legal measures. The maritime authority is also in charge of other situations e.g.: illegal catches.</p> <p><u>During the 2016 GFA</u> DSSA (DGAV) confirmed that its official controls include checks of the purification process of LBM in purification centres. DSSA presented check-list used by inspectors including the legal requirements to be checked in the purification process - point E4 and examples of inspection reports containing findings in this respect.</p> <p>DSSA stated that it drawn-up a Guidance document for official controls; between the other, it covers the purification issue. DSSA presented copy of the Guidance document, an evidence of the purification process validation checks carried out in purification centres and example of a registration document for LBM from "C" areas. The Guidance is available at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=157522&cboui=157522</p> <p>DSSA stated that during the approval procedure of new purification centres it requires that the purification system is validated. DSSA presented example of a report from joint official controls by three competent authorities at purification plant, for which they reject the approval due to the lack of the validation of the purification system (despite the compliant structures was in place).</p> <p>Regarding LBM harvested in "C" production areas, DSSA stated that:</p>	

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Recommendation	Basis for assessment	Current Status
	<p>- there are eight "C" production areas in Portugal. Neither relaying areas nor processing establishments for LBM harvested in "C" are in operation in Portugal; thus all these LBM are dispatch to another EU Member State for processing.</p> <p>- to ensure controls over movement of these LBM, DSSA set up a new system for issuing the registration document in electronic form. This, however, requires adoption of a legal instrument (an ordinance of the Ministry of the Sea) to allow the new system to come into force. DGRM expects the ordinance to be adopted by the end of 2016.</p> <p><u>In the context of the 2019 GFA</u> DSSA confirmed that since August 2017 it has introduced, in electronic form, the registration document satisfying requirements of Paragraph 3 of Chapter I of Section VII of Annex III to Regulation (EC) 853/2004. LBM operators use the form while moving LBM to related establishments (purification and dispatch centres).</p> <p>In spite of the fact that the new ordinance has not yet been published, Ordinance No. 1421/2006 of December 21 allows DSSA to authorize the completion of the registration document, in a system created for that purpose. DSSA confirmed that the vast majority of operators handling LBM use this electronic registration document and this allows full traceability of LBM.</p> <p>DSSA explained that gatherers of LBM from "C" production areas can only obtain the annual licence for this activity under the condition that the gatherer delivers LBM to a processing establishment.</p> <p>DSSA presented copies of electronic registration documents issued for various LBM operators.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

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Recommendation	Basis for assessment	Current Status
<p>2013-6667-12</p> <p>To ensure that only laboratories that are accredited in accordance with specified European standards are designated to carry out the analyses of samples taken during official controls, as required in Article 12.2 of Regulation (EC) No 882/2004, and that laboratories implement good practices.</p>	<p>This recommendation is based on findings from Section 5.6 and related conclusion of the audit report that the laboratory testing for toxin-producing plankton is not accredited and laboratory practices are not in accordance with good practices (e.g. sample results were written with pencil, then transferred in the student's book, then transferred to the registration book and only later recorded in the database; there was no logbook for reagents in use). In consequence the reliability of the testing results could be undermined.</p> <p>In its answer (March 2014) IPMA stated that following its document "<i>Sistema Nacional de Monitorizao dos Moluscos Bivalves</i>" (<i>Monitoring of Bivalve Molluscs National System</i>) the accreditation of the microbiology laboratory of Olhão is scheduled for December 2015. Documentation in this respect is under preparation and twice a year the laboratory participates in inter-laboratory tests. The implementation of Good Laboratory Practices for the laboratory testing for toxin-producing plankton is ongoing and is expected to finish in August 2014.</p> <p>In its further clarification (June 2014) IPMA informed that the microbiology lab of Olhão has not been accredited yet. However, the tests and respective results are obtained using the method of international reference, and that the lab has participated in inter-laboratory tests with satisfactory results.</p> <p>IPMA prepares a process of allocation the staff to the Lisbon lab in order to shift all microbiological analysis from Algarve until the accreditation of the laboratory of Olhão is completed.</p> <p><i>Assessment: IPMA satisfactorily addressed the part of the recommendation related to the laboratory testing for toxin-producing plankton.</i></p> <p>During the 2016 GFA, IPMA confirmed that, as regards microbiological testing for LBM, the Olhão Microbiology Laboratory has implemented a management system according to EN ISO17025 standard. The laboratory also requested an accreditation audit by IPAC that would</p>	<p>Closed due to action taken</p>

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	Current Status
	<p>include the methodology for research and quantification of E.coli, in accordance with the EU reference method (ISO TS16649-3). IPMA stated that IPAC has already appointed the audit team and the audit date is scheduled on 22 June 2016. IPMA expects the accreditation process to be finalised by the end of summer 2016.</p> <p>IPMA stated that until the accreditation process in the Olhão Laboratory is finished, all microbiological analyses of LBM samples are carried out in Lisbon Microbiology Laboratory (since August 2014).</p> <p>In post GFA correspondence (October 2016) DGAV stated that audit in the Olhão Laboratory took place in June 2016. Finalisation of the IPAC assessment and accreditation process is expected in September 2016. DGAV presented evidence of accreditation audit.</p> <p><u>In the context of the 2019 GFA</u> IPMA stated that the accreditation process in the Olhão Laboratory had been successfully concluded and provided a copy of the accreditation certificate together with examples of reports for test analyses.</p> <p><i>Assessment: Closed due to action taken.</i></p>	
<p>2013-6667-13</p> <p>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</p>	<p>This recommendation is based on findings from Section 5.6 and related conclusion of the audit report that the laboratory testing for biotoxins uses analytical method for detection of lipophilic toxins that had not been validated by the EU legislation. Moreover detection of pectenotoxins, yessotoxins and azaspiracids is not performed.</p> <p>In its response (March 2014) 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 finalise the validation</p>	In Progress

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	Current Status
<p>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.</p>	<p>process in the first half of 2014.</p> <p>IPMA scheduled the accreditation process for early July 2015. Once the method receives validation IPMA will include all lipophylic biotoxins (stipulated in Regulation (EC) No 2074/2005) in regular monitoring programme.</p> <p><u>During the 2016 GFA</u> 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.</p> <p>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 lipophylic toxins promoted by the European Reference Laboratory (EU-RLM), and c) it obtained satisfactory results in 2014 (ocadaic acid group) and in 2015 (ocadaic acid group, azaspiracids and yessotoxins).</p> <p>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 ocadaic acid group only, during the second trimester of 2016 IPMA began monitoring for the remaining lipophilic toxins groups such as azaspiracids, pectenotoxins and yessotoxins.</p> <p>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).</p> <p>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</p>	

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	Current Status
	<p>lipophilic biotoxins also in the new LC-MS/MS equipment. This validation is ongoing.</p> <p><u>In the context of the 2019 GFA</u> 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 as azaspiracids, pectenotoxins and yessotoxins.</p> <p>IPMA stated that:</p> <ul style="list-style-type: none"> - 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 ocaidaic 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. <p>IPMA expects that IPAC would carry an accreditation audit in July 2019.</p> <p>In its response to the Draft Country profile (June 2019) IPMA presented copies of validation reports for paralytic shellfish toxins and lipophilic toxins.</p> <p><i>Assessment: In progress</i></p> <p><i>To demonstrate that actions for this recommendation are completed IPMA should provide evidence that accreditation was granted (e.g. accreditation certificate).</i></p>	

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

Audit 2015-7442 of 14 September 2015 in order to evaluate the application of re-enforced checks on imported products of animal origin		
Recommendation	Basis for assessment	Current Status
<p>2015-7442-1</p> <p>To ensure that adequate resources for sampling and testing under the monitoring plan are made available on time for organising effective and appropriate official controls, required by Article 4 of Regulation (EC) No 882/2004, and specifically for allowing (i) the implementation of the monitoring plan throughout the whole year and (ii) the testing of samples without major delay.</p> <p>Recommendation based on conclusion 23.</p> <p>Associated findings: 6, 7, 13, 18.</p>	<p>This recommendation is based on conclusion No: 23 and related findings No: 6, 7, 13 and 18 of the audit report that the competent authority cannot ensure proper implementation of the annual monitoring programme for imported goods. In particular a) the monitoring plans are implemented with few months delays, b) some seasonal products are not sampled, c) collected samples (destined to private laboratories) are stored at BIPs, and d) results of samples tested in state laboratories are not delivered timely. All the above results in inability of the competent authorities to carry out effective monitoring and undertake effective measures for non-compliant products.</p> <p>In its response DGAV stated that it had developed the 2016 monitoring plan, and the laboratory network for official samples analyses has been designated. Once the state budget is approved DGAV would distribute the plan to the regional veterinary services (expected in one month time).</p> <p>In its further correspondence (October 2016) DGAV informed that official laboratories designated to perform the analyses under the monitoring plan (PCAPIF) have analytical methods accredited to EN ISO/IEC 17025, and the microbiological control methods are in compliance with the requirements of Regulation (EC) 2073/2005.</p> <p>The 2016 PCAPIF is in progress and about 67% of the planned controls have already been performed. Laboratories receive samples from in timely manner. On average, laboratories produce analytical results in 19 days.</p> <p>The financial procedure was simplified allowing for faster financing of analyses. DGAV finalised the 2017 PCAPIF and expects it to be approved by the end of October. For budgetary purposes and to avoid delays DGAV presented in advance expected cost of the 2017 PCAPIF.</p>	<p>Closed due to action taken</p>

Audit 2015-7442 of 14 September 2015 in order to evaluate the application of re-enforced checks on imported products of animal origin		
Recommendation	Basis for assessment	Current Status
	<p><u>In the context of the 2019 GFA:</u></p> <p>This recommendation was followed-up on-the-spot during the audit DG(SANTE)/2017-6019. The audit report concluded that DGAV addressed this recommendation (see findings 43 to 45 of the audit report).</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

Audit 2017-6019 of 06 March 2017 in order to evaluate the system of documentary checks at the Union borders		
Recommendation	Basis for assessment	Current Status
<p>2017-6019-1</p> <p>To ensure that documentary checks for live animals, and products of animal and non-animal origin are carried out in line with Annex I to Commission Decision 97/794/EC, Article 1(1) of Commission Regulation (EC) No 136/2004, Article 5(2) of Commission Implementing Decision (EU) No 2011/884, Articles 4, 5 and 9(3) of Commission Implementing Regulation (EU) No 884/2014 and Articles 5 and 6 of Commission Implementing Regulation (EU) No</p>	<p>This recommendation is based on findings No: 6, 21, 23, 24, 25 and 36 and associated conclusions No: 26 and 33 of the audit report that despite of generally correct system for border controls in place, some non-compliances for controls on live animals and products of animal and non-animal origin, even if identified, were accepted and did not trigger corrective actions. These were: the use of improper models of health certificates, the lack or improper analytical results accompanying consignments and late or absent pre-notifications on the consignment arrival. In consequence, these weaken the system of official controls.</p> <p>In its response (November 2017) DGAV stated that it would:</p> <p>a) On import of live animals - to develop an Instruction on actions in case of non-compliances in documentary checks and include the Instruction in the Manual on official controls.</p> <p>b) On products of animal origin falling under competences of DIM - to publish (by the end of 2017) a reviewed version of the Operations' Manual in the BIP. The Manual would contain examples of errors/mistakes that could be accepted by the BIP and solutions for such including also rejection of the consignment.</p>	Closed due to action taken

Audit 2017-6019 of 06 March 2017 in order to evaluate the system of documentary checks at the Union borders		
Recommendation	Basis for assessment	Current Status
2016/6, and to take adequate action when non-conformities are found, in compliance with Article 19 of Regulation (EC) No 882/2004 and Article 12 of Council Directive 91/496/EC. Recommendation based on conclusions:26 and 33 Associated findings: 6, 21, 23, 24, 25 and 36	<p>c) On products of non-animal origin DGAV stressed that evidence of corrective measures were presented in its reply to the draft audit report (see footnote 2,3,5,6 of the final report).</p> <p>Moreover: a) DGAV developed new instructions for DRAPs, b) the Directorate for Nutrition, Food and Feed (DSNA) has included in its supervision procedure (Operative Procedure No. 3) tasks allowing to identify errors in documentary checks and in TRACES. The procedure requires supervisions by regional and the central services, with 10 and 2 analyses of CED and respective processes in each region, respectively. In 2017 two central supervisions have taken place and DGAV presented preliminary supervision report.</p> <p>In 2017 three BIP staff attended BTSF training on TRACES and DGAV plans a national training in this respect in the 1st quarter of 2018.</p> <p>The DSNA also developed a work instruction on the correct completion of CED in TRACES, in particular as regards laboratory and physical controls (Work Instruction No. 4/2017, dated 19/7/2017).</p> <p><u>In the context of the 2019 GFA:</u></p> <p>This recommendation has been followed-up on-the-spot during the audit DG(SANTE)/2018-6329. The audit report concluded that DGAV addressed this recommendation (manuals/instructions have been up-dated and distributed to the BIP staff).</p> <p><i>Assessment: Closed due to action taken.</i></p>	
2017-6019-2 To ensure that racing pigeons originating in non-neighbouring non-EU countries are imported only in accordance with the provisions of	<p>This recommendation is based on finding No: 16 and associated conclusion No: 26 of the audit report that there were some non-compliances in documentary checks for racing pigeons. These were: a) health certificates used did not correspond with the required model (the welfare requirements were missing), and b) some pigeons were imported from non-approved countries and/or non-approved breeding establishments.</p>	Closed due to action taken

Audit 2017-6019 of 06 March 2017 in order to evaluate the system of documentary checks at the Union borders		
Recommendation	Basis for assessment	Current Status
<p>Commission Implementing Regulation (EU) No 139/2013. Recommendation based on conclusion: 26 Associated finding: 16</p>	<p>In its response (November 2017) DGAV stated that it would follow the Commission rules in this respect and also put under discussion further modifications of the animal health legislation related to import of racing pigeons from non-neighbouring third countries.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that:</p> <p>In 2018, DGAV contacted importers of racing pigeons and informed them about additional (missing earlier) requirements on animal welfare.</p> <p>Also in 2018, DGAV modified the authorisation process to allow import of pigeons only from countries listed in the Annex I to Regulation 798/2008.</p> <p>DGAV underlined that since there are no approved breeding establishments for racing pigeons – the approval requires that: a) an approved establishment must be under the supervision of the competent authority, b) the exporting country must be free from highly pathogenic avian influenza and Newcastle disease, and c) birds must follow testing and vaccination protocol and quarantine.</p> <p>DGAV added that this approach reflects the current proposal for the implementing act for the new official controls regulation (OCR) on the animal health conditions for animals entering into the European Union.</p> <p>DGAV stated that, in 2018, PT imported 151 racing pigeons, all originating from a listed country (Canada).</p> <p>DGAV presented: a) the authorisation procedure containing the risk assessment with the list of countries from which racing-pigeons can be imported, b) copy of the communication note containing the import requirements for animal welfare, and c) copy of a health certificate for consignment of racing pigeons imported to PT.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

2.B.4 Feedingstuffs and animal nutrition

There are no recommendations currently open for follow-up.

2.B.5 TSE\ABP

Audit 2015-7609 of 21 April 2015 in order to evaluate the traceability of animal by-products (ABP) and derived products		
Recommendation	Basis for assessment	Current Status
<p>2015-7609-1</p> <p>To ensure that official controls of transporters of ABP/DP check compliance with relevant EU requirements, as set down in Article 45 of Regulation (EC) No 1069/2009 and Article 32 of Regulation (EU) No 142/2011.</p> <p>Recommendation based on conclusion: 26</p> <p>Associated findings: 13 and 23</p>	<p>This recommendation is based on the conclusion No. 26 and related findings No. 13 and 23 of the audit report that although the competent authorities carry out regular controls that focus also on traceability and documentation requirements on most of the operators along the animal by-products (ABP) and derived products chain, transporters of ABP and derived products are not covered by such controls.</p> <p>In its response DGAV stated that the national control plan of ABP establishments, plants and operators is undergoing adaptation in order to include regular controls on traceability and documentation requirements for transporters of ABP and derived products. DGAV expects respective procedures related to these controls to be finalised by the end of 2015.</p> <p><u>During the 2016 GFA</u> DGAV stated that some issues with human resources withhold introduction traceability checks on transporters. As a consequence to introduce the traceability checks DGAV must re-prioritise controls and reallocate the resources. This action would require amending of national legislation defining the frequency and types of controls to be carried out (also in the ABP sector). DGAV submitted to the Ministry of Agriculture the amendment legislative proposal. DGAV presented copy of the proposed amendment.</p> <p><u>In the context of the 2018 GFA</u> DSSA stated that amended legislation has been adopted and the Decree Law 122/2006 of the 27th June 2006 was replaced by the new Decree Law 33/2017 (published on 23 March 2017). The new Decree establishes obligation for all</p>	<p>Closed due to action taken</p>

Audit 2015-7609 of 21 April 2015 in order to evaluate the traceability of animal by-products (ABP) and derived products		
Recommendation	Basis for assessment	Current Status
	<p>transporters of ABP and DP to be registered by DGAV.</p> <p>At the time of the 2019 GFA approximately 1000 transporters were registered and, in the view of the DGAV, this number represents all transporters of ABP and derived products in the country. DGAV maintains the list of registered transporters and publishes it at its website: https://sipace.dgav.pt/Account/LogOn?ReturnUrl=%2f.</p> <p>In addition to the control of establishments, the Control Plan for Establishments of Animal By-products (PACE-SPA) 2019 includes the control of transporters of ABP and derived products, with a frequency of 3 years. Controls started in 2019 and the time of this GFA, DGAV had already carried out 29 controls. Inspectors carry out controls following control procedures as described in PACE-SPOA, and use a specific check-list which includes verification of traceability.</p> <p>DGAV presented: a) the list of registered transporters (with web link), b) the summary of controls on ABP transporters (till end of March 2019), c) examples of control reports on transporters covering aspects of traceability of ABP and DP, d) copy of the Decree Law 33/2017 and e) copy of the Control Plan.</p> <p><i>Assessment: Closed due to action taken.</i></p>	

2.B.6 Veterinary medicines and residues

There are no recommendations currently open for follow-up.

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	Current Status
<p>2011-6260-4</p> <p>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.</p>	<p>This recommendation was based on the conclusion of Section 5.2.9 of the report that the National Reference Laboratory 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.</p> <p><u>During the 2011 GFA</u> the Portuguese authorities stated accreditation request for NRL for GMO is expected to be ready by the end of 2011.</p> <p><u>During the 2014 GFA</u> 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.</p> <p>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.</p> <p><u>During the 2016 GFA</u> 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.</p> <p>INIAV stated that, despite of the above, the laboratory works already in accordance with the</p>	<p>In Progress</p>

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	Current Status
	<p>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.</p> <p>INIAV presented examples of invoices for some purchases of certified reference materials. INIAV officially requested IPAC for accreditation audit.</p> <p><u>In the context of the 2019 GFA</u> 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.</p> <p>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.</p> <p><i>Assessment: In progress</i></p> <p><i>To demonstrate that actions for this recommendation are completed the INIAV should present a copy of accreditation certificate for the GMO Reference Laboratory.</i></p>	

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	Current Status
2015-7461-1	This recommendation is based on the conclusion No: 20 and related findings No: 16 and 17 of	In Progress

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	Current Status
<p>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.</p> <p>Recommendation based on conclusions set out in paragraph 20.</p> <p>Associated findings set out in paragraph No 16, 17.</p>	<p>the audit report that due to absence of procedures for registration of some FNAO operators, acting in the primary production area, these producers are not taken into account when planning of official controls takes place. This concerns also importers and retailers of seeds intended for sprouting.</p> <p>In its response 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.</p> <p><u>In the context of the 2019 GFA DSMDS (DGAV)</u> 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.</p> <p>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).</p> <p>The Legal Service of the Ministry of Agriculture and the Ministry of Economy reviewed the Ordinance and DGAV and expects the Ordinance to be adopted in the second half of 2019.</p> <p>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).</p> <p>DGAV stated that in the country there are only two big producers of sprouts and these two operators obtain seeds for sprouting directly from other MS - mostly from The Netherlands</p>	

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	Current Status
	<p>and Spain.</p> <p>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.</p> <p>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).</p> <p>DGAV presented the 2018 guide (for registering importers of seed for sprouting).</p> <p><i>Assessment: In progress</i></p> <p><i>To address this recommendation DGAV should present evidence that registration of FNAO primary producers under the IFAP project is effectively taking place.</i></p>	
<p>2015-7461-2</p> <p>Ensure that official controls adequately verify implementation of requirements laid down by Annex I, Chapter 3.3 A.1 of Regulation (EC) No 2073/2005 (as regards preliminary testing of seeds intended for sprouting) and Article 3 of</p>	<p>This recommendation is based on the conclusion No: 54 and related findings No: 47, 48 and 50 of the audit report that the official controls system has a number of systemic weaknesses related to seeds intended for sprouting, namely verification on operators own-checks on seeds for sprouting (sampling and testing) and verification on provisions in import health certificates. In consequence these are placed on the market while their safety could be compromised.</p> <p>In its response DGAV stated that since a working instruction for carrying out the controls is in place and covers the provisions of Annex I, Chapter 3.3 A.1 of Regulation (EC) No</p>	<p>Closed due to action taken</p>

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	Current Status
<p>Regulation (EU) No 211/2013 (certificate requirements for imported sprouts and seeds intended for sprouting).</p> <p>Recommendation based on conclusions set out in paragraph 54.</p> <p>Associated findings set out in paragraph No 47, 48, 50.</p>	<p>2073/2005 and Article 3 of Regulation (EU) No 211/2013, DGAV would re-train the staff carrying out controls.</p> <p>In addition, DGAV would verify if official controls in establishments producing sprouts properly assess provisions related operators own-checks (sampling and testing of seeds for sprouting).</p> <p>ASAE stated that it would re-train its inspectors in charge of controls and assessment of accompanying documents for seeds for sprouting and sprouts.</p> <p><u>In the context of the 2019 GFA</u> the competent authorities stated the following:</p> <p>DSMDS: In November 2016 and in March 2017 DGAV organised training for inspectors conducting controls of establishments producing sprouts. Also in 2018 an additional training was conducted.</p> <p>DSMDS presented lists of participants attending training in 2016 and in 2017 and copy of the programme.</p> <p>DRAPLVT: The staff responsible for official controls received a number of training sessions on primary production – sprouts, these were:</p> <ul style="list-style-type: none"> - November 2015: Official Control of Hygiene in establishments that produce shoots – in DGAV Oeiras, attended by two Superior Technicians, - December 2018: Official control of establishments producing shoots: presentation and discussion of guidance (2nd version)" – DGAV Oeiras, attended by three Superior Technicians. <p>DRAPLVT presented copy of the programme and copy of attendance list.</p> <p>ASAE: In December 2016 on-the-spot "in action" training on primary production of</p>	

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	Current Status
	<p>sprouts/shoots took place.</p> <p>ASAE presented: a) the training programme, b) participants list, and c) attendance register.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2015-7461-3</p> <p>Ensure that the NRL undertakes the relevant duties of an NRL as described in Article 33(2)(b-d) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusions set out in paragraph 69.</p> <p>Associated findings set out in paragraph No 66.</p>	<p>This recommendation is based on the conclusion No: 69 and related findings No: 66 of the audit report that NRL for <i>E.coli</i> neither coordinates nor disseminates to other official laboratories (which do not participate in comparative tests) information received from EURL.</p> <p>In its response DGAV stated that INIAV makes available a procedure covering coordination and dissemination issues.</p> <p><u>In the context of the 2019 GFA</u> INIAV clarified that currently the NRL for E.coli is the only one laboratory in the country responsible for official testing on E.coli. As a consequence, the internal management system did not foresee the need for additional documentary procedures that would not be used, even though their presence would be legally justified by the respective legislation.</p> <p>INIAV stated that in recent years the NRL for E.coli has exchanged some correspondence with the National Institute of Health - INSA dealing with samples collected at border points; however, the INSA laboratories belong to another authority and do not fall under NRL supervision.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	Closed due to action taken

2.B.8 Imports of food of plant origin

Audit 2017-6146 of 21 November 2017 in order to evaluate the system of import controls for plant health		
Recommendation	Basis for assessment	Current Status
<p>2017-6146-1</p> <p>Ensure that checks can be, and are, carried out on samples that are representative of the consignment from which they are taken, in line with Article 13a(1)(b)(iii) of Directive 2000/29/EC.</p> <p>The recommendation is based on conclusions No. 73.</p> <p>Associated findings No. 59, 66 and 67.</p>	<p>This recommendation is based on the conclusion No: 73 and related findings No: 59, 66 and 67 of the audit report that although the import checks in Portugal are carried out in line with the EU legislation the way of taking collecting samples undermines their representativeness (all samples are collected from one part of the consignment); moreover, BIP in Lisbon port lacks facilities allowing for unloading the containers and representative sampling of imported goods.</p> <p>In its initial and further correspondence DGAV stated that:</p> <p>a) It arranged an agreement between the veterinary service and phytosanitary service on sharing inspection facilities. In consequence from July 2018 phytosanitary inspectors in the port of Lisbon would have for use one more quay (for accessing containers) with the area sufficient to unload all pallets transported in a container.</p> <p>b) It would modify (by end of June 2018) and implement (by the end of 2018) the Phytosanitary Guide sampling instructions to ensure representativeness of sampling (the size and sampling spot). Moreover, in each of the three regions with the main points of entry of goods into the country, it would introduce a supervision of the procedures applied during the import controls (in the course of 2019).</p> <p><u>In the context of the 2019 GFA</u> DSSV stated that it has up-dated the Phytosanitary Guide (Guia Fitossanitário à Importação), distributed it to all inspectors and published at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=4429906&cboui=4429906.</p> <p>The Guide contains a new chapter (3.6) dedicated to the performance of the plant health inspection split in three elements: a) documentary check, b) identity check, and c) physical</p>	<p>Closed due to action taken</p>

Audit 2017-6146 of 21 November 2017 in order to evaluate the system of import controls for plant health		
Recommendation	Basis for assessment	Current Status
	<p>checks. Particular emphasis is put on the representativeness of the samples taken during border inspection.</p> <p>In addition DSSV developed a protocol for phytosanitary inspectors while unloading consignments in the designated areas of the veterinary service. the protocol is available at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=4054333&cboui=4054333.</p> <p>DSSV stated that in July 2018 it signed a cooperation agreement with the veterinary service carrying out veterinary border controls granting the access to facilities allowing for unloading consignments for phytosanitary inspections and sampling.</p> <p>A supervision of the procedures for import controls will only be introduced from the beginning of summer 2019 due to seasonal import patterns. For this reason no outcome or results of the supervision of phytosanitary inspection on imports could be presented during this GFA.</p> <p>DSSV presented: a) copy of the Guide, b) copy of the cooperation agreement, c) and d) the 2019 supervision plan (covering the main points of entry: Lisbon, Alentejo and Leixões).</p> <p><i>Assessment: Closed due to action taken.</i></p>	

2.B.9 Plant protection products

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides		
Recommendation	Basis for assessment	Current Status
2012-6298-4	This recommendation is based on the finding and related conclusion in Section 5.2.4 that	Action Still required

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides		
Recommendation	Basis for assessment	Current Status
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 29(1)(a), (c), (d) and (h) of Regulation (EC) No 1107/2009.	<p>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 met EU requirements. Moreover, the lack of quality control of PPPs did not ensure that counterfeit or illegal pesticides would be detected.</p> <p>In their response the Portuguese authorities stated that the National Action Plan foresees sampling of 5% of the products on the market implemented in a framework of an annual control plan. Moreover DGAV expressed its intention to re-establish formulation analyses in 2014.</p> <p><u>During the 2014 GFA</u>, 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.</p> <p><u>During the 2016 GFA</u>, DGAV explained that it decided outsourced 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 product on the market) would be collected by the end of September 2016.</p> <p>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 approved the 2016 Plan including formulation analyses.</p> <p><u>In the context of the 2019 GFA</u>, DGAV stated that the 2016 and 2017 National Control Plans were only executed during 2017/2018 and results of analyses were received in 2018.</p> <p>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</p>	

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides		
Recommendation	Basis for assessment	Current Status
	<p>involved ASAE in the collection of samples for 2017 and 2018.</p> <p>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.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> - 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). <p>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.</p> <p>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.</p> <p>DGAV explained that since the 2018 Plan had not been completed, it did not initiate the 2019 Plan.</p> <p><i>Assessment: Action still required</i></p> <p><i>Despite missing the target for sampling in 2016 and 2017 and delays in submitting for examination, collected samples were analysed. However, the 2018 Plan has not been completed (sampling target not achieved) and 16 already collected samples have not been</i></p>	

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides		
Recommendation	Basis for assessment	Current Status
	<p><i>submitted for analyses. Moreover, there is no arrangement for carrying out formulation analyses in an accredited laboratory for samples collected in 2018 and 2019.</i></p> <p><i>To demonstrate that actions for this recommendation are completed DGAV should present the following:</i></p> <p><i>1) Evidence of arrangement allowing for formulation analyses on PPP samples collected by the authorities.</i></p> <p><i>2) Evidence that samples for formulation analyses were collected and submitted for analyses.</i></p>	
<p>2012-6298-5</p> <p>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.</p>	<p>This recommendation is based on the finding and related conclusion in Section 5.2.4 that the official laboratory designated for formulation analysis was not accredited.</p> <p>In their response to the audit report, INIAV stated that the Laboratory for Formulation Analysis has been already reactivated and assessed, and the accreditation request was foreseen for last trimester of 2013.</p> <p><u>During the 2016 GFA</u> 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).</p> <p>DGAV presented a copy of the accreditation certificate of the MAGRAMA laboratory.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that contracting outsourced services requires 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.</p>	Action Still required

Audit 2012-6298 of 20 November 2012 in order to evaluate controls of pesticides		
Recommendation	Basis for assessment	Current Status
	<p>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</p> <p><u>Assessment:</u> Action still required</p> <p><i>At the time of the 2019 GFA no contract with an accredited laboratory capable of carrying out formulation analyses was in place. As a consequence there was no arrangement in place for carrying out formulation analyses in an accredited laboratory of samples collected in 2018 and, possibly, in 2019.</i></p> <p><i>To demonstrate that actions for this recommendation are completed DGAV should present evidence that formulation analyses are being carried out in an accredited laboratory.</i></p>	

Audit 2016-8789 of 14 June 2016 in order to evaluate controls on the marketing and use of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>2016-8789-1</p> <p>Ensure that the information on authorisations of PPPs kept electronically available to the public is accurate and updated at least every 3 months, in line with Article 57(1) and (2) of Regulation (EC) No 1107/2009.</p> <p>Conclusion upon which this recommendation is based: 24</p>	<p>This recommendation is based on findings No.: 8 and 9 and associated conclusion No.: 24 of the audit report that although the official register of PPPs is publicly available it is split in four different files of which one is updated once every six months instead of quarterly, thus is not synchronised with three other files. In addition, the spilt results in some inaccuracies in the data and makes it difficult for navigating when looking for authorisation status and details of the authorisation.</p> <p>In its response DGAV undertook to introduce the following solutions:</p> <p>1) As an <i>ad-hoc</i> solution, it would publish on the web an Excel file referring to PPP authorisations. Whenever any up-date or change in authorisations will take place the file would be up-dated accordingly.</p>	Closed due to action taken

Audit 2016-8789 of 14 June 2016 in order to evaluate controls on the marketing and use of plant protection products		
Recommendation	Basis for assessment	Current Status
Associated findings upon which this recommendation is based: 8 and 9	<p>2) As the ultimate solution DGAV undertook, yet in 2017, to launch a tender for a software allowing for electronic management of authorisation dossiers. Once is introduce the software would allow to publish on the web (without delay) authorisations that have been concluded.</p> <p>3) Also in 2017 the DGAV would add a technical assistant to the technical-administrative team who will manage and disseminate the information relating to authorisations. That individual will be able to work with the EU authorisation management system (PPPAMS).</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that it has launched the Management System for the Authorization of Plant Protection Products (Sistema de Gestão das Autorizações de Produtos Fitofarmacêuticos - SIFITO).</p> <p>The system provides information whether the authorisation of a PPP is still valid or has been cancelled and what are the conditions of use. At the time of this GFA SIFITO held information on approximately 57,000 PPPs. DGAV stated that the information in the system is up-dated on a weekly basis and the system is accessible online and via the DGAV webpage at: http://sifito.dgav.pt/.</p> <p>DGAV stated that SIFITO also enables the management of the authorization processes with their holders, simplifying administrative procedures in this area. ASAE inspectors in charge of market controls also have access to SIFITO.</p> <p>DGAV demonstrated the access to the system and presented recently updated information on some PPPs.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
2016-8789-2 Ensure that the labelling of PPPs reflects the latest authorised	This recommendation is based on findings No.: 18, 19 and 20 and associated conclusion No.: 26 of the audit report that during official controls ASAE could not properly control the content of the labels because:	Closed due to action taken

Audit 2016-8789 of 14 June 2016 in order to evaluate controls on the marketing and use of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>conditions of use and that the labels are legible, in line with Regulation (EU) No 547/2011, Annex I.</p> <p>Conclusion upon which this recommendation is based: 26</p> <p>Associated findings upon which this recommendation is based: 18, 19 and 20</p>	<p>a) These were illegible due to very small print.</p> <p>b) Retaining the genuine authorisation number for re-authorised PPP did not allow to verify whether re-authorised PPP fulfils the same conditions as for genuine authorisation or not.</p> <p>All above increase the risk that growers do not use the PPPs as intended in re-authorisation.</p> <p>In its response DGAV stated that:</p> <p>1) Beginning from 2016 it restarted quality controls of PPPs to check whether labelling and formulations comply with the conditions and specifications from authorisations.</p> <p>2) DGAV keeps updating the Excel file on authorised PPP, containing information on withdrawn authorisations, changes of names and that have undergone ownership transfers.</p> <p>3) Given the conditions of the Portuguese market (small holdings and small packages of PPP) DGAV authorised that additional information, accompanying PPPs in small packages, has form of leaflets. Labels could also be produce in a form of booklets. DGAV undertook to encourage the PPP production industry to adopt these solutions systematically when labels are illegible due to the size of the packages.</p> <p>In addition to the above DGAV informed that, by the end of 2017, would draw up legislation defining the procedures and criteria for defining the period of validity. This would reflect the requirement of the Commission Regulation (EU) No.: 547/2011 that whenever a product has a shelf life of less than two years, it is mandatory to insert the shelf life (validity) as well as the production date of the batch on the label.</p> <p><u>In the context of the 2019 GFA</u> DGAV explained that in 2018, following the inspection plan on retailers and distributors, ASAE carried out checks on labelling, and verified if labels match requirements laid down in Reg. 547/2011 and Reg. 1272/2008. As a result ASAE identified some non-compliance, in particular, that labels/packages of many products did not bear the production date. Toward all operators with identified non-compliance ASAE</p>	

Audit 2016-8789 of 14 June 2016 in order to evaluate controls on the marketing and use of plant protection products		
Recommendation	Basis for assessment	Current Status
	<p>launched administrative measures (including sanctions).</p> <p>DGAV stated that verification of the labels of PPPs reflects the latest authorised conditions of use is now easy because ASAE inspectors have direct access to SIFITO holding the most updated information on PPPs (see also response to recommendation No. 2016-8789-2). Moreover, DGAV made the list of products with valid and cancelled authorisation available at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=3666233&cboui=3666233.</p> <p>DGAV stated that besides market controls by ASAE, DGAV also carries out regular verification on the information published by PPP producers/distributors on internet.</p> <p>In cooperation with ASAE, DGAV developed a Guidance document for proper labelling addressed to operators and to officials in charge of controls, and published it in December 2018. DGAV amends the Guideline as needed and was going to publish the most recent update in April 2019, on its website. DGAV stated that although the Guideline is not legally binding, it has been well received by operators who declared will to follow it on a voluntarily basis. DGAV stressed that harmonisation process on labelling would need some time as some products are already on the market and re-labelling (for better legibility) would bear unnecessary burden and high costs for operators.</p> <p>DGAV provided: a) link to the updated version of the Guideline that is available at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=3665921&generico=3669837&cboui=3669837, b) examples of control notes demonstrating that official controls covered verification of labelling requirement, and c) copy of the <i>2018 Summary report on the controls on the use of plant protection products</i>.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>2016-8792-1</p> <p>Ensure that the fees for processing applications are revised so as to reflect the total cost of the work involved as required by Article 74(2)(b) of Regulation (EC) No 1107/2009.</p> <p>Conclusions upon which this recommendation is based: 2</p> <p>Associated findings upon which this recommendation is based: 1</p>	<p>This recommendation is based on finding No.: 1 and associated conclusion No.: 2 of the audit report that current fees paid by the operators do not reflect the true cost of processing applications by competent authority. This situation concludes from delays in implementation of relevant legislation.</p> <p>In its response DGAV stated that it had drafted an Implementing Order on fees, which currently is at the final stage of adoption by the Portuguese Government.</p> <p><u>In the context of the 2019 GFA</u>, DGAV stated that a new Implementing Order (Portaria No. 86/2017 of 27 February 2017) for fees to be paid under Regulation No. 1107/2009 was published and is in force since 2017.</p> <p>DGAV confirmed that the new fee regime covers the total cost of the work involved in processing of PPPs applications, in line with Article 74(2)(b) of Regulation (EC) No. 1107/2009.</p> <p>DGAV presented a copy of the new Implementing Order.</p> <p><i>Assessment: Closed due to action taken.</i></p>	<p>Closed due to action taken</p>
<p>2016-8792-2</p> <p>Ensure that the system for processing new applications for authorisation is reviewed, and the necessary changes implemented, so as to consistently meet the deadlines laid down in Article 37 (1) of Regulation (EC) No 1107/2009.</p>	<p>This recommendation is based on findings No.: 32 and 35 and associated conclusions No.: 43 and 44 of the audit report that there is a consistent failure to meet prescribed legal deadlines for authorisations issued as the zonal rapporteur Member State (zRMS) and a backlog of unsorted applications grows. In consequence delays in processing applications restrict access to market for new products and result in lost earnings for applicants.</p> <p>This situation, in addition, limits the range of available PPPs, and therefore, the range of Integrated Pest Management tools available to growers.</p> <p>In its response DGAV stated that:</p>	<p>Closed due to action taken</p>

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>Conclusions upon which this recommendation is based: 43, 44</p> <p>Associated findings upon which this recommendation is based: 32, 35</p>	<p>a) From January 2017, it would improve its procedures by enhancing the prioritisation, rejecting applications received on the basis of the Code of Administrative Procedure, giving to applicants 10 days for comments and rejecting those not submitting requested data within 30 days.</p> <p>b) In 2017 it would issue a call of tender for a process management software for managing applications that would allow to electronic management and on-line evaluation of applications and issuing authorisations without undue delay.</p> <p>c) In 2017 it would strengthen the application evaluation team. d) It would use the pool of experts provided for in Decree-Law No 145/2015 to supplement the work of the DGAV experts to reduce the evaluation period.</p> <p><u>In the context of the 2019 GFA DGAV stated the following:</u></p> <p>a) As from 2017 all the incoming applications were either completed or were authorisation renewal requests under article 43, for PPPs already authorised and for which no formal completeness check is carried out.</p> <p>b) DGAV developed the system for management of PPPs files and authorisation - SIFITO that came into operation in 2018 and is available at: http://sifito.dgav.pt/ - (see additional details under recommendation 2016-8789-1).</p> <p>c) In the period 2017 - 2018 DGAV recruited four new staff allowing to handle various types of authorisations.</p> <p>d) Introducing the new fee regime (see recommendation No. 2016-8792-1) allowed to establish a pool of experts (20 at the time of the 2019 GFA). DGAV invites experts on a rotational basis for each area of evaluation, mainly for applications falling under Article 43 and Article 33 of the Regulation (EC) No 1107/2009.</p> <p>DGAV made the procedures, list of experts and Declarations of Interest available on its</p>	

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
	<p>website, at: http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?generico=23600450&cboui=23600450</p> <p>DGAV presented evidence that in the period from 1/1/2017 to 1/1/2019 it received two applications falling only under Article 37(1), and these were completed within the deadline.</p> <p><i>Assessment: Closed due to action taken.</i></p>	
<p>2016-8792-3</p> <p>Ensure that the system for processing new applications for authorisation is reviewed, and the necessary changes implemented, so as to consistently meet the deadlines laid down in Article 37 (4) of Regulation (EC) No 1107/2009.</p> <p>Conclusions upon which this recommendation is based: 43, 44</p> <p>Associated findings upon which this recommendation is based: 33, 35</p>	<p>This recommendation is based on findings No.: 33 and 35 and associated conclusions No.: 43 and 44 of the audit report that there is a consistent failure to meet prescribed legal deadlines for authorisations issued as the concerned Member State (cMS) and a backlog of unsorted applications grows. In consequence delays in processing applications restrict access to market for new products and result in lost earnings for applicants. This situation, in addition, limits the range of available PPPs, and therefore, the range of Integrated Pest Management tools available to growers.</p> <p>In its response DGAV stated that:</p> <p>a) It has already assigned additional specialist to this this task to reduce the response time.</p> <p>b) In 2017 it would issue a call of tender for a process management software for managing applications that would allow to electronic management and on-line evaluation of applications and issuing authorisations without undue delay.</p> <p>c) In 2017 it would strengthen the application evaluation team.</p> <p>d) It would use the pool of experts provided for in Decree-Law No 145/2015 to supplement the work of the DGAV experts to reduce the evaluation period.</p> <p><u>In the context of the 2019 GFA</u>, DGAV stated that actions mentioned under points a) - d) were completed (for details see response to recommendations: 2016-8792-1, 2016-8792-2 and</p>	Closed due to action taken

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
	<p>2016-8789-1).</p> <p>Moreover, DGAV stated that as from 2017, DGAV received 20 application falling under Article 37(4) of which 6 were completed within the 120 days deadline and for 14 their completion took more than the 120 days deadline.</p> <p>DGAV underlined that: a) delays in processing applications resulted from the high number of applications received in 2017, b) the fact that in 2017 the same staff had to complete 13 renewals for active substances that were received from other MS as already delayed - thus with tight deadlines, heavily contributed to the workload and required the allocation of the staff, and c) all applications received under Article 37(4) were ultimately completed, despite that 14 applications did not meet the deadline.</p> <p>DGAV presented data related to the types and time of processed PPP applications.</p> <p><i>Assessment: Closed due to action taken.</i></p>	
<p>2016-8792-4</p> <p>Ensure that the system for processing new applications for authorisation is reviewed, and the necessary changes implemented, so as to consistently meet the deadlines laid down in Article 42 (2) of Regulation (EC) No 1107/2009.</p> <p>Conclusions upon which this recommendation is based: 43, 44</p>	<p>This recommendation is based on findings No.: 34 and 35 and associated conclusions No.: 43 and 44 of the audit report that there is a consistent failure to meet prescribed legal deadlines for mutual recognition (MR) authorisations and a backlog of unsorted applications grows. In consequence delays in processing applications restrict access to market for new products and result in lost earnings for applicants. This situation, in addition, limits the range of available PPPs, and therefore, the range of Integrated Pest Management tools available to growers.</p> <p>In its response DGAV stated that:</p> <p>a) It would improve communication with the other MS of the Southern Zone in order to reduce evaluation times for these applications.</p> <p>b) In 2017 it would issue a call of tender for a process management software for managing</p>	Closed due to action taken

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
Associated findings upon which this recommendation is based: 34, 35	<p>applications that would allow to electronic management and on-line evaluation of applications and issuing authorisations without undue delay.</p> <p>c) In 2017 it would strengthen the application evaluation team.</p> <p>d) It would use the pool of experts provided for in Decree-Law No. 145/2015 to supplement the work of the DGAV experts to reduce the evaluation period.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that actions mentioned under points a) - d) were completed (for details see response to recommendations: 2016-8792-1, 2016-8792-2 and 2016-8789-1).</p> <p>Moreover, DGAV stated that out of 73 applications for Mutual recognition lodged in 2018, 40 were processed below the 120-days deadline and 34 in more than 120-days deadline, with the average processing time of 186 days.</p> <p>DGAV stressed that the measures taken (new staff, pool of experts and SIFITO) have considerably improved the time needed to process these applications; for example: in 2017 the average time for processing an application was 220 days, while in 2018 it significantly decreased to 173 days. DGAV noticed increasing efficiency in processing applications and expects to meet the target of 120 days deadline by the end of 2019.</p> <p>DGAV presented data related to the types and time of processed PPP applications.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
2016-8792-5 Ensure that the system for processing applications for re-authorisation is reviewed, and the	This recommendation is based on findings No.: 38 and 56 and associated conclusions No.: 43, 58 and 59 of the audit report that there is a consistent failure to meet prescribed legal deadlines all types of authorisations (including re-authorisation) and a backlog of unsorted applications grows. In the absence of an overall long term strategy to ensure compliance with	Closed due to action taken

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>necessary changes implemented, so as to consistently meet the deadlines laid down in the relevant Commission Implementing Regulations or Directives.</p> <p>Conclusions upon which this recommendation is based: 43, 58, 59</p> <p>Associated findings upon which this recommendation is based: 38, 56</p>	<p>defined authorisation deadlines and changes in resources and/or procedures, the already significant delays in re-authorisation of PPPs are very likely to worsen.</p> <p>In its response DGAV stated that:</p> <p>a) It has already drawn up Circular No 24/G/2016 dated 3 August 2016 encouraging companies to request applications for mutual recognition from Member States of the Southern Zone where the products had already been evaluated in accordance with the Uniform Principles.</p> <p>b) It has developed a procedure aimed at reviewing provisional sales authorisations to run alongside the procedure for reviewing the authorisations in force under Article 43 to prevent double reviews of the same product in a short period of time.</p> <p><u>In the context of the 2019 GFA</u> DGAV stated that that from August 2016 until December 2017 there was an increase in applications for mutual recognition and to replace provisional authorisations that had not yet gone through re-registration. In particular a considerable number of mutual recognition applications for products containing glyphosate were submitted.</p> <p>DGAV stressed that the staff dealing with mutual recognition authorisations, in parallel, was engaged in concluding the re-registration of provisional authorisations that were due in 2010, 2011 and 2012. As a consequence DGAV is currently processing the re-registration of products for which the corresponding deadline for revision according to Uniform Principles was 2013 and 2014.</p> <p>DGAV explained that in this area delays are often caused by operators not respecting timelines for delivering requested information and/or documents/specimens. Moreover, DGAV stressed that it has reduced its backlog for re-authorisation applications.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
<p>2016-8792-6</p> <p>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.</p> <p>Conclusions upon which this recommendation is based: 66</p> <p>Associated findings upon which this recommendation is based: 63</p>	<p>This recommendation is based on findings No.: 63 and associated conclusion No.: 66 of the audit report that the system for granting Parallel Trade Permits (PTPs), which is purely an administrative task, is not effective or efficient. 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.</p> <p>In its response DGAV stated that:</p> <p>a) In 2017 it would issue a call of tender for a process management software for managing applications that would allow to electronic management and on-line evaluation of applications and issuing authorisations without undue delay.</p> <p>b) In 2017 it would strengthen the application evaluation team.</p> <p>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.</p> <p><u>In the context of the 2019 GFA</u> DGAV stressed that granting Parallel Trade Permits (PTP), is not purely an administrative task.</p> <p>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 application must contact the relevant MS(s).</p> <p>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 requested information.</p> <p>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</p>	In Progress

Audit 2016-8792 of 14 June 2016 in order to evaluate the system for authorisation of plant protection products		
Recommendation	Basis for assessment	Current Status
	<p>consequence, the mitigating measures undertaken by an individual country to meet the deadline for processing applications may be simply jeopardised by external factors.</p> <p><i>Assessment: In progress</i></p> <p><i>To demonstrate that actions for this recommendation are completed DGAV should demonstrate that is able to process applications for PTP within applicable deadline.</i></p>	

2.B.10 Animal welfare

There are no recommendations currently open for follow-up.

2.B.11 Plant health

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
<p>2014-7193-3</p> <p>Ensure that when measures are carried out by persons other than personnel from the responsible official bodies, they act under the supervision of the officials bodies in</p>	<p>This recommendation is based on the conclusion from Section 5.1 and respective findings in Section 5.1.1 and 5.3 of the audit report that in buffer zone ICNF does not supervise systematically the felling and elimination of declining trees which are exempted from declaration to the competent authorities.</p> <p>In its response the Institute for the Nature and Forest Protection (ICNF) stated that it has set up a system for mandatory prior declaration of all felling of trees, disposal of waste and</p>	<p>Closed due to action taken</p>

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
<p>order to guarantee that the measures are correctly implemented and corrective actions are taken when necessary. This relates in particular to the proper treatment and disposal of wood by private forest owners. Article 7(4) of Commission Decision 2012/535/EU requires such supervision.</p>	<p>movements of timber to authorised processing or treatment facilities, whether this is done by the forestry owners and/or by the economic operators.</p> <p>Nonetheless, ICNF stressed that national legislation [Article 6(3) of Decree-Law No 95/2011 of 8 August 2011] provides for an exemption from felling declaration for up to three host conifers or the equivalent of one tonne intended exclusively for own use and provided that, cumulatively, the felling takes place between 1 November and 1 April. The exemption does not affect the obligation to declare any transport of the resulting timber. ICNF plans to remove this exemption (from felling declaration) during revision of DL 95/2011. Moreover ICNF plans to initiate some awareness action for operators in rural areas.</p> <p>In November 2014, during the 1st Task Force meeting, the Portuguese expert informed the expert group that the Decree law 95/2011 is undergoing revision in order to lift the exemption from declaration prior to felling and moving felled susceptible trees that were in place for small amounts of wood felled (up to three host conifers or the equivalent of one tonne intended exclusively for own use). The Task Force report (2014-7402) indicates that in November 2014 the revision was under approval. The answer to this recommendation serves also to recommendation No. 2014-7193-16 that refers to treating of declining trees felled by private owners that use exemptions from declaration to the competent authorities .</p> <p><u>During the 2016 GFA</u> ICNF stated that new legislation (Decree-Law No 123/2015 of 3 July 2015) requires all operators to declare falling trees regardless of their amount and intended use (previous derogation for small amounts has been removed). DSSV organised an awareness campaign to ensure this information reaches all trees / forests owners. Trees owners can notify intention for felling trees in electronic way via internet. Operators are obliged to keep declarations for at least two years. DSSV is of the opinion that in this way, it has an immediate overview on the number of trees to be felled.</p> <p>DSSA confirmed that operators regularly use the new way for notifications and stated that since introducing of that system up to the time of the 2016 GFA it received 130,000</p>	

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for <i>Bursaphelenchus xylophilus</i>		
Recommendation	Basis for assessment	Current Status
	<p>notifications. Local authorities and GNR ensure official supervision during felling of trees.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been verified on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2014-7193-4</p> <p>Ensure that the national measures and the action plans aimed at containing PWN are in line with Commission Decision 2012/535/EU and enforceable, in particular with regard to the sampling of declining trees, the survey on the vector and the implementation of the hygiene protocol. Measures to be taken in the event of a positive finding in the buffer zone should also be included in the action plan for mainland Portugal.</p>	<p>This recommendation is based on the conclusion in Sections 5.1 and 5.3 and findings in Sections 5.1 and 5.3 of the audit report that:</p> <p>a) ICNF does not take to take regularly samples of trees at the time of felling, samples from felling trees are reduced to minimum weight and are often taken from just one drilling,</p> <p>b) ICNF does not carry out survey for the presence of <i>Monochamus</i> infested with pine wood nematode (PWN), in particular it does not use traps for that purpose in fire-affected areas of the buffer zone and in areas where infested trees were detected.</p> <p>c) The legislation endorsing the hygiene protocol related to movement of trees is not yet adopted, thus the protocol is not implemented in practice.</p> <p>All the above mitigate the effectiveness of preventive and eradication measures against PWN.</p> <p>In their response ICNF stated that in general the National Action Plan for control of the PWN in mainland Portugal follows the provisions and measures laid down in Commission Implementing Decision 2012/535/EU. Measures laid down in the Decision are legally binding even though some are not mentioned in the Action Plan; however, these are considered subsidiary to the Plan that had been presented to the Commission for approval.</p>	Closed due to action taken

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for *Bursaphelenchus xylophilus*

Recommendation	Basis for assessment	Current Status
	<p>ICNF stated that Decree-Law 95/2011 of 8 August 2011 is undergoing revision and will contain the rules specifically dealing with the cleaning of vehicles and machinery, obligations for economic operators on the plant health protection measures and specific technical requirements aimed at preventing the spread of PWN - currently laid down in the ICNF hygiene protocol.</p> <p>Concerning monitoring of the PWN vector (including sampling of burned trees and measures in the buffer zone when PWN is detected) ICNF expects that these issues would be duly analysed in the context of the Commission Task Force. As a result of the Task Force work ICNF expects to receive suggestions for revision the current strategy and, possibly, proposals for amendments of existing procedures.</p> <p>This has been partially addressed during the first meeting of the Task Force end of November and subsequently explained in the Task Force report.</p> <p>In their response to the Task Force report, the Portuguese authorities agreed to continue the vector survey in demarcated area of the continental Portugal.</p> <p><u>During the 2016 GFA</u> ICNF stated that in 2015 it up-dated the survey manual that now specifies the procedures for the identification of trees and for collection of samples to be tested for the presence of PWN. All ICNF regional teams received the Manual and used it to train field technicians carrying out conifers forest monitoring and survey (with sampling) of trees with symptoms of decline. Training sessions took place in 2014 and 2015. Training focused on the new sampling procedure and life cycle of PWN.</p> <p>DSSV / ICNF provided a copy of the Manual. According to the procedure each composite sample is obtained from 3 to 5 trees, with at least 3 holes per tree with a 20 mm diameter, and a minimum quantity of 100 gr per sample being collected.</p> <p>ICNF conducts monitoring of the PWN vector (<i>Monochamus</i>) in the buffer zone. Since 2014 ICNF installed 1648 traps especially in areas with trees showing decline symptoms and in the</p>	

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for <i>Bursaphelenchus xylophilus</i>		
Recommendation	Basis for assessment	Current Status
	<p>fire affected areas and in its surroundings. In the fire affected areas 60 % of the 1648 traps were placed in the 5 km buffer radius. ICNF provided maps illustrating location of traps. ICNF stated that traps contain attractant (pheromones) that is vector specific to ensure right insects get to the trap. The Manual contains specific information in this respect.</p> <p>DSSV / ICNF stated that Article 12A of Decree-Law No. 123/2015 sets specific rules on cleaning machinery and vehicles, and Article 24 contains a list of non-compliances and administrative measures against them. DSSV provided copy of the Decree-Law.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been verified on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2014-7193-9</p> <p>Ensure that the annual survey on trees is performed as required by points 2 and 3(a) of Annex II to Commission Decision 2012/535/EU. In particular, fire-affected areas should be systematically surveyed.</p>	<p>This recommendation is based on the conclusion in Section 5.3 and related findings in Section 5.3 of the audit report that in some of the fire-affected areas ICNF does not carry out survey on trees. This limits the effectiveness of the survey and amplifies a risk of not detecting PWN if present. This is particularly problematic in areas where infested trees are being detected in the vicinity of the buffer zone.</p> <p>In its response ICNF stated that, following existing procedures, it implemented measures to monitor host conifers. Measures are aimed, in particular, at identification and sampling trees with decline symptoms, with the exception of those completely destroyed by forest fires.</p> <p>ICNF pays particular attention to the buffer zone, in order to comply with the sampling plan defined by the European Food Safety Authority (EFSA) (EFSA Supporting Publications</p>	Closed due to action taken

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Recommendation	Basis for assessment	Current Status
	<p>2012:EN-385).</p> <p>ICNF stressed that sampling is essentially aimed at detecting the presence of symptoms of decline following the logic that the trees presenting such symptoms: a) are likely to be potential and possible hosts of the PWN, b) the signs indicating the presence of PWN are not absolutely unequivocal, and c) the signs of the presence of the vector insect, <i>Monochamus</i>, are also not obvious.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014. The overview report of the Task Force on the controls of PWN [DG(SANTE) 2015-8956] concludes that organisation of the surveys was appropriate, both in infested and buffer zones. In their response to the report, the Portuguese authorities agreed to continue the current organisation of surveys with additional focus on sampling of symptomatic trees. Moreover, in areas where latent infestation and delayed expression of symptoms are likely, they agreed to complement the survey by analyses of the presence of PWN in vector.</p> <p><u>During the 2016 GFA</u> DSSV / ICNF stated that the PWN monitoring guideline gave special attention to the fire affected areas. In particular these are considered as risk areas and are subject to special procedures for identification, sampling and elimination of decline symptom trees. Additionally DSSV / ICNF pays attention to the vicinity of the fire affected areas (reflected in the Traps installation guideline).</p> <p>DSSV / ICNF provided copies of the PWN monitoring guideline and the Traps installation guideline.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been verified on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities</p>	

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Recommendation	Basis for assessment	Current Status
	<p>addressed this recommendation.</p> <p><i>Assessment: Closed due to action taken.</i></p>	
<p>2014-7193-11</p> <p>Ensure that all declining trees in the buffer zone are identified as required by point 3(b) of Annex II to Commission Decision 2012/535/EU. This is particularly important in fire-affected areas as well as in the eastern part of the buffer zone where infested trees are being detected within a few kilometres from its border.</p>	<p>This recommendation is based on the conclusion in Section 5.3 and related findings in Section 5.3.2 of the audit report that ICNF does not identify declining trees (by a mark on their trunk) unless these were sampled. Moreover, ICNF carried out identification mostly along the roads or tracks in a way that does not cover the whole plots. Not-identified declining trees were present in areas which ICNF considered as completed for identification.</p> <p>In its response the Portuguese authorities stated that the process of identification of trees showing symptoms of decline (dead, in poor health or located in fire- or storm-affected areas), is undertaken throughout the buffer zone, intensively and continuously, with the aim of ensuring correct elimination of any trees identified with symptoms of decline. In this way, elimination will take place until 1 April of all trees showing symptoms of decline identified during the period 1 November until 1 April of the following year and immediately during the period from 1 April to 1 November of any given year. Similar measures are being implemented in the area surrounding the buffer zone, particularly the areas where positive cases of PWN have been detected a few kilometres away from the buffer zone. All trees located in "fire-affected areas" even green trees will be eliminated. This procedure, applicable from 2014 onwards, is currently being implemented.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014. After the Task Force completed its work the Portuguese authorities undertook to implement its recommendations. The outcome of the Task Force established clearly what trees should be identified for elimination in fire-affected areas. In particular the Task Force defined the concept of "fire affected area" where all susceptible trees should be</p>	<p>Closed for other reasons</p>

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Recommendation	Basis for assessment	Current Status
	<p>eliminated.</p> <p><u>In the course of the 2016 GFA</u> ICNF stated that the entire area of the buffer zone is subjected to intensive and continuing monitoring and sampling. All declining trees are marked, sampled and felled. Collected data are kept in database called FITO. The database contains also geolocation coordinates of declining trees sampled. The database compiles all the information related with the identification, sampling, and elimination of trees throughout the year and on a continuous basis.</p> <p>Regional and central ICNF Services have a dedicated structure of technicians and forest rangers that are, on a permanent basis, assigned to the PWN controls.</p> <p>DSSV provided an example of the data, for 2014 and 2015, collected in FITO and locations of trees with declining symptoms and copy of the Survey manual establishing rules in this respect.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that this recommendation had been partially addressed and a new recommendation was issued. This issue is being followed up in recommendation No.1 of audit DG(SANTE)/2017-6167 and 2018-6488.</p> <p><i><u>Assessment:</u> Closed for other reasons</i></p>	
<p>2014-7193-12</p> <p>Ensure that, in the buffer zone, declining trees identified from 1 November to 31 March are felled</p>	<p>This recommendation is based on the conclusion in Section 5.3.2 and related findings in the Section of the audit report that the deadline 31 March for elimination and destruction of declining trees originating in private areas of the buffer zone is not respected. This raises serious concerns, particularly, in areas of the buffer zone close to places where infested trees</p>	<p>Closed for other reasons</p>

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Recommendation	Basis for assessment	Current Status
and disposed of before 31 March each year, in line with point 3(b)(i) of Annex II to Commission Decision 2012/535/EU.	<p>had not been eliminated.</p> <p>In its response ICNF stated that all trees in buffer zone, susceptible to PWN and between 1 April to 31 October of a given year identified as showing symptoms of declining, will be felled and correctly destroyed over the period 1 November to 1 April of the following year. However, ICNF stressed that some natural occurrences (drought, storms and in particular forest fires) may influence or even make impossible implementing of the emergency measures in timely manner. ICNF ensured that regardless of the above it continuously makes an effort to fulfil their commitments in this respect.</p> <p>ICNF stressed that international public multi-annual tender (to run until 31 October 2015), has been launched.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014. During the Tasks Force visit the Portuguese authorities demonstrated that as a result of the measures taken in 2015 all declining trees, identified between 1 November 2014 and 31 March 2015, had been felled and eliminated by 31 March 2015.</p> <p><u>In the course of the 2016 GFA DSSV / ICNF</u> presented a summary of data collected during 2014 and during 2015, until 31 October 2015 concerning identification, sampling, testing and elimination of susceptible trees in the buffer zone and infested zone of continental Portugal. DSSV stated that all trees identified between 1st November and 31st March had been felled and disposed of before 31st March. DSSV stated that it also provided this information to the Task force and to the Commission. In addition DSSV presented similar information covering respective periods of 2015 and 2016.</p> <p>In addition DSSV/ICNF provided an example of the data, for 2014 and 2015, collected in FITO and locations of trees with declining symptoms.</p> <p><u>In the context of the 2019 GFA:</u></p>	

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Recommendation	Basis for assessment	Current Status
	<p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that this recommendation had been partially addressed and a new recommendation was issued. Follow-up is through recommendation No.2 of audit DG(SANTE)/2017-6167 and 2018-6488.</p> <p><i>Assessment: Closed for other reasons</i></p>	
<p>2014-7193-13</p> <p>Ensure that, in the buffer zone, declining trees identified during the flight season of the vector are immediately felled and properly disposed of as required by points 3(b)(ii) and 3(c) of Annex II to Commission Decision 2012/535/EU.</p>	<p>This recommendation is based on the conclusion in Section 5.3.2 and respective finding in the Section of the audit report that the number of not-felled trees in March 2014 have increased almost four times in comparison to these in March 2013. In addition, a large proportion of the felled trees remained still on-site untreated and with the cutting waste. This poses a significant risk of attracting infested beetles to the buffer zone during the flight season as these trees are still very attractive to beetles.</p> <p>In its response ICNF declared that that all declining trees in buffer zone susceptible to PWN identified between 1 April and 31 October will be immediately felled and correctly destroyed.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014.</p> <p>During the Tasks Force visit the Portuguese authorities demonstrated the results of measures taken in 2015. In particular the authorities stated that all trees identified during the flight period of the vector (1 April to 31 October) had been fallen and eliminated by the end of the period, with the exception of trees in fire-affected areas.</p> <p>Excepting of the fire-affected areas from declining and eliminating of trees is not entirely in line with the current EU legislation, in this respect, but it derives from the corresponding recommendation of the Task Force. The Task Force concluded that a forest fire, occurring during the flight period of the vector, attracts vectors from long distances immediately and for</p>	Closed for other reasons

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Recommendation	Basis for assessment	Current Status
	<p>some time after the fire. Thus immediate elimination of trees in this fire-affected area does not lower the attractiveness of the place and moreover may even pose a risk of further dispersal of vectors already attracted.</p> <p>The Portuguese authorities accepted the conclusion acknowledging that in a current situation this approach would prevent movement of vector to other locations and spreading of PWN. In addition, work on revision of the respective EU legislation was going to begin in February 2016 at the Commission Standing Committee on Plants, Animals, Food and Feed - SCPAFF.</p> <p><u>In the course of the 2016 GFA</u> ICNF provided additional data (referred to in recommendation No 2014-7193-12), demonstrating that trees identified during the vector flight season (between 1st April and 31st October) were felled and eliminated by the end of the period. This did not apply to trees in fire-affected areas; that were left to be cut in the next winter period but before the next flight period starts (before 31st March). In addition ICNF presented similar data covering respective periods of 2015 and 2016 presenting that these trees have been eliminated once the activity of the vector ceased.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that this recommendation had been partially addressed and a new recommendation was issued. Follow-up is through recommendation No.2 of audit DG(SANTE)/2017-6167 and 2018-6488.</p> <p><u>Assessment:</u> <i>Closed for other reasons</i></p>	
2014-7193-14 Ensure that, all trees in the infested	This recommendation is based on the conclusion in Section 5.3.2 and related findings in the Section 5.3 of the audit report that wood logs and cutting wood waste were still in place in felling sites once the teams eliminating declining trees completed their work. This poses a	Closed for other reasons

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Recommendation	Basis for assessment	Current Status
<p>zone, found infested with PWN, 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. This is particularly important when these trees are located in the vicinity of the buffer zone.</p>	<p>significant risk of attracting infested beetles to the buffer zone during the flight season as these remains are still very attractive to beetles.</p> <p>In its response ICNF undertook to develop controls in infested areas, with particular focus on those located in the vicinity of buffer zone. ICNF stated that if positive samples are detected in intervention zones in the vicinity of buffer zone, infected tree will be felled and destroyed together with other trees presenting symptoms of decline even though they are not infected.</p> <p>ICNF has a contract with an operator felling and destructing PWN susceptible and declining trees in eight parishes in of the Castelo Branco district. ICNF surveys and samples trees in these areas to identify and eliminate all conifers with decline symptoms.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014. During the Task Force works the Portuguese authorities demonstrated the progress in development of official controls, in particular in the vicinity of the buffer zone.</p> <p><u>During the 2016 GFA</u> ICNF stated that Decree-Law No.123/2015 laid down specific rules that oblige the elimination of trees with decline symptoms, namely those originated from parishes where positive PWN cases have been detected, called Intervention Zones.</p> <p>In accordance with Article 7 and related Annex I of the said Decree-Law, Article 9 (and related Annex II) establishes conditions for circulation of wood originating from these parishes. ICNF provided copy of Decree-Law No.123/2015.</p> <p>In addition ICNF put in place a system for allowing for movement controls of susceptible material, originating from demarcated area and, in particular, from the infested zone. The system operates on the basis of a compulsory declaration (“Manifesto de abate, desramação e circulação de madeira de coníferas”) prior to felling trees and their removal. The declaration identifies the operator which will collect and move trees, and the place of their destination. The declaration contains also information what phytosanitary precautionary measures operators need to implement to avoid spreading PWN and its vector. ICNF stated that</p>	

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Recommendation	Basis for assessment	Current Status
	<p>particular attention is given to infested trees located in intervention parishes in the vicinity of the buffer zone.</p> <p>To ensure that operators are aware of these phytosanitary precautionary measures, in cooperation with local authorities, DSSV / ICNF organised an awareness campaign (mentioned also under recommendation No. 2014-7193-3) supported by posters and leaflets. The latest campaign took place in May 2015. In May 2016 ICNF organised meetings with 19 GNR offices aimed at coordination and cooperation during control activities in the infested zone.</p> <p>ICNF presented examples of the declaration and maps with infested trees located in intervention parishes in the vicinity of the buffer zone and content of the leaflet / poster.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that this recommendation had been not addressed and a new recommendation was issued. Follow-up is through recommendation No 3 of audit DG(SANTE)/2017-6167.</p> <p><u>Assessment:</u> <i>Closed for other reasons</i></p>	
<p>2014-7193-15</p> <p>Ensure that, in the buffer zone, felled declining trees other than those completely destroyed by forest fires, are sampled and tested for the presence of PWN as required by the</p>	<p>This recommendation is based on the conclusion in Section 5.3.2 and related finding in the Section of the audit report that: a) significant number of samples were consisted of only one declining tree even if more declined trees were available for sampling, b) usually one or two trees constituted composed samples, and c) on some cases bark was not removed before sampling.</p> <p>In its response ICNF stated that it follows the monitoring measures (identification and</p>	Closed due to action taken

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
<p>last section of point 3(b) of Annex II to Commission Decision 2012/535/EU. This implies notably that the sampling procedure implemented is appropriate to detect PWN and that the number of trees sampled is adequate, in line with the EFSA technical assistance on sampling statistics to be applied pursuant to Decision 2012/535/EU.</p>	<p>sampling) for host conifers with symptoms of decline. However, ICNF allows for exception from the measures for trees that are completely destroyed by forest fires. ICNF stressed that it pays particular attention to implementation of sampling plan in buffer zone, in order to comply EFSA's scheme, in order to guarantee that the sampling is capable to confirm, with a confidence level of 99%, that the level of presence of PWN in such trees is lower than 0.02%.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in November 2014. During the Task Force visit the Portuguese authorities presented results of measures taken in 2014 and demonstrated that the sampling level exceeded the minimum required by EU legislation.</p> <p><u>During the 2016 GFA</u> ICNF stated that the sampling procedure and sampling carried out meet the sampling level required by the EU Decision. The decision requires Portugal to sample all declining trees (except these completely destroyed) identified in the buffer zone as indicated in table 5/7 of the EFSA document. Thus the sampling and the procedure are in compliance with the EFSA sampling scheme.</p> <p>ICNF presented data illustrating that ICNF samples even more trees than is required under the EFSA scheme. This was the result of decision to sample additional 5% of 'completely burned' trees.</p> <p>In 2014 ICNF sampled 17,732 dead or in decline trees of which only declining trees amounted to 13,467 trees (the difference between 96,094 and 82,627). In the period between 1 April 2014 and 31 March 2015 ICNF sampled 16,942 dead or in decline trees of which 12,453 were declining trees (the difference between 94,887 and 82,434).</p> <p>In addition ICNF presented similar information covering respective periods of 2015 and 2016 showing that in 2015 ICNF sampled 22,751 trees while the number of dead or declining trees, other than completely destroyed by fire, amounted to 21,769 (the difference between 230,421 and 208,652). In the period between 1 April 2015 and 31 March 2016 ICNF sampled 21,863</p>	

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for <i>Bursaphelenchus xylophilus</i>		
Recommendation	Basis for assessment	Current Status
	<p>dead or in decline trees of which 18,268 trees were in decline.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation had been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2014-7193-16</p> <p>Ensure that, in the buffer zone, susceptible wood from the felling of susceptible plants is managed and treated as required by point 3(c) of Annex II to Commission Decision 2012/535/EU. This applies notably to declining trees felled by private owners.</p>	<p>This recommendation is based on the conclusion in Section 5.3.2 and related findings in the Sections 5.1 and 5.3 of the audit report that a large proportion of the trees felled was still on-site, untreated. Private owners could use them for own use and bedding for animals. Cut wood logs stayed in the site without being chipped.</p> <p>In its response ICNF stated that timber from the felling of trees identified as showing symptoms of decline would be destroyed appropriately.</p> <p>ICNF stressed that national legislation (Article 6(3) of Decree-Law No 95/2011 of 8 August 2011) provides for exemption from felling declaration for up to three host conifers or the equivalent of one tonne intended exclusively for own use and provided that, cumulatively, the felling takes place between 1 November and 1 April.</p> <p>ICNF underlined that the exemption does not affect the plant health protection measures applicable to the felling of conifers and destruction of the resulting waste laid down in Annex I to Decree-Law No 95/2011 of 8 August 2011. Moreover, there is no exemption from the requirement to declare any transport of the resulting timber. The revised version of the Decree will not contain the exemption.</p> <p>This issue was proposed to be addressed in the context of the Task Force activities in</p>	Closed due to action taken

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
	<p>November 2014.</p> <p><u>During the 2016 GFA</u> DSSA stated that measures undertaken to address this recommendation are common with measures for recommendation No. 2014-7193-3 as both recommendations concern the same principal issue.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>This recommendation concerned the same issues as recommendation No. 2014-7193-3 and actions proposed by the competent authorities were identical, therefore this recommendation is assessed as addressed, similarly to recommendation No. 2014-7193-3.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2014-7193-17</p> <p>Ensure enforcement of the requirements, laid down in Article 10(1) and section 1 of Annex III of Commission Decision 2012/535/EU for movement of susceptible wood and bark, including WPM from the infested zone into the buffer zone.</p>	<p>This recommendation is based on the conclusion in Section 5.2.2 and related finding in the Section of the audit report that operators were not aware of the obligatory treatment of wood packaging materials (WPM) before moving them from infested zone to buffer zone.</p> <p>In its response DGAV undertook to continue, together with DRAP, to supervise heat treatment facilities.</p> <p>ICNF stated that it will continue with regular controls and monitoring of industrial plants, located in demarcated area, that process and store conifer wood, receive and market the conifer timber. These controls would be risk based, taking into account the potential for the spread of PWN, shipments origin, the level of vulnerability of the materials and the history of operators' compliance. Staff carrying out controls will complete specific control form.</p> <p>While completing its general programme of inspection activities, GNR will pay special attention to movements of susceptible WPM, wood or bark from the infested zone to buffer zone.</p>	Closed due to action taken

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
	<p>In addition, the inspection activities planned by the ASAE will primarily target establishments: a) located in the buffer zone and receiving susceptible materials from the infested zone, and b) located in the infested zone and dispatching goods to the buffer zone.</p> <p>ASAE expressed intention to use an IT tool (Gestao Integrada de Contraordenacoes - GIC) for integrated management of infringements. The tool intended to reduce the reaction time by ASAE. ASAE expected that the tool would increase the level of draft decisions to be prepared, shorten procedures and increase revenue from imposed fines. It should also have positive effect on follow-up on actions in case of non-compliance.</p> <p><u>D uring the 2016 GFA DGAV</u> stated that, together with DRAP, it supervises all authorized heat treatment facilities and plants authorized to produce and mark WPM. In 2015 officials carried out 392 inspections and took 604 samples from those facilities.</p> <p>ICNF stated that it carries out regular controls in sawmills. In 2015 the ICNF officials carried out 169 controls. Following national legislation all newly produced and repaired coniferous WPM within the demarcated area must be treated before movement regardless of its destination. During controls the ICNF officials regularly verify the compliance with this requirement at premises of operators located in the infested zone and in the buffer zone.</p> <p>GNR stated that it organises monthly road checks targeting the movement of WPM from the infested zone to the buffer zone. GNR reports monthly the result of these checks to the Commission. In 2015 GNR carried out 21,161 checks on vehicles with susceptible material. From all checked vehicles 1,743 were destined to the buffer zone of which 1,381 carried WPM. In two vehicles GNR detected non-compliant WPM.</p> <p>GNR explained that when non-compliant WPM is detected during road checks, the operator is obliged to return to the place of loading or to a location nearby the location of the interception for repackaging and destruction or treatment in an authorized heat treatment facility. Moreover non-compliances on movement identified by GNR are communicated to ASAE for</p>	

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
	<p>administrative measures including application of sanctions.</p> <p>ASAE stated that it carries out controls on economic operators using coniferous WPM in their trade. ASAE targets operators located in the buffer zone, and operators from the infested zone dispatching consignments to the buffer zone and/or other Member States. When targeting operators ASAE uses the EUROPHYT notifications and information on non-compliant operators identified by GNR during road checks. In 2015 ASAE carried out controls in 377 establishments out of which 73 were in the buffer zone. This resulted in detection of 26 breaches in 22 operators from the infested zone; however, none related to the movement of non-treated WPM from the infested zone to the buffer zone.</p> <p>Regarding the management of infringement procedures by ASAE, priority is being given to PWN. In 2015 ASAE initiated 18 administrative procedures and 6 criminal prosecutions. Other control bodies (GNR, ICNF and DGAV) initiated 225 procedures for which ASAE has instructional competence.</p> <p>In the period of 2013-2015, ASAE ruled in 94 cases and applied fines amounted to 134,100.00€, of which 60% only in 2015. In the first quarter of 2016 ASAE ruled in 21 cases and applied fines amounting to 103,150.00€.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
2014-7193-18	This recommendation is based on the conclusion in Section 5.4 and related conclusion in the	Closed due to action

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for <i>Bursaphelenchus xylophilus</i>		
Recommendation	Basis for assessment	Current Status
<p>Ensure that the controls of the movement of susceptible wood and bark are done frequently and located according to risk as required by Article 11(1) of Commission Decision 2012/535/EU. In particular, the checks at establishments in the buffer zone receiving susceptible wood and bark, including WPM and at the establishments in the infested zone sending this material out of this zone should take into account past non-compliance and be of an appropriate frequency to achieve an acceptable level of compliance.</p>	<p>Section of the audit report that checks on movement performed by the different bodies are not targeted according to the history of non-compliance; these found as non-compliant by one authority or notified in EUROPHYT are not targeted by ASAE inspections.</p> <p>In its response ASAE stated that factors like: a) the type and nature of non-compliances found during monitoring activities (mainly in buffer zone and during movement checks), and b) places at increased risk are identified, accordingly targeted and prioritised. ASAE includes all these places in its inspection and monitoring plan.</p> <p>ASAE declared that it will also take into account and use the following factors: a) EUROPHYT notification, b) results of road checks reports, c) results of checks on establishments from buffer zone, and d) zones or regions with the highest concentrations of factories producing goods which use packaging materials.</p> <p>ASAE undertook to address this issue as a priority and establish a risk based matrix related to non-compliance rate of the concerned operators.</p> <p>This issue was proposed to be followed-up during a future audit on PWN. The Portuguese authorities confirmed development and publication (July 2015) of the Manual of Procedures for organisation of official checks on the movement of wood and wood packaging materials susceptible to PWN. Officials in charge of these controls received practical training in this respect. The ASAE IT tool for inspections contains a list of operators dispatching and receiving wood material together with their history of compliance.</p> <p><u>During the 2016 GFA</u> ASAE presented data concerning the number of controls carried out in 2015 in establishments located in the buffer (“2015 – ZT”); and establishments located in the infested zone (“2015-ZI”). ASAE underlined that it gave priority to operators that had non-compliances identified by GNR and notified by EUROPHYT. According to the data presented ASAE controlled 304 operators acting in the buffer zone and 73 acting in the infested zone.</p>	<p>taken</p>

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
	<p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been followed-up on-the-spot during audit DG(SANTE)/2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	
<p>2014-7193-19</p> <p>Ensure that the controls of the movement of susceptible wood and bark include a documentary, an identity and, in the case of non-compliance or a suspicion of non-compliance, a plant health check which includes testing for the presence of PWN, as required by Article 11(1) of Commission Decision 2012/535/EU.</p>	<p>This recommendation is based on the finding in Section 5.4.1 and related conclusion in the Section 5.4 of the audit report that ASAE officials carry out checks that often miss one of or the entire range of control practices, namely documentary, identity and/or tests for the presence of PWN.</p> <p>In its response the competent authority stated that whenever GNR identifies the absence of international standards for phytosanitary measures - ISPM, 15 mark or the absence of passport during road-checks, it applies the rules laid down in Article 12 of the Commission Decision 2012/535/EU.</p> <p>ASAE expressed the opinion that there is no significant benefit to collecting samples of such material since the measures to be taken do not depend on the tests results.</p> <p>Concerning the ICNF and ASAE checks carried out in sawmills and commercial establishments in buffer zone, a programme of sample collection will be sent up for situations with a suspicion of non-compliance. The program will be initiated in December 2014 by the ICNF and in March 2015 by the ASAE.</p> <p>This issue was proposed to be followed-up during a future audit on PWN. The Portuguese authorities confirmed publication (July 2015) of the Manual of Procedures for organisation of official checks on the movement of wood and wood packaging materials susceptible to PWN.</p>	Closed due to action taken

Audit 2014-7193 of 18 March 2014 in order to evaluate the situation and control for Bursaphelenchus xylophilus		
Recommendation	Basis for assessment	Current Status
	<p>The checks foresee entire range of control practices to identify the presence of PWN. Officials in charge of these controls received practical training in this respect.</p> <p><u>During the 2016 GFA</u> ASAE stated that the Manual of Procedures for organization of official checks on the movement of wood and WPM, includes sampling collection for situations of suspicion of non-compliance in the buffer zone. The ASAE operations orders include also such instruction.</p> <p>In establishments located in the buffer zone, in 2015, the ASAE inspectors found no cases of non-compliance that would require sampling according to the Manual. For that reason ASAE did not request cooperation with DGAV. A similar situation applied to the ICNF controls carried out in 2015 in sawmills located in the buffer zone.</p> <p><u>In the context of the 2019 GFA:</u></p> <p>Corrective measures to address this recommendation have been verified on-the-spot during audit 2017-6167. The audit report concluded that competent authorities addressed this recommendation.</p> <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

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	Current Status
2016-8749-2	This recommendation is based on findings No.: 16, 17, 32, 45 and 54 and associated	In Progress

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	Current Status
<p>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:</p> <p>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.</p> <p>The results of controls are adequately reported by CBs, as required by Article 5(2)(e) of Regulation (EC) No 882/2004;</p> <p>All CBs are adequately staffed to carry out effective controls, as required by Article 5(2)(b) of Regulation (EC) No 882/2004;</p> <p>Recommendation is based on conclusions No 18, 49 and 55</p> <p>Associated findings No 16, 17, 32,</p>	<p>conclusions No.: 18, 49 and 55 of the audit report that there is no a 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 bodies nor verifies how control plans are designed and implemented by CBs.</p> <p>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.</p> <p>In its response 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.</p> <p>In its additional correspondence (July and September 2017) 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.</p> <p>Moreover IVV,I.P. 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.</p> <p><u>In the context of the 2019 GFA</u>, IVV stated that:</p> <ul style="list-style-type: none"> - 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 used only accredited laboratories, 	

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	Current Status
45 and 54	<p>- 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 specialistic 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.</p> <p>- 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.</p> <p>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.</p> <p><i>Assessment: In progress.</i></p> <p><i>To demonstrate that actions to address this recommendation are completed IVV should provide the following:</i></p> <p><i>1) Copies of legislative acts once they have been published/adopted.</i></p> <p><i>2) The results of the IVV assessment of the information submitted by CBs (annual inspection planning and reports on the results of the control activities carried out by CBs).</i></p>	
<p>2016-8749-3</p> <p>Ensure that a minimum number of operators to be subjected to the annual verification is selected, as required by Article 25(1) of</p>	<p>This recommendation is based on finding No.: 21 and associated conclusion No.: 29 of the audit report that 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.</p>	In Progress

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	Current Status
<p>Regulation (EC) No 607/2009, and that such verification includes bottlers of PDO/PGI wines located outside Portugal.</p> <p>Recommendation is based on conclusion No 29</p> <p>Associated finding No 21</p>	<p>In its response 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'.</p> <p>In its additional correspondence (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.</p> <p><u>In the context of the 2019 GFA IVV stated the following:</u></p> <ul style="list-style-type: none"> - 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 is 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 these 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 waits for the adopted version to make these changes. <p><i>Assessment: In progress</i></p> <p><i>To demonstrate that actions to address this recommendation are completed IVV should provide a copy of the Technical Guidance issued by the CA and evidence that CBs are obliged</i></p>	

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	Current Status
	<p><i>to follow it indicating where in the Guide IVV the minimum number of operators to be controlled annually by CBs is defined, including bottlers of PDO/PGI wines located outside Portugal.</i></p>	
<p>2016-8749-4</p> <p>Ensure that CBs carry out properly the tasks delegated to them, and in particular that:</p> <p>The annual verification is conducted by CBs in accordance with the Product Specification, as required by Article 25(1) of Regulation (EC) No 607/2009, including the processing of wine, as required by Article 5(6)(c) of the Ministerial Decree 22522/2006;</p> <p>All the conditions set out in the Product Specification are verified by CBs, as required by Article 25(1)(c) and 25(4)(b) of Regulation (EC) No 607/2009;</p> <p>Controls include documented traceability checks of the certified</p>	<p>This recommendation is based on findings No.: 22, 39, 40, 45, 47 and 48 and associated conclusions No.: 28, 49, 50 and 51 of the audit report that there is no system in place to verify how CBs fulfil tasks delegated to them by IVV. As a consequence IVV: a) cannot detect failures of the CBs' controls, b) does not evaluate the CBs' control plans thus it cannot ensure that CBs verify all conditions set out in the Product Specification, c) is not aware of the results of CBs controls, and d) cannot ensure that, in case of non-compliance, CBs apply harmonised measures across the country.</p> <p>In its response IVV stated that IVV and IPAC would check if controls by CBs comply both with ISO 17065 and with the control plans and other procedures submitted IVV.</p> <p>IVV intended to verify the compliance with the CBs' planned arrangement for official controls, in particular, to check if plans for controls are followed and CBs verify whether operators comply with products specifications at every stage of the production process.</p> <p>In its additional correspondence (September 2017) IVV stated that the Technical Guidelines - proposed as one of the corrective actions to address recommendation 2016-8749-2 would also aim at addressing this recommendation.</p> <p><u>In the context of the 2019 GFA</u>, IVV stated that:</p> <p>- For the arrangement on verification how CBs carry out the tasks delegated to them see response to recommendation No. 2016-8749-2.</p>	<p>Closed due to action taken</p>

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	Current Status
<p>wines, as required by Article 3.3 (c) of Ministerial Order No 22522/2006. Recommendation is based on conclusions No 28, 49, 50 and 51 Associated findings No 22, 39, 40, 45, 47 and 48</p>	<ul style="list-style-type: none"> - To have a legal ground for requesting the application of the Technical Guidance IVV must wait for the publication of amended Decrees mentioned in recommendation No 2016-8749-2. Despite of the above, the current version of the Guidance requires the traceability checks. - Notwithstanding the absence of the Guidance, traceability checks are already included in official controls by CBs. The Porto and Douro Institute use own internal system, while all other entities use the system of IVV (System ISVV, that holds information on all operators, vineyards, etc.). The traceability checks are computer-based and each CB has full access to the system for wine produced in its region. - Each CB must communicate monthly to IVV information on all certified products: e.g.: brands, volumes produced and type of products. Similarly, Douro producers have to inform the IVV-DP of the certified volumes. - Operators pay a fee to certification bodies, and the stamps on the bottles are determined by IVV; these are also published in the O.J. so allow for material verification during market controls. <p>In its response to the Draft Country profile (June 2019), IVV presented evidence that CBs carry out traceability checks on the PDO/PGI wine; verification of this activity is recorded in the IVV audit/inspection reports on official controls by CBs.</p> <p><i>Assessment: Closed due to action taken.</i></p>	
<p>2016-8749-5 Ensure that controls are undertaken on the market to guarantee that Portugal may stop the unlawful use of any PDO/PGI wines indicated in</p>	<p>This recommendation is based on finding No.: 27 and associated conclusion No.: 30 of the audit report that the control system in place focuses on domestic Portuguese wine producers therefore cannot stop the unlawful use of Portuguese wines. Nonetheless, the system lacks planned controls on the market. As a consequence it cannot prevent unlawful use of registered wines produced in other EU MS.</p>	<p>Closed due to action taken</p>

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	Current Status
<p>Regulation (EU) 1308/2013, as required by Article 90(1) of Regulation (EU) No 1306/2013. Recommendations is based on Conclusion No 30 Associated finding No 27</p>	<p>In its response IVV clarified that IVV coordinates the monitoring of wine certification up to the point where the product is bottled, while ASAE is responsible for inspection of wines on the market, regardless the wine is of Portuguese or imported origin.</p> <p>In order to prevent unlawful use of the wine sector products ASAE would modify its National Food Inspection Plan and specific operational plans by intensifying controls on PDO and PGI wines.</p> <p><u>In the context of the 2019 GFA</u> the competent authorities stated that:</p> <ul style="list-style-type: none"> - IVV and ASAE concluded a <i>Memorandum of Understanding</i> to include controls on protected names wines produced in other MS. - Following an assessment of available data IVV and ASAE concluded that wines from other MS represent marginal volume of the sales on the Portuguese market. Depending on the location it ranges from 0 to app. 2% of wines present on the market. moreover, foreign wines are mostly present in small quantities and usually in the HORECA sector, contrary to the volume sale in shops and supermarkets. - ASAE introduced two-level controls: at producers and at product level. In 2017 and 2018 ASAE examined 108 types of wines of Portuguese origin and 4 types of wines from other countries. Identified non-compliances concerned labelling issues leading to misleading information. ASAE initiated 8 criminal proceedings concerning Portuguese wines. - ASAE underlined that during official controls inspectors take photos of labels. In case of doubts they contact the technical department and consult. Moreover, IVV and ASAE established two contact points for instant contact. <p><u>Assessment:</u> <i>Closed due to action taken.</i></p>	

3. OVERVIEW OF MORE RECENT AUDITS

In addition to the recommendations which are dealt with in chapters 2.B.1 to 2.B.12, the reports of a further 6 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.

The overall conclusions of the audits are set out below.

Audit DG(SANTE)/2017-6167 to evaluate the situation and controls for *Bursaphelenchus Xylophilus* (PWN)

The audit report concluded that since the previous audit carried out in 2014, the system for the containment of PWN in continental Portugal has been amended and was found to be largely in line with the requirements of Decision 2012/535/EU and the Task Force technical advice. A number of outstanding recommendations from the previous audit have been satisfactorily addressed. However, the system does not currently ensure that PWN-infested trees in parts of the infested zone adjacent to the buffer zone are timely felled and disposed of in order to mitigate risks of PWN spreading into the buffer zone by vector dispersal. Although the system aims at implementing containment measures in the buffer zone in line with EU requirements, two major constraints prevented the competent authority from reaching this objective:

- the serious drought and forest fires which affected continental Portugal in 2016 and generated 2.6 times more than the average of dead or declining trees in the buffer zone,
- a four-month interruption of contracts with felling operators operating in private areas of the buffer zone.

In spite of this, from 1 April 2016 to 31 March 2017, the competent authorities felled 1.5 times more trees than in an average year. However, as at 1 April 2017, some 350,000 trees, most of which were severely affected by fire, still had to be felled and disposed of. The competent authorities have taken measures to reduce as much as possible contractual delays and have prioritised the felling of new declining trees, while the backlog is planned to be eliminated by the end of 2017.

Audit DG(SANTE)/2018-6376 to evaluate the system in place for official controls regarding food contact materials

The audit report concluded that a central competent authority and a national reference laboratory responsible for food contact materials have been designated and the competent authorities are largely aware of the business operators involved in the food contact material chain. Official controls are supported by procedures and checklists which should allow the inspectors to fulfil the requirement for a formal verification of declarations of compliance. Additionally, a system of national enforcement measures is in place. All these elements provide a good basis for the implementation of official controls. Although the inspectors are able to verify the presence of declarations of compliance and, to a certain extent, to assess the completeness of those declarations they are not trained or adequately supported to carry out a verification of the business operator's risk assessment, which does not allow the CAs to verify that FCM fulfil all of the legal requirements. Thus, products which do not comply with the legislation or that present a potential health risk could be placed on the market.

Audit DG(SANTE)/2018-6428 to evaluate the official control system in place concerning the implementation of EU legal requirements on food improvement agents

The audit report concluded that the system of official controls in place covering food improvement agents - including import, marketing and their use- is overall fit for purpose, and includes appropriate provisions for action in case of non-compliance. Both competent authorities avail at central level of dedicated staff which provide support to inspection units, while the staff in these units and which perform the official controls, are knowledgeable. The two competent authorities combined cover food improvement agents in all types of food in official controls, either by documentary checks or sampling, even if not all food categories are included in the sampling plan. However, the present laboratory capacity is currently limited to analysis in beverages, but this limitation is being addressed.

Audit DG(SANTE)/2018-6329 to evaluate the official controls on consignments in transit.

The report concludes that there is an adequate framework of official controls in place, implemented by a well-organized and trained competent authority and supported by detailed guidance documents and information technology systems which contribute to consistent implementation of controls on transited goods. The system of controls and the implementation thereof at the entry BIPs is sufficient to ensure that only eligible consignments are permitted to transit the EU via Portugal. Appropriate actions were undertaken by the competent authority to ensure the separate storage of non-conforming products and guarantee their traceability to and from Customs' warehouses. Those actions are sufficient to prevent free circulation of non-conforming products on the EU market. With regard to the suitability of facilities for conduct of official controls on transiting consignments, in general these complied with legal requirements.

Audit DG(SANTE)/2018-6344 to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products

The objective of the audit was to evaluate the monitoring of residues of veterinary medicinal products, pesticides and contaminants in live animals and animal products and the effectiveness of official controls on the use of veterinary medicinal products in food producing animals, in the context of preventing, eliminating, or reducing to acceptable levels risks to humans and animals either directly or through the environment. The audit focused on the legal and administrative measures in place to implement the relevant EU requirements and on the performance of the competent authorities in meeting these requirements. It is concluded that whilst many aspects of the planning and implementation of the residue monitoring plan, laboratory performance and follow-up activities concerning noncompliant results are in line with EU legislation, the imposition of financial management measures and delays in authorising financial expenditure have inadvertently contributed to substantial under-implementation of successive years' plans from 2015 to date. Furthermore late procurement of analytical services and laboratory reagents have delayed analyses being performed and weakened the effectiveness of follow-up of non-compliant results. Consequently residue monitoring of food in Portugal has not been as effective as it should have been in recent years, though, at least for 2018, procurement of services has commenced in a timelier manner.

As regards equine identification – a particularly weak point in the 2011 audit - Portugal has implemented Commission Implementing Regulation (EU) No 2015/262 in accordance with EU rules. Whilst official controls on the distribution and use of veterinary medicinal products do take place and adhere to centrally-issued instructions, the effectiveness of such controls is questionable given the audit team's identification – albeit on a single farm - of incorrectly completed medicines records and subsequent food-chain information documents, which had not been detected by the competent authority

The objectives of the audit were to evaluate the implementation of Commission Decision 2012/535/EU on emergency measures to prevent the spread of *Bursaphelenchus xylophilus* (Pine wood nematode - PWN); the state-of-play concerning the specific action plan against PWN in the 2017 fire affected areas of the Buffer Zone and the action taken to address the recommendations of the previous audit on this topic (DG(SANTE)2017-6167).

The audit found that the organisation of the survey and felling programmes has been strengthened since the previous audit. The annual survey and felling programme in the infested area and Buffer Zone is being implemented, with emphasis on high-risk areas in the Buffer Zone and areas adjacent to it. According to official data, all trees identified with signs of decline (other than those affected by fire in 2017) in the 2017/2018 autumn/winter period were felled before 31 March 2018. All trees identified in the summer period had been felled by 31 October 2018. However, shortcomings in resources and the sampling methods used reduce the likelihood of the early detection of pinewood nematode in new areas.

The risk-based plan for the elimination of trees damaged by fire in 2017 is being implemented and overall the felling programme is progressing in line with what was planned and is necessary to ensure that all relevant trees are felled and removed within the timeline provided in Decision 2012/535/EU. Official checks are carried out to confirm compliance with the requirements for the movement of susceptible wood, wood packaging material and bark. The competent authority satisfactorily followed up the interceptions of bark that were notified by other Member States early in 2018, and have taken appropriate corrective action, which should ensure that the circumstances that gave rise to the interceptions are not repeated. The one outstanding recommendation of the previous report has been partially addressed

ANNEX I – ACRONYMS, ABBREVIATIONS, SPECIAL TERMS

ACRONYM	DESCRIPTION
ABP	Animal By-Products
APP	Animal Protection Plan
ASAE	Economic and Food Safety Authority
BIP	Border Inspection Post
BMEP	<i>Brucella melitensis</i> eradication programme
CB	Control Body
CP	Contingency plan
CVED	Common Veterinary Entry Document
DGADR	Directorate General for Agriculture and Rural Development
DGAV	Directorate General for Food and Veterinary
DGRM	Directorate General for Natural Resources
DG-SANTE	Directorate General for Health and Consumers – formerly DG SANCO
DIM	Division for Internationalization and Markets
DRADR	Directorate Regional of Agriculture and Rural Development
DRAP-AL	Portuguese Regional Agriculture Office of the Alentejo region
DRAP-ALG	Portuguese Regional Agriculture Office of the Algrave region
DRAP-C	Portuguese Regional Agriculture Office of the Centro region
DRAP-LVT	Portuguese Regional Agriculture Office of the Lisboa and Vale do Tejo region
DRAP-N	Portuguese Regional Agriculture Office of the Norte region
DSAVR	Regional Food and Veterinary Directorate
DSAVR-C	Regional Food and Veterinary Directorate of the Centro
DSAVR-N	Regional Food and Veterinary Directorate of the Norte region
DSECI	Directorate of Strategy, Communication and Internationalization
DSNA	Directorate for Nutrition and Feed
DSPA	Directorate for Animal Protection
DSSA	Directorate for Food Safety
DSAVR	Regional Food and Veterinary Directorate
DSVR-C	Regional Food and Veterinary Directorate of the Centro region
DSVR-N	Regional Food and Veterinary Directorate of the Norte region
EFSA	European Food Safety Authority
EURL	European Union Reference Laboratory
FBO	Food Business Operator
FCM	Food Contact Materials
FMD	Foot and Mouth Disease
FNAO	Food of non-Animal Origin
GFA	General Follow-up
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GNR	National Republican Guard
GPP	Policy and Planning Office
HACCP	Hazard Analysis and Critical Control Points
ICNF	Institute for the Nature and Forest Protection
IFAP	Financing Institute for Agriculture and Fisheries
IGAMAOT	General Inspection of the Ministry of Agriculture and Sea

ACRONYM	DESCRIPTION
IGAP	Institute Of Management And Public Administration
INIAV	National Agriculture and Veterinary Research Institute
INRB / LNIV	National Institute of Biological Resources / National Veterinary Research Laboratory
INSA	National Health Institute
IPAC	Portuguese Accreditation Institute
IPMA	Portuguese Institute for Sea and Atmosphere
ISPM	International Standards For Phytosanitary Measures
LBM	Live bivalve molluscs
LVU	Local veterinary unit
MRL	Maximum Residue Level
NRL	National Reference Laboratory
OPP	Livestock producers organisation
PACE	Plan for Approval and Control of Establishments
PAH	Polycyclic aromatic hydrocarbons
PAP	Processed animal proteins
PCB	Polychlorinated biphenyles
PCOL	Plan for Official Control of Raw Milk
PHBIP	Plant Health Border Inspection Post
PIP	Priority Intervention Plan
PISA.NET	Animal health database
PNCA	National Sampling Plan
PNCC	National Control Plan for Contaminants
PNCR	National Control Plan for Residues
PNCUM	National Control Plan for the Use of Medicines
PPCP	Primary Production Control Plan
PPP	Plant Protection Product
PWN	Pine Wood Nematode (<i>lat. Bursaphelenchus xylophilus</i>)
RASFF	Rapid Alert System for Food and Feed
RCA	Regional Competent Authority
SDA	Island authority
SIPACE	Official controls database
SNCP	Salmonella National Control Programme
SNIRA	National System for the Identification and Registration of Animals
SNIRAB	National System for the Identification and Registration of Bovine Animals
TRACES	Traceability Expert System
WPM	Wood packaging materials