In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This report describes the outcome of a Directorate-General for Health and Food Safety audit in Portugal carried out from 15 to 26 October 2018 as part of its programme of audits in Member States.

The objective of the audit was to verify the organisation and functioning of Portuguese control systems, which are implemented to verify that fishery products from tuna species are produced in compliance with the relevant European Union requirements in respect of food hygiene, additives and labelling.

The report concludes that in Portugal, the two designated competent authorities responsible for the official controls of fishery products have developed a coordinated control system based on the relevant provisions of European Union legislation, which is supported by accredited laboratories. This control system, which covers the entire fishery products production chain including tuna species, is in general adequately implemented.

However, some shortcomings were identified such as the difficulties in the effective follow up of the correction of deficiencies identified during controls, the adherence to the established frequency of controls, the implementation of the approval system and the absence of testing for inorganic tin in canned fishery products. The authorities have recently introduced measures to rectify the failings in the follow-up of controls; however it is too early to assess their effectiveness. Fishery products that included Atlantic Bluefin tuna were of good to excellent standard as regards freshness.

The report contains recommendations to the Portuguese competent authorities aimed at rectifying identified shortcomings and enhancing the control system in place.
Table of Contents

1 Introduction ....................................................................................................................................1
2 Objective and scope .......................................................................................................................1
3 Legal Basis .....................................................................................................................................2
4 Background ....................................................................................................................................2
  4.1 General Background .............................................................................................................2
  4.2 Production and Trade Information ..........................................................................................3
  4.3 Rapid Alert System for Food and Feed (RASFF) Notifications and Other National Notifications ..........................................................................................................................3
5 Findings and Conclusions ..............................................................................................................4
  5.1 Competent Authorities ...........................................................................................................4
  5.2 Registration/Approval of Food Business Operators' Establishments Legal requirements .....8
  5.3 Official Controls ......................................................................................................................9
    5.3.1 Official control of production and placing in the market ................................................9
    5.3.2 Official control of the products ......................................................................................16
  5.4 Follow-up of rasff notifications .............................................................................................19
  5.5 Laboratories ...........................................................................................................................19
6 Overall Conclusions .....................................................................................................................21
7 Closing Meeting ...........................................................................................................................21
8 Recommendations .........................................................................................................................21
# Abbreviations and Definitions Used in This Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAC-FF</td>
<td>Administrative Assistance and Cooperation information technology system for Food Fraud</td>
</tr>
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<td>ASAE</td>
<td>Economic and Food Safety Authority</td>
</tr>
<tr>
<td>BIP</td>
<td>Border Inspection Post</td>
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<tr>
<td>CA(s)</td>
<td>Competent Authority(ies)</td>
</tr>
<tr>
<td>DGAV</td>
<td>Directorate General for Food and Veterinary</td>
</tr>
<tr>
<td>DGRM</td>
<td>Directorate General for Natural Resources, Safety and Maritime Services</td>
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<tr>
<td>DG SANTE</td>
<td>Directorate-General for Health and Food Safety</td>
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<tr>
<td>DRA</td>
<td>Regional Directorate for Agriculture</td>
</tr>
<tr>
<td>DSAVR</td>
<td>Regional Food and Veterinary Service Directorates of DGAV</td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>FBO</td>
<td>Food Business Operator</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analyses and Critical Control Point</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<tr>
<td>IPMA</td>
<td>Portuguese Institute of the Sea and Atmosphere</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>PACE</td>
<td>Plan for the Approval and Control of Establishments 2018-2019 (DGAV)</td>
</tr>
<tr>
<td>PACE GA</td>
<td>Plan of Control of Establishments of Food of Animal Origin (PACE GA) (DGAV)</td>
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<tr>
<td>PCAPIF</td>
<td>Control Plans on BIPs (DGAV)</td>
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<tr>
<td>PCB</td>
<td>Polychlorinated Biphenylls</td>
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<tr>
<td>PCON</td>
<td>Control Plan for primary production vessels</td>
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<td>PIGA</td>
<td>Food Inspection Plan (DGAV)</td>
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<tr>
<td>PNCA</td>
<td>National Sampling Plan (ASAE)</td>
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<td>PNFA</td>
<td>National Food Inspection Plan (ASAE)</td>
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<tr>
<td>PT</td>
<td>Proficiency Testing Schemes</td>
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<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<tr>
<td>SIPACE</td>
<td>PACE information System</td>
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<td>UR</td>
<td>ASAEs Regional Units</td>
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</table>
1 INTRODUCTION

The audit took place in Portugal (mainland Portugal and the two autonomous Regions of Madeira and the Azores) from 15 to 26 October 2018 and was undertaken as part of the Directorate-General for Health and Food Safety (hereafter DG SANTE) audit programme.

The audit team comprised two auditors from DG SANTE. An opening meeting was held in Lisbon on 15 October 2018 with the competent authorities (CAs), the Directorate-General for Food and Veterinary (DGAV) and the Economic and Food Safety Authority (ASAE). At this meeting, the audit team confirmed the objective and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit.

2 OBJECTIVE AND SCOPE

The objective of the audit was to verify the organisation and functioning of Portuguese control systems, which are implemented to verify that fishery products from tuna species are produced in compliance with the relevant EU requirements (1,2) in respect of food hygiene, additives and labelling.

The audit focused on the general organisation and performance of the official control system operated by the CAs and covering the fishing, production, processing, distribution and the placing on the market (up to and excluding retail) of tuna fishery products (3). Particular attention was given to the ability of the systems and measures in place to effectively verify, and where necessary enforce, adherence by food business operators (FBOs) to the applicable EU health standards in respect of the production and placing on the EU market of fishery products. Accordingly, relevant aspects of the EU legislation mentioned in the Appendix I were used as a technical basis for the audit.

The scope of the audit included the following specific points:

- Relevant national legislation in force in addition to the applicable EU rules.
- The CAs organisation, competence and their performance.
- Implementation of the official controls covering the production chain of tuna fishery products, both of EU origin and imported into the EU, including the applicable traceability requirements. Particular attention was given to:
  - The official control of freezer and reefer vessels. It includes the different freezing methods used by FBOs and their compliance with the relevant EU rules and also the "dual use" of fish holds (fuel/fish).

(1) All legal references, which can be found in Appendix I, refer, where applicable, to the latest amended version.
(3) The audit covered the production chain of fishery products derived from the various tuna species in particular: vessels (fishing, freezer, reefer and factory vessels, as applicable), landing and first sale sites, imports of raw materials, wholesale markets, cold stores and processing establishments.
- The use of tuna fishery products which have been frozen in accordance with the requirements of Regulation (EC) No 853/2004, in particular the requirements of Chapter I(II)(7), of Section VIII, of Annex III to that Regulation (freezing in brine of whole fish intended for canning).
- The use of additives in tuna fishery products.
- RASFF (Rapid Alert System for Food and Feed) notifications on high levels of histamine in tuna fishery products (Portugal as origin and/or distributing country).

In pursuit of this objective, the audit team visited the following sites:

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY</th>
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<tbody>
<tr>
<td>Central level</td>
<td>2</td>
</tr>
<tr>
<td>Regional level</td>
<td>4</td>
</tr>
<tr>
<td>Border Inspection Post</td>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PRIMARY PRODUCTION</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Fishing vessels</td>
<td>5</td>
</tr>
<tr>
<td>Tuna farm</td>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>LANDING AND FIRST SALE SITES</th>
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<tbody>
<tr>
<td>Landing sites</td>
<td>1</td>
</tr>
<tr>
<td>Auction halls</td>
<td>1</td>
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</table>

<table>
<thead>
<tr>
<th>FACILITIES HANDLING FISHERY PRODUCTS</th>
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</thead>
<tbody>
<tr>
<td>Freezer vessels</td>
<td>1</td>
</tr>
<tr>
<td>Processing Plants</td>
<td>8</td>
</tr>
</tbody>
</table>

Representatives from the CAs accompanied the audit team during the whole audit.

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular, Article 45 of Regulation (EC) No 882/2004.

4 BACKGROUND

4.1 GENERAL BACKGROUND

This was the second audit in a series of audits to EU Member States (hereinafter – Member States) dedicated to obtain a clearer picture of the official controls over the tuna industry as a whole and to assess the organisation and functioning of control systems, implemented to verify that fishery products from tuna species are produced in compliance with the relevant EU requirements in respect of food hygiene, additives and labelling.
From 2016 up to the beginning of 2018, DG SANTE carried out eight audits to non-EU countries to evaluate the official controls over, and the certification of, fishery products derived from tuna species. During these audits DG SANTE identified and confirmed the occurrence of certain breaches of the EU food safety rules.

4.2 PRODUCTION AND TRADE INFORMATION

In 2017, the catches of tuna species in Portugal were 8236 tonnes (5153 tonnes in Madeira, 2052 tonnes in the Azores and 1032 tonnes in the mainland). In the Azores the landing of tuna increased during the first nine months of 2018 (7119 tonnes).

According to the Directorate General for Natural Resources, Safety and Maritime Services (DGRM) there are 1,841 registered primary production vessels that fish for tuna species. According to DGAV, there are 36 approved auction halls, 27 approved freezer vessels that may be fishing for tuna (none were reported to be using brine freezing) and 384 establishments dealing with fishery products of which 137 plants deal exclusively with fresh fish (all these establishments can potentially process tuna).

Based on the information provided by the CAs, in the last 24 months there were 56,513 tonnes of tuna species imported into Portugal mainly through Ponta Delgada (Azores), Porto, Lisbon and to a lesser extent Sines. The three main species imported were Skipjack (Katsuwonus Pelamis) (29,316 tonnes), Yellowfin tuna (Thunnus Albacares) (14,511 tonnes) and Bigeye tuna (Thunnus obesus) (6,677 tonnes). Of these species, 78% was processed tuna (CN Code 1604) and 22% not processed tuna (CN Codes 0302, 0303, 0304). 86% of the tuna received was frozen. The main third countries from which tuna was imported were China (12,214 tonnes), Ecuador (11,795 tonnes) and Mauritius (8,096 tonnes). This product was destined mainly for Portugal and Spain.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS AND OTHER NATIONAL NOTIFICATIONS

From 2015 to the end of the first semester of 2018 members of the RASFF network (4) issued 1,134 notifications on fishery products (EU wide). The table below shows the distribution of these RASFF notifications considering tuna products and histamine.

From that table one can see that since 2015 Portugal was involved in ten RASFF notifications of tuna products (eight notified by Portuguese authorities). One can also note that during the same period there was one RASFF notification concerning Portuguese tuna fishery products from Portugal. This alert, in 2017, was due to histamine levels above the regulatory limits (326 mg/kg ppm) in canned tuna in sunflower oil.

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(4) European Commission, EFSA, EFTA Surveillance Authority, EU member states, Iceland, Liechtenstein, Norway and Switzerland.
The number of RASFF notifications during the same period related to tuna not originating in Portugal rose to nine (four were related to histamine above the regulatory limits, three were caused by health certificates issues, one was due to absence of labelling and the last one was caused by rupture of the cold chain).

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements


Findings

Designated competent authorities and operational criteria

1. In mainland Portugal, the main competent authorities designated for the official controls of fishery products are the DGAV, within the Ministry of Agriculture, Forestry and Rural development and the ASAE, within the Ministry for Economy.

2. According to Decree-Law No 31/2012, DGAV is the authority responsible for the food safety system. That Decree indicates that DGAV is responsible for the definition and coordination of the strategies of promotion of food safety in collaboration with ASAE. In accordance with Articles 2 and 5 of Decree-Law No 113/2006, DGAV and ASAE are responsible for ensuring implementation and compliance with Regulation (EC) Nos 852/2004 and 853/2004 in the mainland.

describes the organisation of the official control systems and of the authorities (including the distribution of competencies).

4. In summary, and amongst other activities, DGAV is largely responsible for the official control plans covering food of animal origin (routine activities) and ASAE is responsible for inspections of FBOs on compliance with the food law and the monitoring of fishery products at retail level.

5. Central DGAV coordinates the implementation of the control plans, which is made by five Regional Food and Veterinary Service Directorates (DSAVR). Those regional services report directly to the central level of DGAV. DGAV also assists the corresponding services of the Autonomous Regions of the Azores and Madeira, to implement the various fishery products official control plans. The audit team visited three DSAVR.

6. To implement their control ASAE divided mainland Portugal into three organic units called Regional Units (URs): North UR, Centre UR and South UR.

7. The Autonomous Regions have their own structures with comparable responsibilities to those of DGAV (Regional Directorates for Agriculture (DRA) in Madeira and in the Azores) and ASAE (ARAE Madeira and IRAE Azores). The audit team visited DRAs in both Autonomous Regions.

8. Impartiality of all staff assigned to official controls is guaranteed by Law No 35/2014.

9. According to Decree-Law No 276/2007 (as last amended by Law No 114/2017), ASAE inspection personnel are bound to professional secrecy and confidentiality.

10. There are DGAV and ASAE "Plans for the prevention of corruption and related infringements".

11. The CAs have a network of laboratories with the adequate technical capability for testing official samples and suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.

12. DGAV official controls on fishery products are carried out by qualified inspectors that also have responsibilities in other sectors. The audit team was informed that a lack of staff resources was responsible for not being able to respect the planned frequency of inspections in one of the Regions (see paragraph 84).

13. ASAE has the powers for carrying out inspections in the official control of fishery products according to Decree-Law No 276/2007. The powers extend throughout the whole food chain including primary production, processing, manufacture, storage, distribution, transport and retail. These inspections are carried out by the Specialized Brigades.

14. DGAV staff carrying out official controls have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively.

15. According to Article 6 of Decree-Law No 276/2007, ASAE has the duty to cooperate with the different inspection services in accordance with their respective legal powers and competences, using the mechanisms that are most appropriate.
16. The audit team was provided with numerous examples of adequate cooperation between the different CAs. In 2016, following the increased RASFF notifications at EU level related to histamine in fresh tuna products and the fraudulent use of additives, DGAV distributed the available information to all the Regional Coordinators including the autonomous Regions and to ASAE.

17. Internal audits are performed by a specific audit unit at DGAV central level. A description of the system is available in the country profile. The annual programme of audits is available in the DGAV website. In the context of the multi-annual audit cycle, the control system over fishery products was last audited in 2014. The audit team was informed that in 2019, audits are again planned for the fishery sector in the Regional Services under the Plan for the Approval and Control of Establishments 2018-2019 (PACE), as part of the next audit cycle.

Delegation of specific task related to official controls

18. Specific tasks related to official controls of fishery products are not delegated to other authorities or control bodies.

Training of staff performing official controls

19. DGAV provided information of training undertaken by veterinary staff in 2017. All the training was imparted by DG SANTE (participation included e-learning) and covered areas referred to in Annex II, Chapter I of Regulation (EC) No 882/2004.

20. ASAE provided information on the training undergone by members of the Specialised Brigades. The internal training in 2017 was mainly related to: a) acquiring legal and technical knowledge in all the areas covered during inspections including fishery products and aquaculture and b) ASAE Inspection Plan general knowledge. External training was mostly provided by DGAV and in 2017, was not specific on fishery products.

21. The audit team noted that the vast majority of staff met during the audit and who are involved in the implementation of the official control of fishery products, was adequately aware of the applicable EU requirements.

Transparency and confidentiality

22. DGAV and ASAE ensure transparency by publishing the control plans and results on their web and intranet.

Documented control procedures

23. DGAV has developed National Control Plans covering all stages in the fish production chain including primary production vessels (PCON) and approved food establishments (PACE) namely freezer/factory vessels, auction halls, whole sale markets, and establishments processing fishery products including cold stores. These plans are described under point 5.3.1 of this report.

24. To implement the PCON, there is a checklist outlining the requirements to be checked during the inspections. This checklist covers the requirements of Regulation (EC) No
854/2004 including general hygiene requirements, landing operations and transport hygiene.

25. To implement the PACE there are comprehensive general and specific checklists mainly covering the requirements of Regulation (EC) Nos 852/2004 and 853/2004 available in DGAV intranet that will allow the performance of harmonised inspections.

26. DGAV avails of the database "PACE Information System" (SIPACE). It is stored in this database the reports of official controls and other documents like the establishment records of non-compliances and the sampling and analyses results. The competent authority informed the audit team that SIPACE will automatically highlight when the next official control is due in an establishment.

27. The audit team noted that DGAV have issued guides including a "Guide of good hygienic practices for fresh fish" and "Fishery products vessels and hygiene".

28. Recently in Madeira, DRA has issued instructions to the FBOs with the requirement that documents accompanying the fishery products must specify the type of freezing procedure used, e.g. whether the fish was frozen in brine or not. The audit team learned that many customers in a Member State are requesting information on the freezing method following numerous RASFF notifications in 2016 related to tuna frozen in brine.

29. ASAE at central level issues specific Operation Orders describing procedures and legal basis to conduct "Proactive" and "Reactive" (i.e unplanned, see paragraph 55) official controls.

30. In order to harmonise the inspections, ASAE has issued "Technical Sheets of Inspection", these are specific checklists for the different fishery products establishments inspected mainly covering Regulation (EC) Nos 852/2004 and 853/2004.

**Control activities, methods and techniques**

31. Official controls are carried out using appropriate methods and techniques such as audit, inspection, sampling and analyses.

**Enforcement measures**

32. DGAV and ASAE have a sanction regime applicable to infringements of Regulations (EC) Nos 852/2004 and 853/2004. This instrument is provided by Decree-Law No 113/2006 and includes economic sanctions, withdrawing of approvals/licences, prohibition to place products on the market and closure of establishments.

33. PACE describes the measures to be taken in the case of non-compliances being identified during inspections to establishments.

34. DGAV has issued Circular No 13/DSSA/2018 last April 2018 in relation to the measures to take in the case of non-compliances identified under PACE aiming at increasing the effectiveness of the official control systems. It provides for more stringent actions to be taken against the FBO if, during official controls, non-compliances were detected and the FBO failed to correct them. Additional official verification visits are to take place if the non-compliance identified had a medium or high probability of putting into question food safety. Suspension of activities is a possibility. The measures to be taken have to be proposed by the inspectors that carried out the inspection. In cases
when there are suspicions of illegal practices or criminal activities by the FBO, DGAV is to inform ASAE. DGAV is to provide technical assistance to ASAE if needed. ASAE is the National Contact Point for the Administrative Assistance and cooperation system for Food Fraud (AAC-FF) notifications. This CA has police and criminal investigation powers and integrates the EU Food Fraud Network.

Conclusions on Competent Authorities

35. The CAs structure and organisation, their procedures, enforcement measures, staff and resources available are adequate for them to perform the majority of their tasks, with the exception of the human resources available in one region for the performance of inspections to establishments within the frequencies set in the official control programmes. The audit team noticed good cooperation and coordination in relation to operational issues between the CAs.

5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS' ESTABLISHMENTS LEGAL REQUIREMENTS


Findings

36. The approval process (in the sense of Regulations (EC) Nos 852, 853, 854 and 882 of 2004) of fishing vessels (non-primary production fishing vessels) and fishery products establishments is carried out by DGAV and it takes place in the framework of an integrated administrative procedure as part of the licensing process that is coordinated by different authorities. In mainland Portugal DGRM coordinates the licensing of factory and freezer vessels, fish auction halls and wholesale markets.

37. In mainland Portugal, DGRM is the authority responsible for the registration of all fishing vessels. The list of registered vessels per region and ports are available in the DGRM website. The national fishing fleet vessels have been registered in the EU database since 1989. DGAV and ASAE, as CAs in relation to the EU food law, are the authorities that assess the conformity of the facilities registered by DGRM with the requirements of Regulation (EC) Nos 852/2004 and 853/2004.

38. DGAV has up to now used the procedure for approval of establishments outlined in PACE (revised in 2013). The approval is granted following specific procedures in line with the EU requirements. Before approval, an inspection of the establishment is planned. Under the draft updated PACE the approval of establishments has been separated as an independent document (see paragraph 45).

39. An up-to-date list of approved establishments (freezer/factory vessels, auction halls, wholesale markets and establishments on land) is available at SIPACE.

40. Adequate approval certificates were available in all the establishments visited during the audit. These certificates specified the activities they were approved for while cold stores have a generic approval covering the storage of products of animal origin.
41. The audit team visited a freezer vessel in the Azores approved in February 2010 (date of attribution of the approval number). During the audit team visit, the inspectors indicated that a Hazard Analyses and Critical Control Point (HACCP) plan was not in place in January 2017 during an official inspection to maintain the approval and that it had taken one year for the operator to correct the non-compliance. The audit team while reviewing the official report on the 2017 visit, noted that this finding was not recorded and that the approval was not questioned. The next official control report dated October 2018 and indicated that a HACCP was implemented. During our current visit, the audit team noted that the HACCP plan showed had been created in April 2017 (i.e. after the inspection to maintain approval).

42. The situation described above, i.e. approval without an HACCP plan in place, is not in compliance with Article 31 (2) (c) and (d) Regulation (EC) No 882/2004.

Conclusions on registration/approval of food business operators' establishments.

43. The procedures applied for the approval of establishments until 2018, can be considered broadly adequate and in line with EU legislation.

44. However, in one autonomous region, the approval of a freezer vessel did not respect the EU rules, in particular Article 31 (2) (c) and (d) Regulation (EC) No 882/2004.

5.3 OFFICIAL CONTROLS

5.3.1 Official control of production and placing in the market

Legal requirements


Findings

General description of the official control system in place

45. The 2013 version of the PACE is in the process of being updated to take into consideration the upcoming implementation of Regulation (EU) 2017/625. Part of the update has been to divide the plan into three areas as follows: Plan of Control of Establishments of Food of Animal Origin (PACE GA), Plan of Control of Animal by-products and Approvals.

46. Under PACE GA, the control system is based on risk analysis that will define the frequency of controls. The establishments are classified in different categories based on the estimated risk. For each category a minimum frequency of inspection is set up. Before 2018, risk on establishments on land was determined taking into consideration the dimension of the establishment, the type of activity and the degree of compliance. In the update, the operator's past record as regards compliance as such, is removed from the calculation of the estimated risk at establishment level. Nonetheless, the system allows
for an extension of the period between inspections to that of the next lowest risk category out of 5 categories, each of which associated with a fixed inspection interval ranging from 12 (cat. 5), to 36 (cat. 1) months), if two consecutive inspections demonstrate compliance.

47. Under PACE GA, freezer and factory vessels risk calculation to determine the frequency of controls has also changed. Before 2018, risk was calculated based on the dimension of the vessel and activity, now only activity is taken into consideration. The inspection frequency has not changed and continues to be fixed at once/36 months.

48. Further changes introduced under PACE GA include the new procedure related to the measures in the case of non-compliances, Circular No 13/DSSA/2018 (see paragraph 34), and the verification inspections to be carried out when the non-compliances identified are classified as serious.

49. Under PACE GA, there are three types of control: 1. Regular Control as planned against the legal requirements, 2. Verification/Follow up Control for assessment of the corrective measures, 3. Verification Controls based upon suspicion.

50. The areas checked by the inspectors to assess compliance (see paragraph 25) includes facilities and equipment, procedures based on HACCP, analytical results, water, traceability, the type of freezing (with the recent introduction in Madeira region of the requirement to indicate whether or not this was brine freezing) and labelling.

51. All the inspections are recorded into SIPACE within 15 working days or 10 in the case of non-compliances graded as "4" (non-compliance with high probability of putting into question food safety). Following the introduction of the reports into the database, the software automatically calculates the date for the next visit. The FBO receives an inspection report. The official control report includes deadlines for correction of non-compliances, potential proposal for suspension or removal of the suspension.

52. The PCON is executed by qualified inspectors. The frequency of controls in mainland Portugal and Madeira is based on the size of the vessels (≥12 meters are a priority), fishing methods, whether they carry out associated operations and fish storage time on board. In the Azores, the audit team was informed that the selection criteria are vessels that are going to be inspected for the first time and vessels that were not controlled for a long time. The control frequency for these vessels in the country is a minimum of 5% of the fleet per year. Inspectors assess compliance with hygiene, equipment and traceability. All the inspections are registered in the DGAV intranet.

53. ASAE's official control system is also based on risk.

54. Within ASAE proactive controls, the National Food Inspection Plan (PNFA) covers primary production, factory/freezer vessels, approved establishments, transport, cold stores and retail. The audit team was informed that operational orders are issued from the central level to the URs on a monthly basis. When the target of those orders is on fishery products, the specialized brigades specifically, but not exclusively, cover the inspection of the production of fishery products. The URs staff has discretionary power to choose the establishments to be inspected but they have to follow the orientations related to the targets selection made on the operational orders. The audit team noted that
in an operation order to South UR (Algarve) in October 2017 to inspect fishery products establishments, it was indicated that six establishments were to be inspected and the Specialised Brigade was to prioritise on the basis of knowledge of non-compliances or illegal operations. The remaining establishments were to be chosen from the approval list in SIPACE taking into account the priorities mentioned on the operational order.

55. ASAE's "reactive" controls are performed in response to non-compliant results under the PNCA, notifications from RASFF and the EU Food Fraud Network, complaints, and claims. Reactive controls in respect of the latter two may be initiated at regional level, as well.

56. The audit team noted that within proactive controls, there were operation orders for factory/freezer vessels and for the supervision of fishery products establishments on land. Within reactive controls, there were operation orders for RASFF, for AAC-FF notifications and for when non-compliant results under the PNCA are found. The audit team noted that an operation order was issued in response to an AAC-FF system notification, describing the fraudulent activity in the treatment of thawed tuna products including photographs (published by the EU fraud network) of tuna loins untreated and treated with additives, showing the difference in colour between the two products.

Primary production (such as fishing vessels and aquaculture farms)

57. The audit team noted that in Madeira the annual inspection programme is designed in accordance with the instructions of PCON as regards vessels selection criteria and frequency of inspections. The PCON is implemented using the central CAs procedures and instructions in place including the use of specific checklists.

58. The audit team noted that, in Madeira, the PCON was fully implemented in 2015, 2016 and 2017, as regards the number of inspection visits. In 2017, the level of inspection was 14 % of the fleet.

59. The audit team visited two primary production vessels in Madeira, both over 12 metres long, and noted that both were in satisfactory condition regarding structure, hygiene, equipment and material. On average, these vessels spend six to seven days at sea and the fish is kept on ice or refrigerated. The fishing technique for tuna of all the vessels is pole and line using live bait.

60. In one vessel the report of an inspection in 2016 indicated that the hygienic and structural conditions were adequate even though non-compliances were identified (e.g. lack of records on board (training of staff on hygiene, pest control, cleaning and disinfection)). These non-compliances were still outstanding at the time of a verification inspection in 2017 and remained outstanding at the time of this audit in October 2018. The fish on board at the time of this audit was of a good standard of freshness and adequately covered in ice.

61. In 2017, in the Azores, there were 56 inspections planned and 58 were done. The level of inspections was 9% of the fleet. The most common non-compliances identified during inspections were training of personnel (52%) and poor state of maintenance of structures and equipment (19%).
62. The audit team visited three primary production fishing vessels in the Azores. The fishing method used for tuna is also poles and line. These vessels stay at sea for less than 48 hours. In general, the vessels were in good structural, equipment and hygienic conditions.

63. The audit team visited, in mainland Portugal, a facility at sea where they used a "set net" to fish for tuna. The audit team observed the slaughter of 30 Atlantic Bluefin tuna (Thunnus thynnus), total weight approximately 5 600 kg (from 85 to 255 kg each). The audit team noted that good hygiene conditions, that the fish was put in a mixture of water and ice immediately after slaughter and quickly transported to the establishment.

**Landing operations, landing sites**

64. The audit team did not have the opportunity of observing landing of tuna. However, as a surrogate, the audit team witnessed the landing at the port in Ponta Delgada (Azores) of dolphin fish (Coryphaena hippurus). These fish were destined for the canning industry. The operation was carried out rapidly and good hygienic conditions were observed. The fish was of excellent quality regarding freshness. The FBO explained that the temperature of the fish was lowered on board to 0°C using water with ice. Once the fish was at the temperature of melting ice it was kept without ice in a refrigerated "dry" hold. At the time of landing, the fish was covered with ice.

**Auction halls and wholesale markets**

65. According to DRA, 95% of the landing of tuna takes place in two auction halls in Madeira. The audit team visited one of these, not operational at the time, and reviewed several DRA official control reports. The report of a regular official control inspection in April 2017 outlined several non-compliances covering hygiene practices (in particular ice contamination), structures, absence of monitoring controls (own-check product testing and organoleptic examinations), calibration of measuring devices and HACCP (to be adapted to the operations carried out and to follow correctly the HACCP principles). Overall, the non-compliances were classified as grade "3" (major) and should have been rectified within six months except for the issue related with the ice that was to be corrected immediately.

66. A verification inspection took place six months later as scheduled (November 2017) and the vast majority of the non-compliances had not been rectified (including the ice contamination). During this inspection the non-compliances were re-rated as grade "2" (minor). A further six months was given for their correction except for the microbiological quality of ice that was to be corrected immediately. A verification inspection was due after our audit.

**Approved fishing vessels handling fishery products (freezer vessels, factory vessels and reefer vessels)**

67. DGAV inspections are carried out at the ports.

68. There are four freezer vessels approved in the Azores of which only one fishes for tuna as a by-catch. According to the CA none was using their freezing capacities at the time.
of the audit. All the vessels approved in the Azores were inspected by DRA Azores in 2017.

69. The audit team examined the documentation related to the DRA Azores official controls carried out in 2017 in one approved freezer vessel. The vessel had an inspection and a follow-up inspection to assess the correction of the non-compliances that was carried out as scheduled. The reports show that one of the initial findings was not followed up and the second one was not reliably followed up.

70. The audit team checked the DGAV official control records of two freezer vessels chosen at random. Both had been inspected in 2018. The vessels had been inspected using DGAV documented procedures and there was evidence of the follow up and closure of the non-compliances by the CAs.

71. The audit team noted that freezing temperature capacities and whether the fish was going for canning was included in the DGAV freezer vessels check list and thus can facilitate traceability of products destined for the canning industry. The audit team also noted that the type of freezing on board is not specified in SIPACE.

72. ASAE carries out inspections of approved vessels at sea when they are in operation and without previous notification. The audit team was provided with three samples (2015, 2016 and 2017) of reports of inspections carried out in three factory vessels. The overall findings related to lack of compliance with the general and specific requirements in hygiene as per Articles 3 and 4 of Regulation (EC) No 852/2004. Economic sanctions were envisaged.

Facilities on land handling fishery products (such as storage establishments and processing establishments)

73. DGAV has found when assessing the outcome of official controls of fishery products including tuna under PACE, that from 2015 to 2018 the most common non-compliances identified were issues with the HACCP system (29%), analyses results (18%) and hygiene (17%). The less common findings were use of additives (2%), by-products of animal origin (3%) and labelling (4%). In 2017, nearly 70% of the non-compliances were classified as grade "2" (non-compliance with low probability of putting into question food safety).

74. The audit team reviewed several ASAE documents related to inspection of establishments under the PNFA. The operation orders and Technical Sheets used for the inspection were available. The control system does not envisage follow-up of non-compliances but a description of the irregularities and whether the product has been confiscated or the establishment suspended. In 2016, ASAE carried out 24 proactive inspections on fishery products and 22 in 2017.

75. The audit team visited three processing establishments in the mainland in two different regions and five between the two autonomous regions.

76. The establishments visited during the audit were, in general, of a satisfactory standard of structure, hygiene conditions and equipment. However, there were exceptions which will be indicated in the paragraphs below.
77. In mainland Portugal, the audit team observed the transport of tuna after slaughter (see paragraph 67) to the establishment where it was cut, frozen to -70°C or sold chilled. At the establishment operators walked on the platform where tuna were cut into loins. The audit team observed that a member of staff left the platform, walked across the production floor and then returned to the cutting platform without cleaning his protective equipment. This establishment processes around 235 tonnes of finished products a year.

78. The audit team visited one establishment on land, in Madeira, providing cold storage services to the owners of the fish. This establishment can also store refrigerated fish and has facilities to freeze tuna in tunnel at -60°C and in brine at around -16°C. Freezing products using brine and not reaching, rapidly, at least -18°C is not allowed in establishments on land; the requirement of Chapter I(II)(7) of Section VIII of Annex III to Regulation (EC) No 853/2004 is not applicable to establishments on land. (5)

79. At the time of the visit, small tuna (circa 5 kg Skipjack) was in the process of being frozen in brine and it took 24 hours to reach a core temperature of -17.3°C (the brine was at -17.9°C). The temperature of the brine is recorded three times a day. The audit team looked at the records for the month of November 2017 and noted that the lowest temperature achieved in the brine was -17.3°C (recorded only once) and that in general the temperatures were higher than -17°C. This freezing operation does not comply with Section VIII, Chapter III(B) of Annex III to Regulation (EC) No 853/2004 – facilities must have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18°C. Neither the regional competent authority nor the central competent authority expressed concerns with regard to the situation observed during the visit to this facility.

80. The audit team reviewed the official controls file for this establishment and noted that yearly inspections had been carried out by the CA – April 2015, June 2016 and December 2017.

a. The inspection report of the 2017 inspection identified several non-compliances, classified as grade "2" (minor), and the operator was given three months to correct those non-compliances. Notably, the HACCP plan was not updated and did not cover all the activities carried at the establishment. This is not compliant with the second paragraph of Article 5 of Regulation (EC) no 852/2004.

b. Moreover, the audit team noted that many of the non-compliances detected in the 2017 had already been recorded in the 2015 and 2016 inspection reports. In particular, the HACCP deficiencies could be tracked down to 2014 (date of the last HACCP revision).

81. During our visit to the establishment, the audit team noted that part of the deficiencies were still present, despite of the deadline established for its correction. The existence of long standing deficiencies and the non-adherence by the FBO to the deadlines

(5) In response to the draft report the CA noted that the Regional CA has instructed the operator to address the non-compliance and some measures will be in place during the 2019 season to ensure compliance with Section VIII, Chapter III, Point B of Regulation (EC) No 853/2004.
established for their correction puts into question the effectiveness of the follow-up activities and highlights a weakness in imposing adequate enforcement measures. This is already partially acknowledged by the central CA with the issuance of Circular No 13/DSSA/2018 (see paragraph 34).

82. Also in Madeira, in another establishment visited, the HACCP plan was not in line with the requirements of Article 5(1) and (2)(b) of Regulation (EC) No 852/2004. Moreover, this deficiency had not been previously detected by the CA.

83. In one of the regions visited, in 2017 the frequency of DSAVRs inspections of establishments was not respected due to staff shortages not in line with Article 3(1) of Regulation (EC) No 882/2004.

84. With regard to imports of tuna products, the audit team noted that the cannery visited in mainland and the cannery in the Azores use mainly imported raw materials (in fact all raw materials imported into the Azores are used by the cannery).

85. In other establishment visited that imports frozen tuna to be sold frozen, the health certificate, bill of lading and associated documents do not allow the CAs to ascertain the EU eligibility of those products (whether they have been frozen in brine at -9°C and therefore can only be canned) under certain circumstances.

86. In three establishments, products chosen at random could be traced backwards to fishing vessels (in some cases including the fishing areas) and forwards to customers.

### Conclusions on official controls

87. The official control system in place covers completely the production chain of tuna fishery products and it is mainly implemented as planned and in line with the EU rules.

88. However, gaps were noted with regard to the timely and effective follow-up of the correction of the deficiencies noted during the controls on board of vessels and on establishments.

89. Furthermore, in one region, the implementation of the frequency of controls of establishments was not in line with the official control plans designed, based on risk and the EU rules, by the competent authorities. This non-adherence to the set frequencies weakness the ability of the control system to effectively verify and enforce compliance of the EU rules by the operators.

90. The methods/equipment used to freeze tuna fishery products, in particular the brine freezing in establishment on land, do not comply with the EU rules. Despite that the FBOs are allowed by the competent authorities to operate and freeze products not in accordance with those EU rules.

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### 5.3.2 Official control of the products

#### Legal requirements


#### Findings
91. DGAV has the following monitoring plans:
   - Food Inspection Plan (PIGA). This is the National Plan on Microbiological Monitoring.
   - National Residues Monitoring Plan (PNPR). The scope of testing includes aquaculture and wild fish. Samples are taken from fishery products establishments to be tested for heavy metals, dioxins and Polychlorinated Biphenyls (PCBs).
   - Control Plan on Border Inspection Posts (BIPs) (PCAPIF). The audit team was informed that this plan covers residues and contaminants and microbiological tests. In addition, other tests can be requested in the scope of reinforced checks.

92. Under the PIGA plan, fishery products, including tuna, are sampled and tested for the presence of histamine. This plan is drawn up by DGAV at central level. The number of samples to be taken in each Region is determined at central level. The Regional CAs will decide on the establishments where samples will be taken. The sample results are registered on SIPACE by DGAV. The measures to be taken in the case of non-compliance include notifying the FBO, implementing corrective measures or withdrawal of the product from the market. A notice report is issued.

93. All fresh fish seen by the audit team during the audit, including tuna (see paragraphs 61 and 64), in the vessels and establishments was of good to excellent quality with regard to freshness.

94. Twenty eight samples were taken to be tested for histamine every year since 2015 by DSAVRs. Tuna is not specifically targeted but it can be included in the sampling. In 2015 and 2016 all samples were compliant. In 2017, one sample was not compliant. The audit team noted that in most of the establishments visited, official samples are collected once a year.

95. Within the PNPR, DGAV tests fishery products, including tuna, for the presence of heavy metals and dioxins and dioxin like PCBs. DGAV is responsible for drawing up the plan based on risk, the evaluation and communication of the results and the organisation of training. The DSAVRs and DRAs will collect the samples and carry out traceability and market withdrawal when necessary. Samples are taken of wild caught fish as part of this plan.

96. Under this plan in 2017, 15 official samples of wild fish were tested for heavy metals (cadmium, lead, mercury) and five samples were tested for dioxins and dioxin like PCBs. No non-compliant samples were found. There were no non-compliant samples in 2016 either.

97. The audit team noted that in one case, DGAV official samples are not taken from the tuna species put in the market (Atlantic Bluefin tuna fished by set net) but from other species due to the value of the tuna.

98. The audit team noted that canned fishery products are not tested for levels of inorganic tin by DGAV.

99. The audit team was informed that under the PNPR, officials may collect samples at Regional level but due to the lack of budget they have to be authorised by the
Department of Finance before they send them to the laboratory to be analysed. This may delay the timely availability of results.

100. At BIPs documentary and identity checks of fishery products are carried out in 100% of the containers and physical checks in 20% of the containers.

101. The audit team noted that in the last 24 months, 1,880 documentary and identity checks of tuna consignments took place at BIPs (this constitutes 100% of the imports). One documentary check (0.05%) and five identity checks (0.27%) were found not satisfactory. Physical controls were carried out in 424 consignments (22.5%) of which six were found not satisfactory (1.41%). Eight consignments of tuna were rejected.

102. The audit team visited the BIP at Lisbon Airport, the DSAVR Lisbon and Tagus Valley. This BIP carries out official controls of food of animal origin at the airport and at the port. The audit team noted that the EU legislation is used when performing controls on imports from third countries of fishery products but the documents checked (country/establishment of origin, health certificate and bill of lading) do not allow the reliable identification of the method of freezing.

103. In the BIPs, samples are taken at random under the PCAPIF monitoring plan to be tested for histamine, heavy metals and other parameters. In these cases, goods are released for circulation before the laboratory results are issued. In the last 24 months, 60 laboratory checks of tuna were carried out at BIPs in Portugal under this plan. 52 results were satisfactory and eight results were awaited and not available at the time of the audit. Tuna samples tested for histamine in the last 24 months were all compliant. In 2017, some tuna samples were tested for mercury, cadmium and lead and the results were satisfactory. In 2018, some tuna fish samples were tested for mercury and the results were also satisfactory.

104. Samples can also be taken at BIPs in the case of suspicion, subsequent to non-compliances been found (reinforced checks) or under special protection measures. In those cases, the goods are detained at the BIP until the laboratory results are available. In the last 24 months, 14 laboratory checks took place for tuna, all the results were satisfactory.

105. ASAE implements the PNCA monitoring plan. Samples are collected at retail level. Fishery products are in the high risk category. Under the PNCA in 2016 and 2017, 31 samples of tuna were taken, 45 analytical determinations took place including for the presence of histamine, heavy metals (mercury, cadmium and lead) and dioxins. One non-compliant result was found related to mercury above the EU legal limit.

106. ASAE also collects samples as a result of unplanned controls. During 2016 and 2017, 10 samples of tuna fish were tested for histamine of which one exceeded the legal limits. In addition, eight samples were tested for the presence of nitrates and all results were "not detected".

107. The audit team was informed that in all the establishments visited the water was supplied by the municipality/public health services. The water is periodically tested in compliance with Council Directive 98/83/EC. The municipalities are responsible for the quality of the water up to the point of entrance of the water in the establishments; from
there on it is the responsibility of the operators. The approved establishments are obliged to have records of the last testing of the water providers.

108. There was no evidence that additives intended to change the colour of the tuna were being used. The CAs stated that they were not aware of the treatment of unprocessed tuna with nitrites/nitrates or additives containing high level of nitrates such as vegetable extract. None of the establishments visited was using any type of additives even though the CAs indicated that the canning industry uses additives in Portugal such as antioxidants.

109. All the labels, examined by the audit team during the audit, used on processed and unprocessed fishery products contained the mandatory information in line with EU legislation.

110. DGAV used checklists during PACE official controls which include the assessment of compliance with Regulation (EC) No 1169/2011 in relation to final information to the consumer and Regulation (EC) No 853/2004 as regards the identification marks.

111. As an example of good practice in the autonomous region of Madeira operators have been instructed to include the type of freezing on the label and in other documents.

**Conclusions on official controls of fishery products**

112. The official controls of fishery products are carried out by DGAV and ASAE as planned and, in general, in line with the EU rules except for testing for the presence of inorganic tin in canned fishery products, which is not in line with Chapter II (D) of Annex III to Regulation (EC) No 854/2004.

113. There is no evidence of the use of additives to change the colour of the final products of tuna.

**5.4 FOLLOW-UP OF RASFF NOTIFICATIONS**

**Legal requirements**

Articles 50 and 52 of Section I, Chapter IV to Regulation (EC) No 178/2002.

**Findings**

114. The National Contact Point for RASFF notifications is DGAV. The follow-up is coordinated at central level but the investigations can be carried out by DSAVR or ASAE or both.

115. Since January 2015 to the 10 October 2018, there has been one RASFF notification concerning tuna fishery products originating in Portugal (point 4.3 of this report). The audit team noted that the lot had been tested for histamine in the establishment of origin and the results were satisfactory. The distribution was in Italy and the product was recalled from the market. ASAE followed up this RASFF. During the same period there were nine RASFF notifications related to tuna not originating in Portugal.
116. The CAs provided the audit team with the documentation related to the follow-up of a RASFF notification on chilled vacuum-packed tuna from Spain and distributed in Portugal. The follow-up was carried out jointly by DGAV and ASAE. Some of the distributed product was withdrawn from the market.

**Conclusions on follow up of RASFF**

117. The limited review of documentation indicated that RASFF notifications had been followed up in line with EU legislation.

### 5.5 LABORATORIES

**Legal requirements**


**Findings**

118. There are two national reference laboratories in Portugal relevant to the scope of this audit. These are the Portuguese Institute of the Sea and the Atmosphere (IPMA) and the ASAE laboratory. These laboratories were not visited during the audit; instead laboratory staff presented information on the laboratories during the opening meeting. Accredited private laboratories may be used for specific tests.

119. IPMA tests for the presence of histamine and heavy metals in fish and fishery products. The laboratory is accredited to ISO/IEC 17025 by the national accreditation body. The scope of accreditation includes histamine (High Performance Liquid Chromatography, HPLC-FL) in fishery products, freshness indicators (Total volatile basic nitrogen, and Trimethylamine nitrogen), and heavy metals including lead, cadmium, mercury (Atomic absorption spectrophotometry).

120. IPMA participates regularly in proficiency testing schemes (PTs).
   a. In 2016, the laboratory participated in a PT organised by the EU Reference Laboratory for heavy metals in feed and food (EU-RL-HM-22). The results were satisfactory for lead, cadmium and mercury. The reference material was tuna fish flesh homogenate.
   b. In 2017 and 2018, the laboratory participated in PTs for the same heavy metals organised by FAPAS. The reference material was canned crab meat. The results were satisfactory.
   c. In 2016 and 2018, the laboratory participated in PTs for histamine organised by FAPAS with satisfactory results. The reference material was canned fish.
121. The Portuguese accreditation body carried out a routine inspection to the IPMA in 2018. The evaluation included testing for histamine, lead and cadmium. The monitoring evaluation report was favourable, although some minor non-compliances were found.

122. ASAE laboratory performs analyses to quantify dioxins and PCBs in fish and fishery products. The laboratory is accredited to ISO/IEC 17025 by the national accreditation body. The scope of accreditation includes histamine (HPLC-FL) in fish and fishery products; determination of mercury in fishery products (Atomic absorption spectrophotometry), dioxins and PCBs in food and determination of metals in food (Atomic absorption spectrophotometry).

123. ASAE participated in 2018 in a PT for dioxins and dioxin like PCBs organised by the EU Reference Laboratory, with satisfactory results.

Conclusions on laboratories


6 **Overall Conclusions**

The report concludes that in Portugal, the two designated competent authorities responsible for the official controls of fishery products have developed a coordinated control system based on the relevant provisions of EU legislation, which is supported by accredited laboratories. This control system, which covers the entire fishery products production chain including tuna fish, is in general adequately implemented.

However, some shortcomings were identified such as the difficulties in the effective follow up of the correction of deficiencies identified during controls, the adherence to the established frequency of controls, the implementation of the approval system, and the absence of testing for inorganic tin in canned fishery products. The authorities have recently introduced measures to rectify the failings in the follow-up of controls; however it is too early to assess their effectiveness. Fishery products that included Atlantic Bluefin tuna were of good to excellent standard as regards freshness.

7 **Closing Meeting**

During the closing meeting held in Lisbon on 26 October 2018, the audit team presented the main findings and preliminary conclusions of the audit to the CAs,

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the audit team.

8 **Recommendations**

The competent authority should provide the Commission services with an action plan, including a timetable for its completion, within twenty-five working days of receipt of the translated report, in order to address the following recommendations:
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| 1.  | To ensure that the implementation of the approval procedures followed respect the EU rules, in particular Article 31 (2) (c) and (d) Regulation (EC) No 882/2004, and that those procedures are correctly applied by all relevant competent authorities.  
*Recommendation based on conclusion No 44*  
*Associated findings Nos 41 and 42* |
| 2.  | To ensure the timely and effective follow-up of the correction of deficiencies identified during controls and the implementation of controls on the production chain following the frequency defined in the in the official control plans.  
*Recommendation based on conclusion 34, 88 and 89*  
*Associated findings 12, 65, 66, 69, 80, 81 and 83* |
| 3.  | To ensure that establishments freezing in brine shall have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of no more than -18°C as required under Section VIII, Chapter III point B of Regulation (EC) No 853/2004.  
*Recommendations based on conclusion 90*  
*Associated findings 78 and 79* |
| 4.  | To ensure that official controls cover all the checks described in Annex III, Chapter II of Regulation (EC) No 854/2004, in order to ensure compliance with Regulation (EC) No 1881/2006 as regards the testing for inorganic tin in canned foods.  
*Recommendation based on conclusion 112*  
*Associated finding 98* |

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

## ANNEX 1 – LEGAL REFERENCES

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<th>Legal Reference</th>
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