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 Austria carried out from 20 to 24 January 2020, as part of its work programme of controls in Member States.

The objective of the audit was to assess whether the organisation and operation of the official control systems put in place by the competent authorities meet the requirements of the relevant European Union law, and to what extent the correct implementation of European Union rules, relevant to fishery products, is effectively enforced.

The report concludes that the control system in place is based on the relevant provisions of European Union legislation and supported by accredited laboratories. This control system is in general, adequately implemented. However, there is a lack of official controls over water and ice in certain establishments (i.e. those lacking relevant own-checks) to verify compliance with the minimum requirements laid down in Council Directive 98/83/EC. Other shortcomings were identified regarding the implementation of official controls, such as the inadequate assurances on the maintenance of the frozen fish at the adequate temperature and lack of follow up on issues identified during controls.

In relation to the approval system for establishments, the procedures implemented after Regulation (EC) No 853/2004 became applicable are in themselves in line with the relevant European Union requirements. However, the system of re-approval of establishments (approved before the application of this Regulation), does not adequately assess the food business operators' awareness of the national legal requirements or the activities performed by them. It was acknowledged by the central competent authority that both they and food business operators can be unaware of the activities carried out at the time of the original approval, which in turn impacts on the obligation of operators to reliably notify the competent authority of any significant changes to production conditions. The central competent authority gave undertakings at the closing meeting to investigate this weakness.

The official controls of fishery products demonstrate some deficiencies, as the required checks for some parameters are not carried out.

The report contains recommendations to the Austrian competent authorities aimed at rectifying identified shortcomings and enhancing the control system in place.
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# Abbreviations and Definitions Used in This Report

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<tbody>
<tr>
<td>AAS</td>
<td>Atomic Absorption Spectrometry</td>
</tr>
<tr>
<td>AGES</td>
<td>Austrian Agency for Health and Food Safety</td>
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<tr>
<td>ALIAS</td>
<td>Common information system of the food inspectorate</td>
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<tr>
<td>BAES</td>
<td>Federal Office for Food Safety</td>
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<tr>
<td>BMASGK</td>
<td>Federal Ministry of Labour, Social Affairs, Health and Consumer Protection</td>
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<tr>
<td>CA</td>
<td>Competent Authority</td>
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<tr>
<td>CCA</td>
<td>Central Competent Authority</td>
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<tr>
<td>DG Health and Food Safety</td>
<td>Directorate-General for Health and Food Safety of the European Commission</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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<tr>
<td>FBO</td>
<td>Food Business Operator</td>
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<tr>
<td>FI</td>
<td>Provincial Food Inspectorates</td>
</tr>
<tr>
<td>ICP-MS</td>
<td>Inductively Coupled Plasma Mass Spectrometry</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
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<tr>
<td>LMSVG</td>
<td>Food Safety and Consumer Protection Act</td>
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<tr>
<td>NCP</td>
<td>National Control Plan</td>
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<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
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<tr>
<td>PAH</td>
<td>Polycyclic Aromatic Hydrocarbons</td>
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<tr>
<td>PCB</td>
<td>Polychlorinated biphenyls</td>
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<tr>
<td>PTs</td>
<td>Proficiency Testing Schemes</td>
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<tr>
<td>PVS</td>
<td>Provincial Veterinary Services</td>
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<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<tr>
<td>RTE</td>
<td>Ready-to-eat</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>TVB-N</td>
<td>Total volatile basic nitrogen</td>
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1 INTRODUCTION

The audit took place in Austria from 20 to 24 January 2020 and was undertaken as part of the work programme of the Directorate-General for Health and Food Safety of the European Commission (DG Health and Food Safety). The audit team comprised two auditors from DG Health and Food Safety.

An opening meeting was held in Vienna on 20 January 2020 with the central competent authority (CCA), the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMASGK), and representatives from the Austrian Agency for Health and Food Safety (AGES), Federal Office for Food Safety (BAES), competent authority (CA) Vienna, CA Lower Austria and CA Upper Austria. At this meeting the audit team confirmed the objectives of, and itinerary for, the audit, and requested additional information required for the satisfactory completion of the audit.

2 OBJECTIVES AND SCOPE

The objective of the audit was to assess whether the organisation and operation of the official control systems put in place by the CAs meets the requirements of the relevant European Union (EU) law, and to what extent the correct implementation of EU rules relevant to fishery products is effectively enforced.

In terms of scope the audit focused on the organisation and performance of the CA and the official control system in place covering production, processing (at approved establishments) and distribution stages applicable to fishery products placed on the market. Accordingly, relevant aspects of EU legislation, referred to in Annex 1 of this report, were used as technical basis for the audit.

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

<table>
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<tr>
<th>COMPETENT AUTHORITY</th>
<th>FACILITIES HANDLING FISHERY PRODUCTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central level</td>
<td>2 Opening Meeting/Closing Meeting</td>
</tr>
<tr>
<td>Processing Establishments</td>
<td>5 Upper Austria (one linked to a fish farm)</td>
</tr>
<tr>
<td></td>
<td>2 Lower Austria</td>
</tr>
<tr>
<td></td>
<td>1 Vienna</td>
</tr>
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</table>

Representatives from the competent authorities 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, Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council.
Full legal references to EU legal acts quoted in this report are provided in Annex 1 of this report and refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 GENERAL BACKGROUND

A previous audit took place in Austria in 2000, in order to assess the conditions of production of fishery products, the report of which (ref. DG (SANCO)/1144/2000) is available at:


Three out of nine of the country’s provinces were visited during this audit: Vienna, Lower Austria and Upper Austria, representing 50% of the total number of fishery products approved establishments in the country.

4.2 PRODUCTION AND TRADE INFORMATION

According to the Austrian Statistics Institute, the country produced 3,865,686 tonnes of live weight of aquaculture products in 2017 and 4,084,324 tonnes in 2018. The main species produced were rainbow and salmon trout (33.7% of the total amount) followed by common carp (16%) and brook trout (14.2%). The statistical office of the EU (Eurostat) shows that the majority of the fishery products traded in 2017-2018 was intra-EU. Trade was mostly in smoked trout, followed by smoked salmon (CN 305). The second highest amount of trade was in prepared or preserved fish, caviar and caviar substitutes prepared from fish egg (CN 1604). The country imported over 85,000 tonnes of fishery products in 2017 and again in 2018.

According to the list set up by the CA and available on the CA website (as at 8 January 2020), at the time of the audit there was a total of 56 establishments producing fishery products (eight in Carinthia, 17 in Lower Austria, seven in Upper Austria, four in Salzburg, five in Styria, five in Tyrol, five in Vorarlberg, and five in Vienna) and four wholesale markets (one in Lower Austria, one in Styria, and two in Tyrol).

Based on the information provided by the CA, there are 482 registered fish farms in the country. The audit team learnt that there are no fishing vessels registered in the country.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED NOTIFICATIONS AND OTHER NATIONAL NOTIFICATIONS

From 2017 to the end of 2019, there were 36 notifications on fishery products concerning Austria issued by the Rapid Alert System for Food and Feed (RASFF) network. The most frequent were: 13 related to mercury in swordfish, seven caused by histamine above the regulatory limits in tuna fish and anchovies, three due to the presence of chlorate in pangasius fillets and three caused by microbiological contamination. None of the notifications involved fishery products originating in Austria.
5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements

Articles 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 28, 29, 31, 32, 33, 138 and 139 of Regulation (EU) No 2017/625.

Findings

Designated competent authorities and operational criteria

1. The CCA for controls of food of animal origin is BMASGK. The audit team was informed that the name of the Ministry is in the process of being changed\(^1\). Within BMASGK, Department IX/B/13 is responsible for food safety legal affairs and the coordination of controls on fishery products.

2. AGES provides laboratory services, risk assessment and scientific advice. AGES is a limited liability company owned by the Republic of Austria.

3. BAES is an independent authority reporting to the Ministry of Sustainability and Tourism\(^2\). Under § 11(1) of the Marketing Standards Act, as amended, BAES carries out controls on imports and exports where marketing standards for fish and fishery products are applicable (consumer information and labelling). In addition, BAES is responsible for the implementation of the EU legislation on illegal, unreported and unregulated fishing. BAES cooperates with AGES.

4. The enforcement of the law and the implementation of the National Control Plan (NCP) (inspections and sampling) is the responsibility of the provinces. At provincial level control responsibilities are shared between the provincial Veterinary Services (PVS) and the provincial Food Inspectorates (FI).

   a. In the visited provinces of Upper and Lower Austria and Vienna, the PVS and FI have been merged.

   b. Within the provinces of Upper and Lower Austria there is a provincial and a district level. The audit team was informed that in Upper Austria, fish farms were under the responsibility of the district veterinarians of the province, including collection of samples for residue analysis. Veterinarians from the provincial office appointed by the Governor, were responsible for authorising the movement of live fish into establishments (and associated health certificates) and controls at slaughter. In the province of Vienna, the CA of the provincial office decides on

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\(^1\) In their response to the draft report the Competent Authority noted that this Ministry has been renamed the Federal Ministry of Social Affairs, Health, Care and Consumer Protection.

\(^2\) In their response to the draft report the Competent Authority noted that this Ministry has been renamed the Federal Ministry for Agriculture, Regions and Tourism.
the official controls to be carried out by the veterinarians appointed by the Governor.

5. The country profile for Austria, which is available on the internet at:  
http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=AT  
describes the organisation of the official control systems and of the authorities  
(including the distribution of competencies).

**Powers, independence and supervision of the competent authority**

6. Powers to carry out official controls are as described in the country profile.

7. The legal framework (Federal Civil Service Act and Provincial Civil Service Laws) and  
the mechanisms to ensure that civil servants are free of conflict of interest are described  
in the country profile.

8. The audit team learnt that in Upper Austria the system for the supervision of staff is  
carried out applying the four-eye principle, i.e. sending two inspectors together for a  
control visit. In Lower Austria, food inspectors carry out the inspections on their own.  
The audit team was informed that each province is inspected every three years by the  
CCA.

9. BMASGK has a system in place for internal audits in the food sector. The audit  
programme is based on risk analyses and three audits are carried out in three provinces  
each year. The audit team learnt that none of the audit programmes from 2017 to 2019  
covered fishery products specifically, under the scope of this audit.

**Training of staff performing official controls**

10. The audit team noted that food inspectors do not require a university qualification;  
secondary school education is sufficient. In accordance with national law, before  
becoming food inspectors, they must undergo at least four months training and pass an  
examination thereafter.

11. The audit team was informed that there is a National Plan for Training in place. In  
accordance with the “Food Safety and continuous Training Regulation”, food inspectors  
must carry out eight training sessions (of 24 hours each) every two years. The training is  
ot specifically on fishery products but subjects like the control and monitoring of  
Listeria monocytogenes or Hazard Analysis and Critical Control Points (HACCP).

12. The audit team learnt that in the provinces the CAs have specific food inspectors trained  
on fishery products. There are three food inspectors in Upper Austria, allocated to  
approved establishments, of which one is an expert on fishery products. The audit team  
mets two of these inspectors, not the expert, and they had a good knowledge of the  
applicable EU legislation.
13. The audit team noted that the majority of staff met during the audit, who are involved in the implementation of the official controls of fishery products, were adequately aware of the applicable EU legislation.

Transparency

14. In accordance with Article 32 of the national Food Safety and Consumer Protection Act (LMSVG), BMASGK and AGES ensure transparency by publishing an annual Food Safety Report, detailing the results of the official food inspections and of the sampling/testing carried out. There are other reports, such as the national Potable Water Report and reports on RASFF.

15. The “Annual Food Safety Report” is published summarising the results obtained from the enforcement of official food inspections, in line with Article 31 LMSVG.

Documented control procedures

16. CAs have developed a Quality Management Manual for the food inspectors in Austria. In this manual there are detailed procedures covering the official control tasks including check lists.

17. The provincial CAs avail of databases where the following information is stored: inspector assessment of the different modules in the form of a check list (i.e. building/equipment/plant technical requirements, hygienic conditions of the establishment), records of non-compliances, sampling and results of analyses.

18. The NCP for 2019 includes guidelines on the enforcement of the control of trade in the goods covered by the LMSVG and the 2019 Sampling and Reporting schemes. This plan is adopted annually in accordance with Section 31 of LMSVG.

19. There is a manual available to assist in the implementation of the NCP. This manual explains the risk-based system for performing official controls in establishments, the criteria for taking samples for official analyses, and establishments with specific requirements. The reporting system is also outlined.

20. There is an additional document to the manual, A-600-19, describing the process for the implementation of the priority control system for 2019 as part of the NCP. There is a description of the system for implementation, including the frequency of inspections and sampling for microbiological parameters. Inspectors avail of a more detailed check list to carry out inspections in these establishments (see paragraph 50).

21. There is a Standard Operating Procedure (SOP) for the “Planning, Preparation and Implementation of food official controls”. Controls are to be carried out by the food/veterinary inspectors on the basis of this SOP and of the specific check lists for each type of operation and sector.
22. In the database named “Common information system of the food inspectorate (ALIAS)”, a summary of all official controls is stored.

23. There are guidelines available online issued by BMASGK for food business operators, including the “Guideline for the slaughter and processing of wild fish or aquaculture products” and the “Guideline for implementation of food traceability in accordance with Articles 18 and 19 of Regulation (EC) No 178/2002”.

24. There is a recommendation from BMASGK in relation to the performance of the challenge test and/or storage test with regard to *Listeria monocytogenes* to objectively ensure the stability requirements, as per the provisions of Commission Regulation (EC) No 2073/2005.

25. There is a *Codex Alimentarius Austriacus*, which provides physical descriptions, definitions, analyses methods and assessment principles, as well as guidelines for placing foodstuffs (as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council) on the market. It was originally established by the Austrian-Hungarian Empire in 1891 and is still in use today.

26. There are specific documents such as “Application for approval as a fish processing plant and issue of an approval number in accordance with the Food Hygiene Authorisation Regulation receiving agency”, which is issued by the CA in Lower Austria.

**Control activities, methods and techniques**

27. The audit team noted that tasks related to official controls of establishments, are carried out by food inspectors using appropriate methods and techniques such as inspections using check lists, sampling and analyses.

28. Routine inspections of establishments are unannounced.

**Enforcement measures**

29. The legal basis for food inspection authorities, as regards enforcement measures and sanctions in respect of infringements, is LMSVG, as described in the country profile.

30. The audit team reviewed the reports of one processing establishment in the country which had been reported as having infringements in 2018. The report was available, non-compliances were identified and deadlines given for completion. Follow-up continued until all non-compliances were rectified. The audit team noted that the non-compliances did not translate in enforcement actions.

**Conclusions on the competent authority**

31. The CA is clearly designated for the official controls of fishery products, throughout the entire production chain. The structure, organisation, its powers, staff knowledge in most cases, as well as documented procedures in place, can support the
implementation of official controls and provide a good basis for meeting EU requirements.

5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS' ESTABLISHMENTS

Legal requirements


Findings

32. The legal basis for the approval of establishments is the “Food Hygiene Establishment Approval Regulation”, BGBI.II No 231/2009 and the LMSVG for registration and approval of establishments.

33. Registration/approval of establishments in compliance with national and EU law is the responsibility of each provincial CA, including:
   a. Registration of fish farms;
   b. Registration of establishments supplying small quantities of primary products directly to local retailers or the final consumer where Regulation (EC) No 853/2004 does not apply. Some of these establishments have associated small fish farms and slaughter their own fish;
   c. Approval of processing establishments.

34. In Upper Austria there are 37 registered and seven approved establishments. In Lower Austria there are 49 registered and 17 approved establishments. In Vienna there is one registered and five approved establishments.

35. The steps to be followed for approval include an application for authorisation from the food business operator (FBO) to the provincial CA and a desk evaluation of the documents submitted in line with the requirements of BGBI.II No 231/2009. If the documents are complete, an on-site inspection of the establishment and verification of own-checks take place. The provincial CA may issue a draft recommendation for final approval, conditional approval or a refused approval that will be sent to the FBO for comments. If after one week the FBO has not responded, a final notice is prepared.

36. The audit team noted that applications for the approval of a fish processing establishment are available online in Lower Austria and the information requested from the FBO is in line with BGBI.II No 231/2009.
37. In accordance with Article 10(2) of the LMSVG, the obligation to apply for approval does not apply to establishments that, before the entry into force of the LMSVG, were assigned a control number in line with the Fish Hygiene Regulation, BGBI. II No 260/1997.

38. The audit team noted that there were 37 establishments listed nationally in 2018 that had been approved before the entry into force of Regulation (EC) No 853/2004 and that 19 establishments had been approved afterwards.

39. In the provinces of Upper and Lower Austria, the audit team visited four establishments approved before the application of Regulation (EC) No 853/2004. The original approval certificates including information on original activities were not available. Nonetheless, new approval numbers had been assigned automatically under national legislation, Article 10(2) of the LMSVG. The audit team noted that there is no documented guidance regarding the issuing of new approval numbers to these establishments. The approval letters issued by the CA did not specify what processing activities the FBOs were approved for nor the conditions of approval—such as the obligation to inform the CA of changes in the circumstances of approval as required under national law, BGBI.II No 231/2009. Thus jeopardising compliance with national legislation and Article 6 (2) of Regulation (EC) No 852/2004 that requires FBOs to ensure that the CA has always up-dated information on establishments, including by notifying any significant change in activities and any closure of an existing establishment. According to the national legislation, the need to notify the provincial CA includes a “substantial change in production conditions”. The audit team noted that for one of the officials interviewed, this statement meant changing the type of production from fish to meat but not starting the production of, for example, smoked fish.

40. In Vienna, an establishment visited had been approved before the application of Regulation (EC) No 853/2004, but the CA had also issued a new approval certificate, specifying that it was also approved for a new activity of processing smoked products.

41. According to the CA, Statistics Austria is required, on behalf of BMASGK, to keep an electronic register of approved establishments. The supervisory bodies of the provinces enter directly into the register newly approved establishments and changes to establishments already approved. The Provincial Governor does not need to notify the approved establishments to BMASGK.

42. The list of approved establishments and the approval numbers assigned thereto shall be published by BMASGK in an appropriate manner.
Conclusions on registration/approval

43. The procedures for approval of establishments can be considered broadly adequate and in line with EU legislation.

44. However, in four out of five re-approved establishments, the approval letter did not specify what processing activities they were approved for nor the need to notify the authorities if there was any change in production conditions as required under national law. The original activities and conditions of approval were not available. This approval system does not guarantee the FBOs’ awareness of the national legal requirements.

5.3 OFFICIAL CONTROLS

5.3.1 Official controls on production and placing in the market

Legal requirements


Articles 9, 15 and 18 of Regulation (EU) 2017/625.

Articles 67 and 68 of Regulation (EU) 2019/627.

Findings

General description of the official controls system in place

45. Official controls are carried out in line with the LMSVG, laying down the requirements for foodstuffs, water intended for human consumption, consumer products and cosmetic products and the associated responsibilities of operators. It applies to all stages of production, processing and distribution. This federal act, which entered into force in January 2006, also transposes and implements related legal acts of the EU.

46. In accordance with the LMSVG, the provincial CA is responsible for monitoring compliance with the provisions of food law.

47. The NCP provides the framework for the activities of the authorities in each province (inspections of FBOs and sampling) and the official laboratories.

48. All the official controls are carried out by food/veterinary inspectors and are recorded in the ALIAS database and provincial databases. The provincial CA have access to test results data for all establishments nationwide. The audit team was informed that
BMASGK is in the process of being granted access to ALIAS and until then, it receives data covered by reporting requirements.

49. Food establishments are classified based on risk within ALIAS that will define the frequency of controls (minimum one annual inspection for establishments in the higher category risk 9, and one inspection every 10 years for establishments in the lower category of risk 1).

50. In addition, the NCP has an annual priority control system. In 2018, 2019 and 2020 the priority was verification of own-checks in high risk establishments processing food of animal origin approved in accordance with Regulation (EC) No 853/2004, concentrating in establishments producing ready-to-eat (RTE) food (smoked fish, fish salads, fish pies, fish spreads). The verifications under this priority control system, A-600, were to be carried out at least twice a year. For establishments without non-compliances in the last three controls, the A-600 priority control may be extended to once every two years. Official environmental and fish samples are to be taken. Establishments categorised as risk 7 are to be visited once every two years but if they are included in the priority control system A-600, they will be inspected twice a year using a different, more specific, check list.

51. The actual frequency and scope of the inspection for each establishment is defined by the provincial CA, based on the risk category and the establishment type of activity and past record, as outlined in the Quality Management Manual of the official food inspectorate (see paragraph 16).

52. The audit team did not visit any small/non-approved establishments but was informed that the minimum frequency of inspection is once every two and a half years.

*Primary production (aquaculture farms)*

53. The audit team visited a fish farm with an associated approved establishment in Upper Austria. This establishment also received live fish for slaughter. The audit team was informed that controls on the fish of the farm were under the responsibility of the district veterinarians of the province, including the collection of samples for residue analysis. Veterinarians from the province regional headquarters were always present at the time of consignments of live fish arriving for slaughter. They check the health certificates and the general condition of the fish. In general, these fish are left in ponds overnight, for recovery prior to slaughter.

The audit team was informed that in Lower Austria food inspectors are present at the time of slaughter. This is not the case if the farms are small and the products are sold on the national market.

*Facilities on land handling fishery products (processing establishments)*

54. The level of compliance with the NCP regarding the number of inspections carried out is assessed and reported in accordance with the manual of the NCP.
55. According to the summary provided by the CA, in 2018 there were 37 inspection controls carried out in approved establishments of which one establishment was reported as having infringements. The audit team reviewed the report of this infringement (see paragraph 30).

56. The audit team visited five establishments, all falling into the A-600 priority control system, and altogether they presented good structure, equipment and hygiene conditions. The activities in these establishments included marinating, cold and hot smoking, filleting, freezing, ready-to-cook meals with fresh fish (salmon and prawns) and imported tuna (canned).

57. The frequency of inspections was respected in four of the establishments.

58. In one establishment, crates were being washed with a detergent next to a fish filleting operation running the risk of contaminating the fish. The food inspector took immediate action.

59. The audit team observed that not all cold stores had a temperature recording device, contrary to Annex III, Section VIII, Chapter III, Part B of Regulation (EC) No 853/2004. The audit team was informed by the CA that there is a derogation for having temperature recording devices in cold stores under Commission Regulation (EC) No 37/2005. However, Article 3 (2) of this legislation refers to cold store facilities of less than 10m$^3$ for storing stock in retail outlets, not applicable to the cold stores in the establishments visited. In one approved establishment in particular, the audit team witnessed that the cold store did not have a temperature recording device and the temperature of the fish was -14°C and not -18°C as required by EU legislation. The check list used during priority control inspections (A-600) has a point questioning whether the storage temperatures are respected and whether the storage temperatures comply with the requirements of Regulation (EC) No 853/2004. No problems were identified in this regard during an inspection that was carried out in February 2019.

60. The FBO’s lack of documented recording of time and temperature, for parasite treatment of fish (24 hours at -20°C), was brought up during this audit by the inspector responsible for the establishment.

61. The official controls did not always verify the FBO’s own-sampling and testing for Polycyclic Aromatic Hydrocarbons (PAH) in smoked products.

62. The audit team observed that in inspection reports where issues were identified, there was not always a description of the measures to be taken or the deadline for corrective action. In one establishment, shortcomings identified at the beginning of 2019 remained unresolved at the time of this audit [lack of an FBO plan to test the product (RTE) or the environment for microbiological criteria (Listeria monocytogenes)]. This is not in line with the requirements of Article 12 (3) (a) and Article 13 (1) (d) of Regulation (EU) 2017/625.
63. The legal framework for laying down requirements for the quality of water intended for human consumption is the Drinking Water Ordinance 3/12/2019. BMASGK is responsible for the quality of water.

64. The audit team learnt that official controls of water or ice do not take place at the level of the establishment. The responsibilities for the quality of water are with the supplier and the FBO. In cases where the FBO have their own supply of water, they must carry out their own checks.

65. According to the CA, the water supplier is responsible for the controls. Authorised staff take samples (in line with Article 73 of the LMSVG) at the level of the water supply installations and will obtain an expert opinion in the results of analyses. The results of sampling for Vienna are published on the water supplier website; in other provinces the results have to be requested. Every year the CCA takes priority actions that might include checking the water supplies.

66. National legislation requires that the FBOs take routine samples for testing. The number of samples taken by the FBO depends on the volume of water used. In general, samples are taken four times per year. The audit team noted that this requirement is not always complied with and may not be identified during inspections. The audit team observed that in the establishments visited, the number of samples taken by the FBOs ranged between zero and four times per year. This practice does not guarantee compliance of the water with the quality standards at the point where the water is used in the undertaking as required under Article 6 (1) (d) of Directive 93/83/EC. The approved establishments are not obliged to keep records of the last testing carried out by the water suppliers.

Conclusions on official controls on production and placing on the market

67. The official controls system covers the parts of the production chain included in the scope of this audit.

68. There is a documented risk-based official control system in place for establishments, which includes criteria to define the inspection frequencies and reporting in compliance with Article 9(1) of Regulation (EU) 2017/625.

69. While all establishments visited complied with the general hygiene and structural requirements, the control system was not fully effective as some operators cannot reliably demonstrate the maintenance of the frozen fish at the temperatures required by EU legislation and this issue had not been noticed during official controls.

70. Some official inspections were not effective since the issues identified were not followed up.

71. The lack of verification during official controls of the quality of water and ice used in establishments, does not guarantee compliance with the minimum requirements laid
5.3.2 Official controls of fishery products

Legal requirements

Article 18 of Regulation (EU) 2017/625.

Articles 70, 71 and Chapter I of Annex VI to Regulation (EU) 2019/627.

Findings

72. The number of samples to be taken in each province is determined at central level. The provincial CAs will decide on the establishments where samples will be taken by the inspectors. Samples are taken in line with the specifications of the NCP (company type, product group/fish).

73. In accordance with the manual of the NCP there are also specific reporting systems for samples taken, tested and the results thereof.

74. The sample results are evaluated by the services of AGES and the inspection institutes in the provinces. These results are registered on the ALIAS database.

75. The audit team was informed that official fishery products samples can be both, planned or unplanned.

76. Planned samples are taken on a routine basis throughout the year. These samples are taken at three levels:

   a. FBO establishment;
   b. Retail level (directly passed to the consumers);
   c. Targeted samples as part of focused audits. As an example, under the priority control system A-600, fishery products and process hygiene criteria samples are to be taken during the inspection visits. Fishery products are to be tested for microbiological parameters on arrival and until the end of the best before date, including *L. monocytogenes*, *Staphylococcus aureus* and *Escherichia coli* (size of sample 25 g). The audit team noted that testing for PAH in smoked products was not included under this priority control system (please, see paragraph 61).

77. There are no planned samples for the primary production level.

78. Unplanned samples are taken following complaints, based on suspicions, EU warnings or follow-up samples.

79. In 2017, a total of 151 planned and 14 unplanned samples of fishery products were tested. Of the planned samples, 32 were from processing establishments and 118 samples were from the retail level.
80. In 2018, a total of 144 planned and 14 unplanned samples were tested. Of the planned samples, 21 were from processing establishments and 121 samples were from the retail level.

81. The official controls on fishery products do not include testing for dioxins or polychlorinated biphenyls (PCBs). The CA indicated that the water in fish farms is tested for dioxins and PCBs but that they stopped testing fishery products in 2014 as all results were satisfactory and as a consequence they consider that there is no risk in fish from the production in the country.

82. In relation to testing for inorganic tin, no samples were tested in 2018 and one sample was tested in 2019 (compliant). At the closing meeting, the CCA stated that there are no cannery fish processing establishments in the country.

83. In 2018, four samples were tested for PAH and 18 in 2019 at trade level; all of the results were compliant.

84. Numerous samples were tested for heavy metals (lead, cadmium and mercury):
   a. In 2018, 260 samples were tested for mercury (five non-compliant), 152 samples were tested for lead (all compliant) and 152 samples were tested for cadmium (one non-compliant).
   b. In 2019, 140 samples were tested for mercury (all compliant), 141 samples were tested for lead (all compliant) and 141 samples were tested for cadmium (one non-compliant).

85. In 2018, 29 samples were tested for histamine of which one was above the maximum permitted limits. In 2019, 27 samples were tested (all compliant).

86. The audit team noted that fishery products also undergo organoleptic examinations, checks for freshness indicators (Total volatile basic nitrogen, TVB-N), for presence of additives, parasite testing and identification of poisonous fish.

**Conclusions on official control of fishery products**

87. Official controls of fishery products do not include all of the elements (dioxins/PCBs) outlined in Article 70 and Chapter I of Annex VI to Regulation (EU) 2019/627. In addition, the monitoring arrangements do not guarantee compliance of traded smoked fishery products with maximum levels of PAH as required under Article 1 of Regulation (EC) No 1881/2006.
5.4 FOLLOW UP OF iRASFF NOTIFICATIONS

Legal requirements

Articles 50(5) and 52 of Section 1, Chapter IV to Regulation (EC) No 178/2002 of the European Parliament and of the Council.

Findings

88. Within AGES, Salzburg is the national contact point and ensures the national coordination for dealing with iRASFF (i) notifications. This is where all notifications are registered, evaluated and passed on to the CA or other relevant authorities.

89. The audit team requested information on the follow-up of two notifications and noted that these were both followed in a timely manner.

<table>
<thead>
<tr>
<th>Conclusions on follow-up of iRASFF notifications</th>
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<tr>
<td>90. There is a system in place to adequately investigate and when relevant, take action in response to iRASFF notifications.</td>
</tr>
</tbody>
</table>

5.5 LABORATORIES

Legal requirements


Article 2 to Regulation (EU) No 2074/2005


Articles 34, 35, 37, 39, 100 and 101 of Regulation (EU) 2017/625.


Chapter II of Annex VI to Regulation (EU) 2019/627.

Findings

91. There are several official laboratories within the BMASGK relevant to the scope of this audit. All are accredited to EN ISO/IEC 17025 by the national accreditation body. Most of the methods for analyses are in line with EU requirements except for the determination of histamine. These laboratories were not visited during the audit; instead laboratory staff presented information during the opening meeting.

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3 iRASFF means the electronic system implementing the RASFF and the Administrative Assistance and Cooperation System procedures in line with Commission Implementing Regulation (EU) 2019/1715.
92. Some laboratories are within the organisational units of AGES.

93. Within the Department of Food Safety of AGES there are three Institutes. These are:

   a. Institute for Food Safety Vienna. Its scope of accreditation includes testing for biogenic amines including histamine (this is a High Performance Liquid Chromatography (HPLC) method with UV detection but not the ISO 19343 HPLC method with UV detection outlined in Regulation (EC) No 2073/2005), determination of TVB-N in accordance to EU legislation, sensory test methods, parasites in fish, several microbiological parameters in food using ISO methods including *Listeria monocytogenes*, *Salmonella spp*, *Clostridium botulinum*, *E. coli* and *Enterococci*;

   b. Institute for Food Safety Innsbruck. Its scope of accreditation includes sensory test methods, PCBs in fatty foods (EN-1528-2), several microbiological parameters in food using ISO methods including *Listeria monocytogenes*, *Salmonella spp*, *Clostridium botulinum*, *E. coli* and *Enterococci*. Testing for microbiological parameters in water and environmental samples (using ISO methods) are also included in the scope;

   c. Institute for Food Safety Linz. Its scope of accreditation includes testing fish for PAHs (National Reference Laboratory (NRL)) (HPLC- fluorescence detection), several microbiological parameters in food using ISO methods including *Listeria monocytogenes*, *Salmonella spp*, *Staphylococci* and *Enterobacteriaceae*.

94. Within the Business Area of Food Security of AGES the relevant laboratories are:

   a. Linz. Accreditation for testing food for several microbiological parameters using ISO methods including *Listeria monocytogenes*, *Salmonella spp*, and *Enterobacteriaceae*. The scope also includes testing for heavy metals, using different methods:
      i. Determination of cadmium, mercury and lead in foodstuffs by inductively coupled plasma mass spectrometry (ICP-MS) after pressure digestion (CSN EN 15763);
      ii. Determination of mercury by cold-vapour atomic absorption spectrometry (AAS) after pressure digestion (CSN EN 13806);
      iii. Determination of cadmium and lead by AAS after microwave digestion (CSN EN 14084).

   b. Vienna. The scope of accreditation includes testing water for several physicochemical parameters (using ISO methods).

in fish and fishery products (Chapter II of Annex VI to Regulation (EU) No 2019/627, colony count at 30°C (ISO 4833-1:2013), biogenic amines including histamine in fish and fishery products (HPLC) and numerous tests for testing physico-chemical characteristics and microbiological parameters in water (using ISO methods).

96. The audit team noted that the Environment Agency Austria is the NRL in relation to dioxins and PCBs in food and feed.

97. The laboratories participate regularly in both national and international proficiency testing schemes (PTs). The audit team reviewed some of these participations as outlined in the paragraphs below.

98. Within the Business Area of Food Security, the laboratories have participated in an average of six PTs per year (2017 to 2019) for heavy metals (lead, cadmium and mercury). Matrices included canned bivalve molluscs and marine fish products. All of the results were satisfactory. In relation to PTs in tin, the laboratory participated in a PT in 2017 and two PTs a year in 2018 and 2019. None of the matrices were fish. The results were satisfactory. The PTs providers included the EU Reference Laboratory for metals and the Federal Office for Consumer Protection.

99. The Vienna Food Safety Institute participates annually in PTs for biogenic amines including histamine. Since 2017, most PTs have been organised by LVU Comparison Studies. The reference material was always canned fish. The results from 2017 to 2019 were satisfactory.

100. Linz Food Safety Institute participated in PAH PTs in 2017 and 2019. In 2017, it participated in two PTs (20 samples were tested of which three were edible oils and 17 were sausages). In 2019, it participated in one PT (13 samples), the reference material was mainly chocolate. The results were satisfactory. The PTs were those organised by the EU Reference Laboratory and BVL-Berking.

**Conclusions on laboratories**

101. The official laboratories involved in the testing of samples are accredited to EN ISO/IEC 17025 as required under Article 37 of Regulation (EU) 2017/625 offering guarantees as to the quality of the test results.

102. Most of the methods of analyses used in the context of official controls are in line with EU legislation ensuring uniformity of the testing data.

### 6 Overall Conclusions

The audit found that the control system in place is based on the relevant provisions of EU legislation and supported by accredited laboratories. This control system is in general, adequately implemented. However, there is a lack of official controls over water and ice in
certain establishments (i.e. those lacking relevant own-checks) to verify compliance with the minimum requirements laid down in Council Directive 98/83/EC. Other shortcomings were identified regarding the implementation of official controls, such as the inadequate assurances on the maintenance of the frozen fish at the adequate temperature and lack of follow up on issues identified during controls.

In relation to the approval system for establishments, the procedures implemented after Regulation (EC) No 853/2004 became applicable are in themselves in line with the relevant EU requirements. However, the system of re-approval of establishments (approved before the application of this Regulation), does not adequately assess the FBOs' awareness of the national legal requirements or the activities performed by them. It was acknowledged by the CCA that both they and FBOs can be unaware of the activities carried out at the time of the original approval, which in turn impacts on the obligation of operators to reliably notify the competent authority of any significant changes to production conditions. The CCA gave undertakings at the closing meeting to investigate this weakness.

The official controls of fishery products demonstrate some deficiencies, as the required checks for some parameters are not carried out.

7 CLOSING MEETING

A closing meeting was held in Vienna on 24 January 2020. At the meeting, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CA acknowledged the findings and preliminary conclusions presented by the audit team and provided a commitment to look into the issues identified.
The competent authority should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of the translated report, in order to address the following recommendations:

<table>
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<tr>
<th>No.</th>
<th>Recommendation</th>
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| 1.  | The competent authority shall ensure that a system is in place to guarantee that food business operators are aware of and comply with the requirements of Article 6 of Regulation (EC) No 852/2004, in particular with regard to notifying the competent authority of any significant change of activities after the approval has been given.  
*Recommendation based on conclusion No 44*  
*Associated finding No 39 and 40* |
| 2.  | The competent authority should verify and effectively enforce that approved establishments comply with relevant requirements of Article 4 (3) (c) and (d) and point 2 (d), Chapter I of Annex II to Regulation (EC) No 852/2004 and Section VIII, Chapter III, Part B of Annex III to Regulation (EC) No 853/2004 in particular temperature requirements for freezing products and cold stores equipped with temperature recording devices.  
*Recommendation based on conclusion No 69*  
*Associated finding No 59* |
| 3.  | The competent authority should take action to ensure that food business operators remedy non-compliances and prevent further occurrences of such non-compliances, in line with Article 138 of Regulation (EU) 2017/625.  
*Recommendation based on conclusion No 70*  
*Associated finding No 62* |
| 4.  | The competent authority should carry out official controls, as required by Article 14(g) of Regulation (EU) 2017/625 and Article 3 (1) (f) of Regulation (EU) 2019/627, to verify that water and ice used at establishments’ level comply with the minimum requirements laid down in Annex I of Directive 98/83/EC.  
*Recommendation based on conclusion No 71* |
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<tr>
<td></td>
<td>Associated findings Nos 64, 65 and 66.</td>
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<td>5.</td>
<td>The competent authority should ensure that the official controls of fishery products include all the elements (dioxins/PCB) laid down in Article 70 and Chapter I of Annex VI to Regulation (EU) 2019/627 and maximum levels of PAH are not exceeded as required in Article 1 of Regulation (EC) No 1881/2006.</td>
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<tr>
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<td>Recommendation based on conclusion No 87</td>
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<td>Associated findings Nos 61, 76(c) and 83.</td>
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## ANNEX 1 – LEGAL REFERENCES

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<tr>
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