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 Indonesia carried out from 3 to 12 March 2020, as part of its programme of audits.

The objective of the audit was to verify compliance of Indonesia’s legislation and systems, including official certification, with the European Union food and food safety rules, and to verify the capacity of the control systems in place to ensure that fishery products exported to the European Union comply with those rules, and, in particular, with the health attestations contained in the models of official certificates of Part II to Annex III to Commission Implementing Regulation (EU) No 2019/628 of 8 April 2019.

The report concludes that the official control system developed by the competent authorities is based on legislation and - in themselves largely adequate - procedures aiming to provide the guarantees required by the export health certificate. In response to the recommendations of the audit carried out in 2017, a number of new legal acts entered into force to address the deficiencies identified. The audit established that this legislation presents certain important gaps with regard to freezer vessels (temperature recording devices) and fish suppliers (Hazard Analysis Critical Control Points) and is on certain points contradictory.

Moreover, the implementation of these new legal acts is in its initial stages and therefore at a low level (artisanal fishing vessels). The part of the control system covering the primary production and not EU-listed freezer vessels and fish suppliers was not implemented in all food business operators participating in the EU export chain.

As a consequence, those exporting facilities often use raw materials for European Union exports which are not eligible for that purpose. The fact that in practice, non-compliances in respect of the eligibility identified during official control do not give rise to no or inadequate enforcement actions, exacerbates this situation.

These deficiencies continue to substantially undermine the guarantees required in this respect by the European Union export health certificate, even if the certification procedures themselves are adequate.

Otherwise, the audit found that the official controls of fishery products themselves is overall in line with the European Union requirements (except for tin), and that the competent authority adequately investigates and follows up notifications through the Rapid Alert System for Food and Feed.

Finally, and in respect of laboratory examinations, the audit established that the competent authority is not a position to demonstrate the full reliability of the test results for heavy metals and histamine, because the methods used are not the European Union reference ones or because the performance criteria of the methods are not aligned with the European Union rules.

The corrective actions taken to address five of the recommendations of the 2017 audit report did not effectively correct the associated deficiencies. For three other recommendations the corrective actions taken addressed partially the recommendations but some of the associated deficiencies
The report addresses recommendations to the 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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<th>Abbreviation</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>CBIB</td>
<td>“Certificate of Good Aquaculture Practices”</td>
</tr>
<tr>
<td>CN</td>
<td>Combined Nomenclature</td>
</tr>
<tr>
<td>CPIB</td>
<td>“Certificate of Good Fish Handling Practices”</td>
</tr>
<tr>
<td>DG SANTE</td>
<td>Directorate-General for Health and Food Safety</td>
</tr>
<tr>
<td>DGA</td>
<td>Directorate General of Aquaculture</td>
</tr>
<tr>
<td>DGCF</td>
<td>Directorate General of Capture Fisheries</td>
</tr>
<tr>
<td>EC</td>
<td>European Community</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EU export certificate</td>
<td>Model official certificate for the entry into the Union for placing on the market of fishery products as defined in Article 13 of Commission Implementing Regulation (EU) 2019/628 and in particular its Part II of Annex III</td>
</tr>
<tr>
<td>EUROSTAT</td>
<td>The statistical office of the European Union</td>
</tr>
<tr>
<td>FBO/s</td>
<td>Food business operator/s</td>
</tr>
<tr>
<td>FQIA</td>
<td>Fish Quarantine and Inspection Agency</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard analysis and critical control points</td>
</tr>
<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>PAH</td>
<td>Polycyclic aromatic hydrocarbons</td>
</tr>
<tr>
<td>PCBs</td>
<td>Polychlorinated biphenyls</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>TIU</td>
<td>Technical Implementing Units</td>
</tr>
<tr>
<td>TRACES</td>
<td>Trade Control and Expert System</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

The audit took place in Indonesia from 3 to 12 March 2020, as part of the Directorate-General for Health and Food Safety (hereafter DG SANTE) work programme. The audit team comprised two auditors from the Directorate-General.

An opening meeting was held in Jakarta on 3 March 2020 with representatives of the competent authorities from the Ministry of Marine Affairs and Fisheries involved in the official control of fishery products to be exported to the EU: the Fish Quarantine and Inspection Agency (FQIA), the Directorate General of Aquaculture (DGA) and the Directorate General of Capture Fisheries (DGCF). At this meeting the audit team confirmed the objective of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit. Representatives from the competent authority accompanied the audit team throughout the audit.

2 OBJECTIVES AND SCOPE

The objective of the audit was to verify compliance of Indonesia’s legislation and systems, including official certification, with the European Union (EU) food and food safety rules, and to verify the capacity of the control systems in place to ensure that fishery products exported to the EU comply with those rules, and, in particular, with the health attestations contained in the models of official certificates of Part II to Annex III to Commission Implementing Regulation (EU) No 2019/628 of 8 April 2019 (hereinafter referred to as the EU export certificate).

In the context of this audit the audit team also verified the extent to which the corrective actions submitted to the Commission services in response to the recommendations following the previous audits concerning fishery products, in 2013 and 2017 (hereafter: respectively "the 2013 audit" and "the 2017 audit") (1) were implemented, and assessed their effectiveness in addressing the deficiencies found during that audit.

In terms of scope, the audit covered the national legislation in force, the organisation and competencies of the competent authorities, its performance in terms of both the design and on-the-ground implementation of the official control systems in respect of the production chain of fishery products intended for export to the EU, and the operation of export certification procedures. Accordingly, relevant aspects of the EU legislation (2) listed in the Annex to this report were used as a technical basis for the audit.


(2) EU legislation available at: http://eur-lex.europa.eu/homepage.htm. Full legal references to EU legal acts quoted in this report are provided in the attached Annex I and refer, as appropriate, to the last amended version and applicable at the time of the audit.
In pursuit of this objective, the audit team visited the following sites:

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Central level</td>
<td>3</td>
<td>Main Headquarters</td>
</tr>
<tr>
<td>Provincial Level</td>
<td>3</td>
<td>Two Port offices and one Technical Inspection Unit (TIU)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRIMARY PRODUCTION</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquaculture farms</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Fishing vessels</td>
<td>3</td>
<td>Two of them only carrying out transport operations</td>
</tr>
<tr>
<td>Landing sites</td>
<td>3</td>
<td>Unloading fresh and frozen fishery products</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FACILITIES HANDLING FISHERY PRODUCTS</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Freezer vessels</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Processing establishments</td>
<td>7</td>
<td>4 EU-listed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 not EU-listed but supplying EU-listed ones</td>
</tr>
</tbody>
</table>

3  LEGAL BASIS

The audit was carried out under the relevant provisions of EU legislation and, in particular, Articles 120 and 122 of Regulation (EU) No 2017/625.

4  BACKGROUND

4.1  GENERAL BACKGROUND

Indonesia is included in Annex II to Commission Implementing Regulation (EU) 2019/626 of 5 March 2019, which sets out the list of third countries or regions thereof authorised for the entry into the European Union of fishery products, and in Commission Decision 2011/163/EU of 16 March 2011, as having an approved residue monitoring plan. Indonesia can export fishery products into the Union from 173 EU-listed establishments (*3), of which 97 are also authorised to export aquaculture products. The EU-list for Indonesia currently does not include any freezer vessel.

The previous fishery products audits to Indonesia took place in 2013 and 2017. The 2013 audit report made eleven recommendations to the competent authority covering the following aspects:

- **Standards for fishery products**, in particular the maximum limits for mercury and lead (recommendation No 8).


2
• Official controls of aquaculture farms (recommendation No 1), fishing vessels (recommendation No 2) and establishments on land not EU-listed (recommendation No 6).

• The level of compliance of fishing and freezer vessels with standards aligned with the EU rules and/or adherence to those standards (recommendations No 3 and 4).

• The origin of domestic raw materials used for the manufacture of products for export to the EU, in terms of compliance with the EU rules of supplying freezer vessels (implementation of “hazard analysis and critical control points” (HACCP) principles and temperature recording devices) (recommendation No 4) and supplying establishments on land not EU-listed (recommendation No 5).

• Official control of fishery products for dioxins and polychlorinated biphenyls (PCBs), and control of poisonous fishery products (recommendation No 7).

• Analytical method used to test fishery products for histamine (recommendation No 8).

• Use of potable water (recommendation No 9) and EU-authorised additives (recommendation No 10).

• Accreditation of testing laboratories to ISO/IEC 17025 (recommendation No 11).

The 2017 audit, in terms of follow-up of the 2013 audit report recommendations, found that for recommendations No 2, 3, 4 and 8, the corrective actions announced by the competent authority had not been properly implemented, or its implementation did not or not adequately address the identified shortcomings. Recommendations No 6 and 9 had been partially addressed. The 2017 audit report made ten recommendations to the competent authority covering the following aspects:

• Standards for:
  o freezer vessels and establishments on land not EU-listed (HACCP) (recommendation No 1);
  o fishery products (maximum levels of certain contaminants – heavy metals, polycyclic aromatic hydrocarbons (PAH), dioxins and polychlorinated biphenyls (PCBs)) (recommendation No 2);
  o and, primary production fishing vessels (artisanal fisheries) (recommendation No 3).

• Official controls of fishing and freezer vessels (recommendation No 7) and establishments on land (both EU-listed and not EU-listed) (recommendation No 4).

• The control and origin of domestic raw materials used for the manufacture of products for export to the EU, in terms of compliance with the EU rules of supplying fishing
and freezer vessels (temperature requirements and HACCP) (recommendation No 5) and supplying establishments on land not EU-listed (recommendation No 6).

- The level of compliance of fishery products with regard to temperature (chilled and frozen) (recommendation No 8) and manufacture requirements (recommendation No 9).

- The performance criteria of the analytical methods used to test fishery products for heavy metals (recommendation No 10).

The relevant sub-sections of section 5 of the report presents the follow-up of all these recommendations.

4.2 PRODUCTION AND TRADE INFORMATION

Between 2017 and 2019, and according to EUROSTAT, the EU imported approximately 166,080 tonnes of fishery products from Indonesia (roughly 55,360 tonnes/year). Those imports consisted of: tuna products – 62,200 tonnes; cephalopods – 41,200; crustaceans (mainly from aquaculture) – 33,650 tonnes; and other fresh/frozen fishery products – 24,720 tonnes. Roughly 80% of the tuna products imported were processed products and the remainder were frozen products. TRACES and EUROSAT have comparable figures.

The main importing Member States were Italy (29.7%), United Kingdom (16.9%), the Netherlands (11.9%), Spain (11.7%) and France (10.2%). Germany, Portugal, Belgium and Greece also imported fishery products from Indonesia (14.3% in total).

TRACES data suggests that the most of the imported products have been dispatched from Indonesia.

According to the competent authority, Indonesia imported from other third countries approximately 100 tonnes in 2018 and 50 tonnes in 2019 of raw materials to be used in the manufacture of products to be exported to the EU. This information does not coincide with other figures seen by the audit team during the visits to one of the establishments.

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

Since the 2017 audit, members of the RASFF network (⁴) issued 34 notifications (iRASFF (⁵) notifications) for Indonesian fishery products. Section 5.5 indicates how the competent authority handled those notifications. The products concerned and the causes for the notifications are indicated in the table below.

---

⁴ European Commission, European Food Safety Authority (EFSA), European Free Trade Association (EFTA) Surveillance Authority, EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

### Summary table for iRASFF notifications

<table>
<thead>
<tr>
<th>Product concerned</th>
<th>Cause for the notification</th>
<th>No of notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cephalopods</td>
<td>Levels of cadmium above the EU limits</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Presence of unauthorised additive</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Rupture of the cold chain</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Presence of <em>Vibrio vulnificus</em></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Consignment with products not covered by the EU export certificate</td>
<td>1</td>
</tr>
<tr>
<td>Crustaceans</td>
<td>Levels of heavy metals above the EU limits (mercury and cadmium)</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Levels of histamine above the EU limits</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Rupture of the cold chain</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Presence of carbon monoxide</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Incorrect labelling</td>
<td>1</td>
</tr>
<tr>
<td>Fish</td>
<td>Levels of heavy metals above the EU limits (mercury and cadmium)</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Levels of histamine above the EU limits</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Rupture of the cold chain</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Presence of carbon monoxide</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Incorrect labelling</td>
<td>1</td>
</tr>
</tbody>
</table>

5 **FINDINGS AND CONCLUSIONS**

5.1 **LEGISLATION**

**Legal requirements**

Articles 120(1)(a), (2)(a) and (3)(a), and 127(3)(a) of Regulation (EU) 2017/625.


**Findings**

1. As indicated in the 2017 audit report the Indonesian legal acts relevant for the scope of this audit have a hierarchical structure comprised of Laws and Governmental Regulations which overarch the Ministerial Decrees and Regulations. The latter are the basis for the different Directorate-Generals to issue their own Decrees and Regulations.

2. According to the competent authorities, since the 2017 audit several new Government/Ministerial legal acts were adopted:

   a. Government Regulation No. 28 of 2017 on aquaculture practices and establishing the requirements to be followed by the concerned food business operators (FBOs).

c. Ministerial Regulation No. 54/PERMEN-KP/2017 replacing Ministerial Regulation No. PER.25/MEN/2011 (identified in the 2017 audit report as No. PER.23/MEN/2011) concerning the organisation and procedures of the TIUs of FQIA.

d. Ministerial Regulation No. 51/PERMEN-KP/2018 (6) to implement the provisions of Article 20(5) of Government Regulation No 57/2015 – HACCP certification for fish processing establishments.


f. Ministerial Regulation No. 7/PERMEN-KP/2019 (8) to implement the provisions of Article 14(5) of Government Regulation No 57/2015 – CPIB for fishing/transport vessels. This regulation also repeals the relevant parts of Ministerial Regulation No. 19/PERMEN-KP/2010 and Ministerial Decree No. 52A/KEPMEN-KP/2013.

g. Ministerial Regulation No. 11/PERMEN-KP/2019 implementing, together with Ministerial Regulation No. 74/PERMEN-KP/2016, Article 32(5) of Government Regulation No. 57/2015, on controls of imports of fishery products and establishing an import model certificate.

3. In addition to the above, the three Directorates-General of the Ministry of Marine Affairs and Fisheries also issued after the 2017 audit the following legal acts:

a. FQIA Decree No. 96/KEP-BKIPM/2017 (9) amending Form 8 of Annex I of FQIA Decree No. 37/KEP-BKIPM/2017, which clarifies and details the provisions of FQIA Decree No. 259/KEP-BKIPM/2013 on the monitoring of fishery products (including parameters to be checked and maximum admissible levels for those parameters).

b. FQIA Decree No. 9/KEP-BKIPM/2018 on Technical Guidance to TIUs on the official control of landing sites, fishing ports and fish suppliers (establishments on land).

c. DGA Regulation No. 13/PER-DJPB/2018 on the implementation of instructions for the issuance of “Certificate for Good Aquaculture Practises (CBIB)” in accordance with the Ministerial Regulation No. 02/MEN/2007.

d. FQIA Regulation No. 47/PER-BKIPM/2019 implementing the provisions of Ministerial Regulation No. 52/PERMEN-KP/2018.

(*) According to the authorities relevant for recommendations No 1 and 5 of the 2017 audit report.
(?) According to the authorities relevant for recommendations No 1, 5, 7 and 8 of the 2017 audit report.
(?) According to the authorities relevant for recommendations No 1, 3 and 5 of the 2017 audit report.
(?) According to the authorities relevant for recommendations No 2 of the 2017 audit report.
c. DGCF Regulation No. 7/PER-DJPT/2019 (10) to implement the provisions of Articles 7 and 13 of Ministerial Regulation No. 7/PERMEN-KP/2019.

d. DGCF Regulation No. 1/PER-DJPT/2020 (11) amending DG Capture Fisheries Regulation No. 7/PER-DJPT/2019. According to the DG Capture Fisheries its Decree No. 84/PER-DJPT is no longer applicable.

4. Part of the above-mentioned legal acts were issued to address the points raised in recommendations Nos 1, 2, 3, 5, 7 and 8 of the 2017 audit report. In their initial responses to address the 2017 audit report recommendations, the competent authority also announced a modification of the Ministerial Decree No. 52A/KEPMEN-KP/2013. This decree contains the main legal provisions covering the entire production chain of fishery products and to be followed by the relevant FBOs. By a letter of 8 January 2018 (ref. 13/BKIPM/2018) the competent authority informed that, according to their legal services, the publication of some of the above-mentioned legal acts, superseding the Ministerial Decree No. 52A, would suffice to provide the guarantees sought by the report recommendations. The audit team found that both the old ministerial decree and the new ministerial regulations are addressed to FBOs, contain in certain points contradicting information (HACCP requirements) and it is not clearly indicated which legal acts supersede and which ones are superseded.

5. In this regard the audit team noted that the provisions adopted to address recommendation No 1 of the 2017 audit report in relation to HACCP, require that all establishments on land processing fishery products and/or manufacturing final products and freezer vessels must put in place, implement and maintain procedures based on the HACCP procedures.

6. However, and as already mentioned in the 2017 audit report, the same legal provision is not applicable to fish suppliers handling, freezing and storing fishery products to be used as raw materials for the manufacture of products for EU exports, which is not in line with the requirement of Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council.

7. Therefore, the actions proposed to address recommendation No 1 of the 2017 audit report did not effectively correct all the shortcomings identified.

8. Concerning recommendation No 2 of the 2017 audit report, the audit team noted considerable improvements in relation to the standards on the maximum admissible levels of lead, mercury, PCBs, dioxins and PAH in fishery products. However, the standards applied to fishery products for the maximum admissible levels of cadmium still differ from the EU rules, in particular with the levels indicated in Commission Regulation (EC) No 1881/2006. Therefore, it may be concluded that the actions

(10) According to the authorities relevant for recommendations No 3, 5 and 7 of the 2017 audit report.
(11) According to the authorities relevant for recommendations No 3, 5 and 7 of the 2017 audit report.
proposed and implemented to address recommendation of the 2017 audit report were effective with the exception of those applicable to cadmium.

9. With respect to recommendation No 3 of the 2017 audit report the audit team noted that the new legal acts adopted include provisions requiring that all fishing and transport vessels must comply with standards aligned with the EU rules of Regulation (EC) No 853/2004 of the European Parliament and of the Council. Moreover, those fishing vessels supplying fishery products for the manufacture of products for export to the EU also need to have a valid CPIB. Therefore, the actions proposed to address recommendation No 3 of the 2017 audit report effectively corrected the associated shortcoming.

10. From the cursory review made to the legal acts provided the audit team noted that, as in the past, they are broadly aligned with the EU applicable rules. However, the new Ministerial Regulation No. 7/PERMEN-KP/2019 and DG Capture Fisheries Regulation No. 1/PER-DJPT/2020 are not aligned with the EU rules, in particular with the requirement of point I(C)(2) of Chapter I of Section VIII of Annex III to Regulation (EC) No 853/2004 – the Indonesian regulations allow for manual temperature records for the storage holds of frozen products, which is not in line with EU rules.

**Conclusions on legislation**

11. The Indonesian legal provisions applicable to fishery products to be exported to the EU production chain cover entirely that chain and is largely in line with the EU rules except for specific points which were already flagged to Indonesia in the previous 2013 and 2017 audits.

12. The Indonesian standards are not aligned with the EU rules concerning the HACCP requirement for certain establishments on land handling, freezing and storing fishery products, the maximum admissible levels of cadmium in fishery products and the need for vessels storage holds for frozen products to be equipped with temperature recording devices.

13. While the measures announced to address recommendation No 3 of the 2017 audit report were adequately implemented and effective and the ones in respect of recommendation No 2 were largely effective, the measures announced to address recommendation No 1 did not effectively correct all the shortcomings identified.

**5.2 COMPETENT AUTHORITY**

**Legal requirements**

Article 120(1)(a) and (b), (2)(b) to (e) and (3)(a) of Regulation (EU) 2017/625.

Chapter III of Title II of Regulation (EU) 2017/625.
Findings

Structure and organisation

14. The competent authorities relevant for the scope of this audit remain the ones identified in the previous reports of the 2013 and 2017 audits. In summary, within the Ministry of Marine Affairs and Fisheries:

a. DGA – covering aquaculture farms in terms of registration, issuance of “Certificate of Good Aquaculture Practices” CBIB certificates and official control.

b. DG Capture Fisheries – covering wild caught fisheries in terms of vessels registration, issuance of vessels CPIBs, vessels official controls and control at landing.

c. FQIA – covering the remaining part of the production chain, namely the establishment on land, and in particular issuing establishments CPIBs, HACCP certificates (with a view of approval and EU-listing), official controls of and at the establishments, RASFF follow-up and issuance of EU export certificates.

d. DG of Product Competitiveness – providing technical guidance and assistance to FBOs on pre-requisite programmes, structural requirements and hygiene practices and governing the import permits and the fishing activity licence (commercial purposes).

15. The general description of the structure of the competent authorities of the 2013 and 2017 audit reports is still valid.

16. The Provincial Fisheries Services also play a role in the official control of fishing vessels and landing in lading sites/fishing ports that do not have a DGCF-TIU (approximately 478 locations) and in the official control aquaculture farms.

17. The following organigramme provided by the competent authorities shows the relationship between them:
Currently, the implementation of the control system at local level is carried out by:

a. FQIA – comprises 46 TIUs and 1 reference laboratory in 34 provinces.
   i. The control is implemented by 22 TIUs located in 16 provinces relevant for the export of fishery products to the EU.

b. DGCF – 500 fishing ports/landing sites in 34 provinces.
   i. The control is implemented by DG TIUs in 22 main fishing ports.
   ii. The control is implemented by the provincial services in the remaining locations.

c. DGA – the control is implemented by 15 TIUs of the provincial services covering 31 out of the 34 provinces of Indonesia.

Powers, Independence and Supervision

19. The duties and the powers conferred on the different competent authorities by the Law No 31/2004 and Law No 18/2012 remain unchanged since the 2017 audit. These laws also contain relevant provisions for sanctions and enforcement actions.

20. The new Government Regulation No. 86 of 2019 also prescribes sanctions to be imposed on FBOs that do not follow the food safety provisions and allows authorities to enforce measures such as product recall.

21. All staff of the competent authorities are civil servants and as such they are subject to the Indonesian Civil Servant rules on impartiality and freedom of conflict of interest. The laws No 31/2004 and No 18/2012 also include provisions to impose penalties to official staff if they breach the rules on their duties. As indicated in the 2017 audit report, official staff signs an “integrity letter” covering conflict of interest matters.

22. The FQIA arrangements for supervision and internal audits described in the 2017 audit report are still valid. The audit team observed evidences of the implementation of those arrangements.

23. The DGCF and the DGA also have in place arrangements for the supervision of the correct implementation of the control programmes by the different TIUs and provincial services. They include revision of inspection reports, accompanied visits and regular meetings held at the offices of TIUs or at the Provinces.

Training – Knowledge of EU requirements

24. The competent authorities presented detailed information concerning the training provided to official staff after the 2017 audit. The trainings covered aspects relevant and specific for each one of the DGs involved. The most relevant trainings were: evaluation/audit techniques and soft skills for evaluators/auditors (relevant for the three DGs); specific training sessions on the newly adopted regulations (HACCP and CPIB certifications); assessment of HACCP and quality management systems; sampling of
fishery products; general food safety requirements and specific seafood safety requirements (including specific training for tuna and crustaceans); traceability systems (including auditing); and, evaluation/testing of fishery products (e.g. sensory parameters, microbiology, chemical parameters).

25. The audit team found that all staff of FQIA it engaged with had an adequate knowledge on the relevant Indonesian and the applicable EU requirements. The same could be generally observed in relation to staff of the other DGs but while DGA staff presented weaknesses in relation to knowledge on auditing and inspection techniques, DGCF staff did so in relation to the correct assessment and evaluation of the ability for freezer holds to freeze rapidly and on the ability to ascertain the reliability of the temperature records.

Resources available to the competent authority

26. In terms of resources available for the performance of controls, the three DGs presented the current figures for the staff available for the official control tasks. None of the DGs informed on issues related to staff numbers. However, staff from one FQIA TIU audited informed the audit team that the overlapping of duties between official control visits and laboratory testing, did not allow them to respect the stipulated frequency for the visits to the fish supplier establishments.

27. The audit team noted that staff interviewed during the audit had access to adequately equipped offices and means of transport. The audit also observed that while some staff availed of equipment to perform their tasks (thermometers and protective clothing) others were using the equipment made available by the FBOs but also established that this did not have an evident impact on the performance of their duties.

28. For food safety aspects, FQIA avails of a network of 28 laboratories distributed across Indonesia to test fishery products, water and ice (see details in section 5.6 below).

Documented control procedures

29. As indicated in the 2017 audit report, the competent authorities issued/adopted several procedures covering their main tasks. Those procedures are part of the Quality Manual of FQIA and also of the legal acts currently in force. The procedures cover:


b. Licensing and Good Hygiene Practices certification of vessels and fish supplier establishments.

c. Licensing and HACCP certification of processing establishments.

d. Official control of licensed facilities (aquacultures, vessels and establishments on land).

e. Official control of fishery products (monitoring) for export to the EU.
f. Monitoring of water and ice.

g. Export certification.

30. The audit team noted that the documented procedures are routinely used by official staff in the course of their duties.

31. The audit team found that the procedures included in the new legal acts took into account the findings of the 2017 audit on the lack of definitions for the categorisation deficiencies: now these procedures clearly set what constitutes a “critical”, a “serious”, a “major” and a “minor” deficiency. However, the attribution of the categories of deficiencies remains pre-determined and official control staff tends to use it as a definitive classification, rather than guidance, and without fully considering the associated risks or impact. Therefore, the actions taken by competent authority were effective in addressing part of recommendation No 4, i.e. the part dealing with the drafting of procedures.

32. The consequence of this rigid pre-determination was evident in the checklist and procedures for the control of EU-listed establishments, in which FQIA has categorised the use of raw materials originating from suppliers without a valid CPIB, as a “major” deficiency, and which is not followed by immediate corrective action (see paragraphs 43 to 45). However, given that a valid CPIB is the key mandatory requirement that allows FBOs of establishments on land to supply EU-listed establishments, this deficiency should, in terms of the relevant EU rules and considering the Indonesian control system, be categorised as “critical”, followed by immediate corrective action, as the products from the listed establishment would be no longer eligible (see also below).

33. As a consequence, the procedure and its current implementation are also not in line with the commitment of FQIA to ensure EU-eligibility, communicated during the audit opening meeting and supported by Circular Letter No. 857/BKIPM/VIII/2018 of 30/08/2018, to the EU-listed facilities. In that letter FQIA informed EU-listed establishments that products intended for export to the EU were to be produced only from raw material obtained from suppliers with a CBIB and/or CPIB. FQIA also had sent Circular Letter No. 598/ BKIPM/VII/2017 of 23/07/2017 on the same topic to all FBOs concerned. As already indicated, the issuance of a CPIB certificate is the formal confirmation by the competent authority that the facility in question respects the applicable EU rules, and that it is controlled (see section 5.3).

Conclusions on competent authority

34. The competent authorities have a structure, organisation, powers, staff (including provisions regarding freedom from conflict of interest), written control procedures and resources available appropriate to implement an official control system covering the production chain of fishery products for EU export. Nevertheless, official staff present weaknesses in their knowledge of specific areas covered by the official
controls.

35. However, one element of those procedures, allows EU-listed establishments to remain EU-listed and export to the EU products manufactured with raw materials received from suppliers without a valid CPIB.

36. The measures announced by the authorities were effective to address part of recommendation No 4 (drafting of procedures).

5.3 NATIONAL PROVISIONS AND PROCEDURES FOR LISTING ESTABLISHMENTS FOR THE EXPORT OF FISHERY PRODUCTS TO THE EU

Legal requirements

Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625 and Articles 5(1) and (2), 10 and 11 of Commission Delegated Regulation (EU) 2019/625.

Findings

37. The listing procedure described in FQIA Regulation No. 03/PER-BKIPM/2011 has not changed but now it will take into account not only of the Ministerial Decree No. 52A/KEPMEN-KP/2013 but also the new adopted legal acts indicated in section 5.1 above.

38. The major change since the 2017 audit relates to the HACCP category C establishments. Contrary to the past, where HACCP C would mean implementation of good practices and pre-requisite programmes, now all establishments with an HACCP certification (A, B or C) must set up, implement and maintain permanent procedures based on the HACCP principles.

39. As such, the current arrangements to include and maintain establishments in the EU-list is based on a tier system of FBOs certification, as follows:

a. Primary production providing products to fish suppliers and/or EU-listed establishments:

i. Aquaculture farms – must have a CBIB certificate; farms wishing to participate in the production chain for the export to the EU must have a CBIB and this is currently ensured by the EU-listed establishments (list approved suppliers). The certificate is valid for 2, 3 or 4 years, depending on the outcome of the audit for the issuance of the CBIB certificate. According to DGA, there are currently 4,555 farms with a CBIB.

ii. Fishing vessels (chilled fishery products) –must have a CPIB certificate. The certificate is valid for 2 years.
b. Post-primary production and fish suppliers providing products to EU-listed establishments:

i. Freezer vessels – same as for fishing vessels above. In the case of freezer vessels a CPIB is only issued if the vessel complies with standards aligned with the EU (with the exception mentioned in paragraph No 12) and has set up, implements and maintains permanent procedures based on the HACCP principles.

According to DGFC, from the vast Indonesian fleet (according to DGFC statistical data, 869,579 fishing vessels in 2018), only 515 CPIBs were issued in 2019; according to one TIU-DGFC the CPIB issuance started in that TIU in 2019 and was mainly done to freezer vessels. Like for CBIB, the CPIB for fishing vessels is a mandatory requirement for the participation in the production chain for exports to the EU, but it is ensured by the EU-listed establishments (approved suppliers). The low number of CPIB certified vessels creates a problem to FBOs to secure EU-eligible raw materials.

ii. Establishments on land handling raw material (unprocessed), including freezing and storage of frozen products – to be able to supply raw materials an EU-listed establishment the fish supplier must have a CPIB certificate. The certificate is valid for 4 years. These establishments are not required to set up, implement and maintain permanent procedures based on the HACCP principle.

iii. Establishments on land processing fishery products – these establishments are required to have an HACCP certificate (A, B or C). The certificate is valid for 2 years.

c. EU-listed establishments:

i. These establishments must have a HACCP certificate (A, B or C) and the products to be exported to the EU can only be manufacture with raw materials sourced from other FBOs with a valid CBIB, CPIB and HACCP certificates (as applicable).

40. The audit team noted that FQIA, DGFC and DGA have, in addition to the EU-list, “internal” lists of FBOs authorised to participate in the EU export production chain. FQIA has updated lists of fish supplying establishments with HACPP certification and CPIB, DGCF has a list of the CPIBs issued in 2019 and DGA has an updated list of aquaculture farms with CBIB.

41. These lists were made available to the audit team and are available from the different authorities. However, apparently FBOs and FQIA does not have access or use the different lists to cross-check the eligibility status of the raw materials suppliers. In practice, FQIA regularly asks FBOs to provide them and maintain a list of their suppliers and verifies if the raw materials are sourced from the declared suppliers. In addition, and as mentioned in paragraph 32, when FQIA officials detect that raw
materials have been provided by non-eligible suppliers there is no effective corrective measure or action taken.

42. The above-mentioned tier system can, in theory, provide the guarantees sought by the EU rules if correctly implemented. All certifications are based on on-the-spot assessments and the level of compliance with requirements aligned with the EU rules.

43. However, the audit team noted several instances where this system was not implemented as required with little or no corrective action by the competent authorities. The audit team observed that EU-listed establishments exported to the EU products manufactured with raw materials obtained from fishing vessels without CPIB, freezer vessels without CPIB, fish supplier establishments without CPIB and fish suppliers with CPIB when they should have HACCP certification. The audit team checked several lists of suppliers and found that many of the suppliers would not be eligible to provide raw materials for the manufacture of products to be exported to the EU.

44. Moreover, the audit team noted that two out of three fish suppliers with valid CPIB and/or HACCP certificates visited, did not comply with requirements pertinent to having such a certificate (e.g. poor state of maintenance and repair, cold stores not equipped with temperature recording devices, absence of displays in blast freezers, identification of products not allowing the maintenance of traceability).

45. The above findings call into question the ability, in practice, of the competent authority to provide the guarantees required by Article 5(2) Regulation (EU) 2019/625. This, in turn, calls into question the reliability of guarantees that all products exported to the EU have been obtained, manufactured and stored in accordance with the EU rules. The current implementation of the system, heavily relying on the list of approved suppliers made and maintained by the FBOs, in the case of vessels and farms (respectively CPIB and CBIB), instead of using the official lists made by the relevant competent authorities, hinders the capability of the officials of FQIA to adequately perform all the necessary tasks to deliver the guarantees sought in Article 5(2)(a) Regulation (EU) 2019/625.

46. Currently, the arrangements set by Indonesia, if adequately implemented and after the correction of the deficiencies related to the standards referred to in section above 5.1, are satisfactory to implement the provisions of Articles 5(1) and (2), 6 and 10 of Regulation (EU) 2019/625 and to provide the guarantees sought by Article 127(3)(e)(i) of Regulation (EU) 2017/625. Therefore, and with the caveat mentioned, Indonesian procedures allow for the inclusion in the EU-list of all facilities involved in the production chain of fishery products to be exported to the EU.

47. To address the recommendations Nos 5 and 6 of the 2017 audit report Indonesia indicated that the adoption of new regulations, updating standards and procedures and the implementation of the said regulations and procedures, would address those recommendations and would ensure the correction of the deficiencies linked with those recommendations. Moreover, the competent authority also addressed to the FBOs two Circular Letters reminding them of the obligation to only obtain raw materials EU-
eligible (from certified suppliers – CBIB, CPIB and HACCP certified) for the manufacture of products for export to the EU.

48. An assessment of the new legal acts was already provided in Section 5.1; the adoption of the legal acts for DGFC contributes positively to addressing the issues related to the vessels (recommendation No 5). However, those legal acts have been recently adopted, and as such not yet fully implemented, and there are still standards that are not aligned with the EU rules (see paragraph 12). Therefore, the actions proposed to address recommendation No 5 of the 2017 audit report, also because of the early stages of implementation, were not (yet) effective in correcting all the associated shortcomings.

49. In relation to the Recommendation No 6 of the 2017 audit report, the audit team noted that the measures announced to address the recommendation have not been properly implemented and the standards applicable to establishments on land still differ from the EU rules.

Conclusions on national provisions and procedures for listing establishments for the export of fishery products to the EU

50. Currently, and with the caveat on the standards for HACCP and temperature recording devices, Indonesia has satisfactory procedures to approve (authorise) establishments involved in the exports to the EU and to include those establishments in the EU list.

51. However, one important element, i.e. the assessment of the EU-eligibility of raw materials provided by national suppliers (vessels and establishments on land), does not guarantee that eligibility due to shortcomings in the procedure itself and its incorrect implementation.

52. Therefore, Indonesia cannot provide the guarantees sought by Article 127(3)(e)(i) of Regulation (EU) 2017/625 and Article 5(2)(a) Regulation (EU) 2019/625.

53. The measures announced to address recommendations Nos 5 and 6 of the 2017 audit report were not yet fully implemented and some of the measures (standards) are not adequate to address the recommendations. Therefore, and to a certain extent, the deficiencies identified in the 2017 were not corrected.

5.4 OFFICIAL CONTROLS

5.4.1 Official control of the production chain

Legal requirements

Article 120(2)(g) and (h), (3)(a) and 127(3)(c) and (e)(iv) of Regulation (EU) 2017/625.

Point II.1 of the EU export certificate, and in particular the controls laid down in in Articles 67 and 68 of Commission Implementing Regulation (EU) 2019/627 of 15 March 2019.
Findings

General description of the official control system in place

54. The official controls implemented by the different authorities are clearly defined in their procedures, which include instructions and guidelines to official staff and the different forms to be used (reports, notices, letters and inspection checklists).

55. DGA carries out the control of aquaculture farms with a frequency that depends on the outcome of the evaluation carried out for the issuance of the CBIB (inspection for certification). During those inspections, DGA staff check the relevant food safety requirements aligned with the EU rules, in addition to other requirements under their remit.

56. DGFC annually controls vessels having a CPIB. At the time of the issuance of the CPIB certificate, and in principle once every two years thereafter, DGFC carries another in-depth inspection. In addition, DGFC also carries out landing controls to verify the hygiene conditions at landing both on the vessel and on the landing site.

57. FQIA carries out “surveillance” inspections to CPIB and HACCP certified establishments. The frequency of the “surveillance inspections” of the HACCP certified establishments depends on the classification obtained during the audit for the issuance (or reissuance) of the certificate but it is at least quarterly. In addition to that surveillance all those establishments are subject to an annual audit (“verification”) which includes an in-depth assessment of the facilities structures, equipment, hygiene practices, HACCP procedures and traceability. The frequency of visits to CPIB certified establishments is set at one per year, and an in-depth audit is carried out at the time of the issuance (or reissuance) of the certificate.

58. When deficiencies are detected during regular controls, the authorities issue a non-compliance report/notice and FBOs are requested to present an action plan with measures aimed at addressing those deficiencies, or to communicate immediately which measures will adopted. In all cases for the three DGs, additional visits may be necessary to verify the implementation of those actions plans/corrective measures (follow-up).

59. The three authorities may also carry out additional unscheduled visits for the investigation of particular incidents or for sampling of fishery products.

Aquaculture farms

60. Aquaculture farms with valid CBIB are regularly visited by official staff of DGA and/or Provincial services. The authorities presented in one province the data on those controls and the audit team visited one aquaculture farm (for shrimps).

61. At the farm the audit team noted that the certification procedure had been adequately followed, the farm had been visited in accordance with the set frequencies, the
applicable forms had been correctly used and the farm was in general compliant with the EU rules.

62. The farm records reviewed showed several discrepancies between the Good Practice Manual and operational criteria defined by the FBO on the one hand, and the practice on-site on the other. The main differences were the substances used during the production cycle, for the preparation and maintenance of the ponds, and for the feed of the shrimps. The audit team did not identify substances prohibited in the EU, amongst these.

Primary production fishing vessels, landing operations, landing sites

63. According to DGFC, due to the low number of operators requesting the issuance of CPIBs, the biggest effort was made in terms of training of fishermen in good handling practices and, also linked with their role in fisheries policy, in terms of landing inspections.

64. These landing inspections are carried out by TIU-DGFC staff at the main 22 ports and by provincial staff in the remaining ports. In the main fishing ports, DGFC carried out approximately 21,700 landing inspections in 2018, and approximately 15,300 in 2019.

65. In two fishing ports visited, the audit team checked DGFC files related to the landing inspections and confirmed that the vast majority of these were carried out in vessels without CPIBs. The audit team also noted that many landing inspection reports recorded temperatures of frozen fish which did not respect the EU rules. Use of these products for EU exports could not be confirmed but, equally, not ruled out.

66. The audit team visited one fishing vessel and two transport vessels for chilled fish and found them largely in compliance with the EU rules. All vessels had valid CPIBs and had been subject to landing inspections throughout the last year. The audit team noted that DGFC officials followed inspection procedures for CPIB and landing as required, including the use of the correct forms.

67. In respect of recommendation No 7 of the 2017 audit report, the audit team acknowledges the publication of the new legal provisions and that they are in an early stage of implementation, but the issues identified that supported that recommendation persist – not all fishing vessels involved in the production chain for export to the EU are under official control.

Freezer vessels handling fishery products

68. In the two main ports visited, and in respect of freezer vessels, several CPIBs had been issued and the audit team found that that the relevant procedures were followed and the associated forms correctly used. As for the fishing vessels, the number of CPIB certificates issued and the number of yearly routine visits is very low when compared with the number of suppliers of EU-listed establishments.
69. In all six freezer vessels visited, two of which with a CPIB, the audit team noted significant deficiencies, precluding them from being deemed compliant with EU rules.

70. All HACCP plans presented were of a general nature, and not adapted to the real operations carried out on-board. Moreover, the records drawn up in accordance with the HACCP plan were unreliable (temperatures records were indicated for holds that didn’t have temperature displays). None of the HACCPs defined the operational criteria for the freezing process, demonstrating that freezing takes place rapidly and that the products reach at least -18°C at core after thermic stabilization. The audit team observed the holds used to freeze the fish and noted that, for four vessels, it is highly unlikely that they would be able to comply with the EU rules in terms of freezing.

71. In one case, the audit team found one fish hold with a strong smell of fuel, a possible sign that this fish hold had been used to store fuel. This practice is not allowed by the EU rules.

72. For all vessels visited, records of fishermen training on hygiene practices and landing inspection reports were available. The audit team noted in one case a strong discrepancy between the temperature recorded at the landing inspection record and the receiving temperature at the establishment In another case, the temperature of frozen fish at landing was above the EU limits.

73. In order to address recommendations Nos 8 (temperature of the products) and 9 (preparation of loins) of the 2017 audit report the DGFC announced the publication and implementation of the new legal acts. The audit team noted improvements in that regard and verified that vessels that produce frozen loins are requested to include that operation in their HACCP plans. However, and despite improvements noted during the audit, there are still situations were frozen products do not comply with the EU rules when stored on board and when landed.

*Establishments on land handling fishery products*

74. The audit team visited three fish suppliers (not EU-listed – two with HACCP certification and one with CPIB) and four EU-listed establishments.

75. In all cases, established procedures were followed and the different inspection visits took place, globally, within the set frequencies. FQIA officials made adequate use of the correct forms, and inspection reports had been issued. In the case of detection of deficiencies during the inspections, non-conformity reports had been issued, the FBOs had submitted corrective action plans within the deadlines set, and officials verified the implementation of these action plans.

76. The audit team noted that one CPIB certified fish supplier and one HACCP certified fish supplier did not comply with the relevant EU rules (details in paragraph 44). In this respect, FQIA staff had overlooked the deficiencies and applied more tolerant criteria because the establishments concerned were not EU-listed and not producing fishery
products for direct export, overlooking the fact that they were supplying EU-listed establishments.

77. In relation to the CPIB certified establishment, the audit team noted that, due to the discrepancy between the EU rules and the Indonesian standards, an HACCP plan is not required, despite the activities performed (freezing and the storage of frozen fishery products

78. The audit team found the EU-listed establishments visited largely compliant with the EU rules except for the eligibility of the raw materials as, indicated in section 5.3. Specifically, the audit team found that raw materials used in the manufacture of products to be exported to the EU were sourced from non-eligible sources, as follows:

a. Fishing and transport vessels for chilled products without valid CPIB certificate.

b. Freezer vessels without a valid CPIB.

c. Fish supplier establishments handling and storing fishery products without CPIB.

79. In addition, one establishment was supplied by a pre-processing establishment cooking crabs holding a CPIB-, instead of an HACCP certificate. The competent authority could not explain why an establishment which under their rules requires an HACCP certificate held, instead, a CPIB certificate. Discussions with the FBO suggested that this case was not unique for the suppliers of that establishment, in that province. This issue had already been identified in the 2013 audit.

80. Although recommendation No 4 of the 2017 audit report was effectively addressed in relation to the establishment of procedures (see also paragraph 36), the procedures were not fully and/or correctly implemented and deficiencies noted in the 2017 audit persist.

Checks on the EU-eligibility of imported raw materials

81. Currently Indonesia requires that imported raw materials are sourced from countries authorised to export fishery products to the EU, and from establishments included in the EU-list for those countries.

82. The Indonesian rules require that imported consignments are accompanied by an export certificate (Indonesian official model) attesting that the products are fit for human consumption, and have been produced in an establishment approved and controlled by a competent authority and implementing HACCP procedures.

83. No additional attestation/certificate on the EU requirements is sought for the imported consignments. Therefore, their compliance with EU requirements is not confirmed and as such, they cannot be deemed eligible for the manufacture of products for export to the EU.

84. The above was demonstrated in respect of one consignment of crustaceans exported to the EU, which had been was manufactured with raw materials imported from another
third country, and in which the procedure above was followed correctly, that is, without the presence of nor request for an attestation as to eligibility of the products concerned.

**Conclusions on official control of the production chain**

85. Based on the relevant legal acts and defined procedures the official controls system covers the entire production chain.

86. However, its level of implementation is insufficient when it concerns fishing and freezer vessels, as demonstrated in particular by the significant deficiencies observed in all freezer vessels visited.

87. Moreover, the implementation of the controls in the establishments on land supplying fishery products to EU-listed establishments is incorrect, either because the establishment is incorrectly certified or because it presents deficiencies that would preclude its certification.

88. The controls over aquaculture farms and EU-listed establishments is implemented adequately and in line with the EU rules, except for the EU-eligibility of the domestic raw materials supplying EU-listed establishments.

89. The current procedures in place do provide sufficient evidence that imported raw materials used in the manufacture of products for export to the EU are EU-eligible.

90. In term of the 2017 audit report recommendations, the measures announced were effective in addressing recommendation No 9 and, by and large, recommendation No 8, but did not effectively address recommendation Nos 4 and 7.

**5.4.2 Official control of the products**

**Legal requirements**

Point II.1 of the EU export certificate, and in particular official controls laid down in Article 70 of Regulation (EU) 2019/627.

**Findings**

91. The official control of fishery products is carried out by the different competent authorities in accordance with their remits.

92. Organoleptic examinations are performed by DGFC during landing inspections, and by FQIA at the establishments on land. The authorities record those checks in the relevant forms/checklists, and made these available to the audit team.

93. Official control laboratories can carry out an assessment on the freshness indicators if the authorities have doubts following organoleptic examinations. FQIA provided the audit team with results of those assessments, and all respected the EU rules.
94. Fishery products are regularly sampled at the establishments on land, to be tested for -as applicable-, histamine, heavy metals (lead, cadmium and mercury), PAH, dioxins, PCBs and microbiological parameters (*Listeria*, *Salmonella* and *E. coli*). However, testing for tin is not carried out.

95. For certain relevant products the competent authority also samples for additives testing.

96. Parasite checks are carried out at the establishments on land during the inspection visits, and where necessary.

Conclusions on official control of the products

97. The official control of fishery products is carried out in accordance with the procedures and is overall in line with the EU requirements, except for tin.

5.5 FOLLOW UP OF RASFF NOTIFICATIONS

Legal requirements

Article 125(1)(f) and 127(3)(d) of Regulation (EU) 2017/625.

Article 4(c) of Commission Delegated Regulation (EU) 2019/625.

Findings

98. The number of RASFF notifications and the reasons for those notifications are indicated in section 4.3.

99. All these notifications were adequately followed up and in line with applicable procedure. The details of follow-up actions provided to the audit team demonstrated that adequate measures were put in place aimed at preventing reoccurrence.

100. The investigations carried out allowed in certain cases the identification of the likely causes, thus assisting the adoption of corrective and preventive measures. The competent authority also adopted additional measures, like re-enforced sampling and additional checks at export, where deemed necessary.

101. To note that certain notifications cannot be controlled and or prevented by the competent authorities as they may occur outside its or FBO control, such as the rupture of the cold chain, environmental contamination of predatory fish species.
Conclusions on follow-up of RASFF notifications

102. The competent authority investigates adequately iRASFF notifications and takes adequate measures when investigations identify Indonesian operators as responsible for events leading to those notifications.

5.6 LABORATORIES

Legal requirements

Article 120(2)(d) of Regulation (EU) 2017/625.


Findings

103. FQIA avails of a network of 28 laboratories distributed across Indonesia to test fishery products, water and ice (1 FQIA central laboratory, 1 private laboratory, 6 provincial laboratories and 20 TIU-FQIA laboratories).

104. One of those laboratories acts as the reference and the network coordinating laboratory. This laboratory supports technically the other laboratories of the network, develops analytical methods, organises national proficiency tests and it is used as the reference laboratory for confirmation results and dispute resolutions.

105. This laboratory is accredited to EN ISO/IEC 17025:2005 and carries out the following testing:

a. Determination of heavy metals levels in fishery products. The methods are included in the scope of the accreditation, the laboratory participated in proficiency tests with satisfactory results but the performance criteria (limits of detection and of quantification) in relation to lead and mercury differ from the EU rules for the limit of detection in both cases and for the limit of quantification in the case of mercury.

b. Determination of histamine levels in fishery products. The method is included in the scope of the accreditation, the laboratory participated in proficiency tests with satisfactory results but the analytical method is neither the EU reference one, nor is it validated against it.

c. Microbiological parameters in fishery products – Listeria and Salmonella.
d. Microbiological parameters in water and ice.

106. Samples of fishery products are also tested in six provincial laboratories.

   a. All laboratories are accredited to EN ISO/IEC 17025:2005, the testing methods are included in the accreditation scope and the laboratories participated in proficiency test with satisfactory results except for one laboratory (methods for the determination of cadmium, mercury and histamine (HPLC)).

   b. All laboratories test water and ice for microbiological parameters and for *Salmonella* in fishery products. Three of the laboratories test fishery products for *Listeria*.

   c. Four of the laboratories test fishery products for heavy metals. Two have methods with performance criteria aligned with the EU rules. In the other two laboratories the performance criteria for the methods for lead, in one, and for cadmium and mercury, in the other, are not in line with the EU rules for the limit of detection. Moreover, in the latter the limit of quantification for the method for mercury is also not in line with the EU rules.

   d. The same four laboratories also test fishery products for histamine. One laboratory stated that it uses an HPLC method while the other three stated to use an HPLC method with fluorometric detection. None of the laboratories specified that the methods used were validated against the EU reference method (ISO 19343:2017).

107. The private laboratory tests fishery products for heavy metals, histamine, dioxins, PAH and microbiology. This laboratory also tests water and ice for microbiology. The laboratory is accredited to EN ISO/IEC 17025:2005, the testing methods are included in the accreditation scope and participated in proficiency test with satisfactory results. This is the only laboratory that stated to use an HPLC with an UV detector (i.e. uses the same principle of the method ISO 19343:2017) to determine the levels of histamine. The performance criteria of the methods for heavy metals testing is not in line with the EU rules for cadmium (for both the limit of detection, as well as of quantification).

108. All TIU-FQIA laboratories are accredited to EN ISO/IEC 17025:2005, the relevant methods are included in the accreditation scope and participated in proficiency testing with, in general, satisfactory results.

   a. Almost all these laboratories test fishery products for Salmonella and E. coli and seven test water and ice for microbiological parameters.

   b. Only two laboratories test fishery products for heavy metals and the performance criteria of the method used by one laboratory for cadmium (limit of detection) is not in line with the EU requirements.
c. Six laboratories test fishery products for histamine with other methods than EU reference one. None of the laboratories indicated that the methods used have been validated against the EU reference method.

109. From the above the audit team found that fishery products are not tested for histamine with the EU reference method, or with methods validated against that reference method, and that several laboratories do use methods respecting the EU rules concerning the performance criteria of those methods.

110. To address recommendation No 10 of the 2017 audit report, the competent authority announced that the laboratories which were the object of the recommendation would perform an internal re-validation of the analytical methods to align their performance criteria with the EU rules. The findings above indicate that the measures presented, and implemented by the laboratories, were not fully effective.

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<tr>
<th>Conclusions on laboratories</th>
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<tr>
<td>111. The competent authority has access to a network of laboratories able to perform the necessary analytical tests to fishery products, water and ice. However, the competent authority is not a position to demonstrate the full reliability of the test results for heavy metals and histamine, because the methods used are not the EU reference ones or because the performance criteria of the methods are not aligned with the EU rules.</td>
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<tr>
<td>112. The implementation of the measures announced to address recommendation No 10 of the 2017 audit report did not result in providing satisfactory guarantees that all laboratories performing testing of official controls samples would use methods with performance criteria aligned with the EU rules.</td>
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5.7 **Official Certification**

**Legal requirements**

Articles 87 and 126(2)(c), (d), and (3) of Regulation (EU) 2017/625.

Regulation (EU) 2019/628, and in particular the model official certificates defined in Article 13 and detailed in Part II of Annex III.

**Findings**

*Issuance of EU export certificates*

113. There are no significant changes in the export certification procedures since the 2017 audit. In summary, TRACES is used for the issuance of certificates, FBOs submit a request for certification accompanied with relevant documentation, and, there is also a field verification of the consignments to be exported to the EU.
Checks of EU export certification of products exported to the EU

114. The audit team checked several export certificates and confirmed that the procedures in place were adequately followed.

115. Those checks also confirmed the export of products to the EU manufactured from EU-ineligible raw materials (from non-certified suppliers – CPIB and HACCP).

116. In addition, they also confirmed the use of raw materials used in the manufacture of products for export to the EU that were imported without being accompanied by an attestation (certificate) as to their EU-eligibility.

Conclusions on certification

117. The export certification procedures are aligned with the EU rules of Regulation (EU) 2017/625 and are, in themselves, satisfactorily implemented. This is notwithstanding the fact that the reliability of the attestations in the certificates is affected by the shortcomings identified in the course of this audit.

6 Overall Conclusions

The audit team found that the official control system developed by the competent authorities is based on legislation and -in themselves largely adequate- procedures aiming to provide the guarantees required by the export health certificate. In response to the recommendations of the audit carried out in 2017, a number of new legal acts entered into force to address the deficiencies identified. The audit established that this legislation presents certain important gaps with regard to freezer vessels (temperature recording devices) and fish suppliers (Hazard Analysis Critical Control Points -HACCP) and is on certain points contradictory.

Moreover, the implementation of these new legal acts is in its initial stages and therefore at a low level (artisanal fishing vessels). The part of the control system covering the primary production and not EU-listed freezer vessels and fish suppliers was not implemented in all food business operators participating in the EU export chain.

As a consequence, those exporting facilities often use raw materials for EU exports which are not eligible for that purpose. The fact that in practice, non-compliances in respect of the eligibility identified during official control do not give rise to no or inadequate enforcement actions, exacerbates this situation.

These deficiencies continue to substantially undermine the guarantees required in this respect by the European Union export health certificate, even if the certification procedures themselves are adequate.

Otherwise, the audit found that the official controls of fishery products themselves is
overall in line with the EU requirements (except for tin), and that the competent authority adequately investigates and follows up notifications through the Rapid Alert System for Food and Feed (RASFF).

Finally, and in respect of laboratory examinations, the audit established that the competent authority is not in a position to demonstrate the full reliability of the test results for heavy metals and histamine, because the methods used are not the EU reference ones or because the performance criteria of the methods are not aligned with the EU rules.

The corrective actions taken to address five of the recommendations of the 2017 audit report did not effectively correct the associated deficiencies. For three other recommendations the corrective actions taken addressed partially the recommendations but some of the associated deficiencies persist.

7 CLOSING MEETING

At the closing meeting held in Jakarta on 12 March 2020, the audit team presented the main findings and preliminary conclusions of the audit. The competent authority acknowledged the findings and preliminary conclusions of the audit and committed to correcting the deficiencies found by the audit team.
# Recommendations

The recommendations set out below are aimed at rectifying the deficiencies identified during the audit, and at enabling the competent authority to provide reliable assurances that the health attestations contained in the models of official certificates of Part II to Annex III to Regulation (EU) No 2019/628, are met in respect of exports of fishery products to the EU.

The competent authority should provide the Commission services with an action plan, including a timetable for its completion and within one month of receipt of the report, addressing these recommendations.

<table>
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<tr>
<th>No.</th>
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<tr>
<td>1.</td>
<td>The competent authority should adopt standards to ensure that the relevant EU rules are applied by all fish suppliers involved in the production chain of fishery products for EU export, namely, the requirements of Article 5 of Regulation (EC) No 852/2004 (HACCP), and, can be effectively enforced. Recommendation based on conclusions Nos 12 and 13. Associated findings Nos 5, 6 and 7.</td>
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<td>2.</td>
<td>The competent authority should adopt standards to ensure that fishery products exported to the EU comply with the maximum admissible levels for cadmium established in the EU rules, in particular those provided for in Regulation No (EC) 1881/2006, and can be enforced. Recommendation based on conclusions Nos12 and 13. Associated finding No 8.</td>
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<td>3.</td>
<td>The competent authority should adopt standards to ensure that FBOs of freezer vessels involved in the production chain for EU exports equip storage fish holds with temperature recording devices, as required in point I(C)(2) of Chapter I of Section VIII of Annex III to Regulation No (EC) 853/2004, and that these standards can be effectively enforced. Recommendation based on conclusion No 12. Associated finding No 10.</td>
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<td>4.</td>
<td>The competent authority should ensure that official staff has sufficient and adequate knowledge to enable them to perform adequately their official control tasks. Recommendation based on conclusion No 34. Associated finding No 25.</td>
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<td>5.</td>
<td>The competent authority should correct, and implement, the procedures in place in order to demonstrate that, all vessels and establishments on land involved in the production chain for the export to the UE comply with the EU rules and to be able to provide the guarantees required in Article 127(3)(e)(i) of Regulation (EU) 2017/625 and Article 5(2)(a) Regulation (EU) 2019/625. Recommendation based on conclusions Nos 35, 51 and 52.</td>
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<td>6.</td>
<td>Further to recommendation No 5, the competent authority should implement and maintain regular controls on fishing and freezer vessels involved in the production chain for export to the EU to demonstrate that they comply with the applicable EU rules and as required in Article 67(b) of Regulation (EU) 2019/627. Recommendation based on conclusions Nos 86 and 90. Associated finding Nos 56, 63 to 67, and 68 to 72.</td>
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<td>7.</td>
<td>Further to recommendation No 5, the competent authority should ensure that the regular controls on all establishments involved in the production chain for export to the EU (fish suppliers) demonstrate that they comply with the applicable EU rules as required by Article 67(b) of Regulation (EU) 2019/627. Recommendation based on conclusions Nos 87 and 90. Associated findings Nos 76, 77 and 80.</td>
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<td>8.</td>
<td>The competent authority should implement adequate procedures to establish the eligibility of consignments of the imported raw materials used in the manufacture of products for export to the EU are EU-eligible. Recommendation based on conclusion No 89. Associated finding Nos 81 to 84.</td>
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<td>9.</td>
<td>The competent authority should ensure that, where applicable, fishery products are tested to determine their compliance on the levels of inorganic tin as required in point D of Chapter I of Annex VI of Regulation (EU) 2019/627. Recommendation based on conclusion No 97. Associated finding No 94.</td>
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<td>10.</td>
<td>The competent authority should use for testing official control samples only laboratories that use EU reference methods, or methods validated against the EU reference ones, and that use analytical methods with performance criteria in line with EU rules and have adequate quality controls are in place to provide for the reliability of test results (Codex Alimentarius, CAC/GL 26-1997). Recommendation based on conclusions Nos 111 and 112. Associated findings Nos 105 to 110.</td>
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The competent authority's response to the recommendations can be found at:

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<tr>
<th>Legal Reference</th>
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<tr>
<td>Regulation</td>
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