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DG(SANTE) 2024-8018

FINAL REPORT OF AUDIT
CARRIED OUT IN
ITALY
FROM 25 FEBRUARY 2024 TO 13 MARCH 2024
IN ORDER TO
EVALUATE THE FOOD SAFETY CONTROL SYSTEMS IN PLACE GOVERNING THE
PRODUCTION AND PLACING ON THE MARKET OF FISHERY PRODUCTS

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 Italy, from 26 February to 13 March 2024, as part of its work programme of controls in Member States.

The overall 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 food law relevant to fishery products is effectively enforced. An additional objective was to follow up on the actions taken by the competent authorities in response to certain recommendations of a previous audit report on (tuna) fishery products.

The report concludes that, overall, the organisation and operation of the official control system put in place by the Italian competent authorities largely meet the requirements of the relevant EU law, it is correctly implemented in the vast majority of the cases and it is effectively enforced.

The official control system in place is well organised, risk based, covers completely the production chain and it is supported by extensive and detailed written instructions/guidance. The guidance document for fishery products is not fully aligned with the EU rules in certain particular aspects related to primary production.

The control system is implemented by and large adequately as required by the EU rules, by knowledgeable staff, in accordance with the adopted procedures and the defined frequencies.

However, the control frequencies for primary production fishing vessel and for approved fishing vessels are not respected. Moreover, the procedures for granting the conditional approval and subsequent “final” approval are not always correctly implemented. The approach on the assessment of shelf-life studies is not consistent between the local authorities within the same Region – one of the approaches can be considered the most appropriate one.

The situation observed during the audit suggest that the weaknesses identified above have a limited impact in the overall objective of the official control system governing the production and placing on the market of fishery products.

The report contains recommendations to the competent authorities to address the identified shortcomings.

Table of Contents

| | | |
|-------|---|-----------|
| 1 | Introduction..... | 1 |
| 2 | Objectives and scope..... | 1 |
| 3 | Legal basis | 2 |
| 4 | Background..... | 2 |
| 4.1 | General background | 2 |
| 4.2 | Production and trade information..... | 2 |
| 4.3 | Rapid Alert System for Food and Feed (RASFF) notifications | 3 |
| 5 | Findings and conclusions | 4 |
| 5.1 | Competent authorities | 4 |
| 5.2 | Registration/approval of food business operator establishments | 8 |
| 5.3 | Official controls..... | 10 |
| 5.3.1 | <i>Official controls on the production and placing on the market.....</i> | <i>10</i> |
| 5.3.2 | <i>Official controls of fishery products</i> | <i>15</i> |
| 5.4 | Follow up of iRASFF notifications | 17 |
| 5.5 | Laboratories..... | 18 |
| 5.6 | Follow-up | 19 |
| 6 | Overall Conclusion | 20 |
| 7 | Closing Meeting..... | 21 |
| 8 | Recommendations..... | 21 |
| | Annex 1 – Legal references | |

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

| Abbreviation | Explanation |
|---------------------------|---|
| ASL | Local Health Units (<i>Aziende Sanitarie Locali</i>) |
| AUSL | Local Health Unit (<i>Azienda Unità Sanitaria Locale</i>) |
| DG Health and Food Safety | Directorate-General for Health and Food Safety of the European Commission |
| DGFHFSN | Directorate-General for Food Hygiene, Food Safety and Nutrition |
| DGHFS | Directorate-General for Hygiene and Food Safety |
| EC | European Commission |
| EU | European Union |
| EUROSTAT | Statistical office of the European Union |
| HACCP | Hazard analysis and critical control points |
| ISS | National Health Institute (<i>Istituto Superiore di Sanità</i>) |
| IZS | Zooprophylactic Institutes (<i>Istituti Zooprofilattici Sperimentali</i>) |
| MANCP | Multi-annual national control plan |
| PAH | Polycyclic aromatic hydrocarbons |
| PCBs | Polychlorinated biphenyls |
| RASFF | Rapid Alert System for Food and Feed |
| S.Inte.S.I.S. | Integrated System for Trade and Imports (<i>Sistema Integrato per gli Scambi e le Importazioni</i>) |

1 INTRODUCTION

The audit took place in Italy, from 26 February to 13 March 2024 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 was carried out by (a) assessing the information and documentation provided in response to the pre-audit questionnaire, followed by (b) video-conference meetings that took place from 26 February to 1 March, and (c) on-the-spot assessment visits that took place from 4 to 8 March. The audit team comprised two auditors from DG Health and Food Safety and was accompanied throughout the on-site part of the audit by representatives of the designated competent authorities (national, regional, and local levels).

2 OBJECTIVES AND SCOPE

The overall 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 (EU) law and to what extent the correct implementation of food law relevant to fishery products is effectively enforced. An additional objective was to follow up on the actions taken by the competent authorities in response to certain recommendations of a previous audit report ⁽¹⁾ on (tuna) fishery products.

In terms of scope, the audit focused on the organisation and performance of the competent authorities and the official control system in place covering the production, processing and distribution stages applicable to fishery products placed on the market.

Accordingly, relevant aspects of the EU legislation, referred to in the attached Annex ⁽²⁾, were used as the technical basis for the audit.

In pursuit of the audit objectives, the audit programme comprised the following meetings and/or visits:

| COMPETENT AUTHORITY | | |
|---|---|---|
| Central level | 3 | Audit opening, closing and technical meetings (by videoconference). |
| Regional level | 2 | Audit technical meetings (by videoconference) with the authorities of the region visited. |
| Local level | | Several interviews/dialogues during the visits to premises. |
| PRIMARY PRODUCTION | | |
| Fishing vessels | 1 | |
| Landing sites | 2 | Not in operation at the time of the visit (one of them as part of the auction hall). |
| Aquaculture farm | 1 | Fin fish farm. |
| FACILITIES HANDLING FISHERY PRODUCTS | | |
| Auction hall | 1 | Not in operation at the time of the visit. |
| Other approved establishments | 5 | Establishments manufacturing fishery products (e.g. smoked, marinated, frozen). |

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.

⁽¹⁾ Audit reference number DG(SANTE)/2019-6747, available at: <https://ec.europa.eu/food/audits-analysis/audit-report/details/4159>.

⁽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 and refer, as appropriate, to the last amended version and applicable at the time of the audit.

4 BACKGROUND

4.1 GENERAL BACKGROUND

The last DG Health and Food Safety audit on fishery products in Italy took place in 2016. Later, in 2019 (hereinafter the 2019 audit), DG Health and Food Safety carried out an audit to Italy on fishery products derived from tuna species. The report of that audit⁽³⁾ identified several deficiencies for which the competent authority presented an action plan aimed at addressing these deficiencies. This action plan was deemed at the time as satisfactory. Section 5.6 below provides information on the follow-up of the recommendations that remain open at this stage.

4.2 PRODUCTION AND TRADE INFORMATION

According to the information provided by the competent authorities on their website (list of approved establishments)⁽⁴⁾, Italy has 2 710 approved establishments, with the following distribution: auction halls – 28; wholesale markets – 198; freezer vessels – 256; factory vessels – 14; and, 2 214 other establishments on land (some of these establishments are approved for more than one activity).

According to the information provided by the competent authorities, Italy has 477 aquaculture farms registered as involved in the supply of products for human consumption. Due to incomplete responses to the pre-audit questionnaire and additional requests, it was not possible to determine with precision the number of existing primary production fishing vessels in Italy.

The information above is not supported by, and not aligned with, those provided in the annual report on official controls⁽⁵⁾ issued by the Italian competent authorities. According to that report and in relation to 2022, Italy had 3 893 approved establishments for the fishery products sector, 716 operators registered for aquaculture and 5 964 registered fishing vessels (primary production).

EUROSTAT figures suggest that in 2022 Italy produced approximately 48 261 tonnes of fin fish from aquaculture and that approximately 112 460 tonnes of fishery products have been caught and landed by 12 231 Italian fishing vessels (both registered and approved vessels).

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

Since 2020, members of the RASFF network⁽⁶⁾ have issued 38 notifications (iRASFF⁽⁷⁾ notifications) involving fishery products manufactured in/by Italian operators.

⁽³⁾ Audit reference number DG(SANTE)/2019-6747, and report available at: <https://ec.europa.eu/food/audits-analysis/audit-report/details/4159>.

⁽⁴⁾ List of approved establishment according to Regulation (EC) 853/2004 available at: <https://www.salute.gov.it/consultazioneStabilimenti/ConsultazioneStabilimentiServlet?ACTION=gestioneSingolaCategoria&idNormativa=2&idCategoria=8>.

⁽⁵⁾ Report submitted by Italy in accordance with Article 113(1) of Regulation (EU) 2017/625, in line with the standard model adopted following Article 113(2) of the same Regulation.

⁽⁶⁾ European Commission, EFSA, EFTA Surveillance Authority, EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

| iRASFF notifications by: | | Year | | | | |
|--|-------------------------------|------|------|------|------|-------|
| Product category | Type | 2020 | 2021 | 2022 | 2023 | Total |
| Cephalopods and products thereof | Heavy metals (cadmium) | | 4 | | 1 | 5 |
| | Rupture cold chain | | | | 1 | 1 |
| Total for cephalopods and products thereof | | | 4 | | 2 | 6 |
| Crustaceans and products thereof | Additives | | | | 1 | 1 |
| | Heavy metals | | 1 | | | 1 |
| Total for crustaceans and products thereof | | | 1 | | 1 | 2 |
| Fish and fish products | Histamine | | 1 | | 3 | 4 |
| | Additives | | 3 | 2 | | 3 |
| | Heavy metals | 1 | 5 | 3 | 3 | 12 |
| | <i>Listeria monocytogenes</i> | 1 | 2 | | | 3 |
| | Establishment not approved | | | | 3 | 3 |
| | Parasites | | | | 1 | 1 |
| | Foreign bodies | 1 | 1 | | 0 | 2 |
| Total for fish and fish products | | 3 | 12 | 9 | 6 | 30 |
| Grand Total | | 3 | 17 | 9 | 9 | 38 |

Section 5.4 below describes how the competent authority handles RASFF notifications.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements

Articles 4, 5, 6, 8, 11, 12, 18(10), 28 to 33, and 139 of Regulation (EU) 2017/625.

Findings

Structure and Organisation

- As indicated in the Italian multi-annual national control plan (MANCP) 2023-2027 (available at: [Multi-year National Control Plan 2023-2027 \(salute.gov.it\)](https://salute.gov.it)), the competent authorities for the food safety aspects of fishery products, and their official control system, are defined in Article 2 of Legislative Decree No. 27 of 2 February 2021 "Provisions for the adaptation of national legislation to the provisions of Regulation (EU) 2017/625 pursuant to Article 12, letters a), b), c), d) and e) of Law no. 117 of 4 October 2019.". They consist of

(7) 'iRASFF' means the electronic system implementing the RASFF and Administrative Assistance and Cooperation (AAC) procedures described in Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, and in Articles 102 to 108 of Regulation (EU) 2017/625 respectively.

the Ministry of Health (the national level), 19 regions and two Autonomous Provinces of Trento and Bolzano (the regional/provincial level), and the different Local Health Units (*Aziende Sanitarie Locali* – ASL) (the local level).

2. The structure, organisation and responsibilities of each of the authorities identified above is described both in the MANCP 2023-2027 and the country profile for Italy – control systems, last updated January 2024 ⁽⁸⁾ (hereinafter “the country profile”).
3. The Ministry of Health was recently reorganised. The Directorate-General for Food Hygiene, Food Safety and Nutrition (DGFHFSN), which was under the Secretariat General of the Ministry of Health, is now replaced by a Directorate General for Hygiene and Food Safety (DGHFS), which is now under the Department of Human Health, Animal Health and Ecosystem (One Health), and International Relations ⁽⁹⁾. Office 2 of the DGFHFSN is now part of DGHFS and remains in charge of food hygiene at national level.
4. The former Offices of DGFHFSN remain with the same structure, organisation, and responsibilities, with Office 2 (steering the control system, management of information system for registration and approval), Office 3 (audits), Office 6 (contaminants control plan and designation of laboratories) and Office 8 (MANCP coordination and iRASFF) being the ones relevant for the scope of the current audit. In the specific case of fishery products, Office 2 is in charge of the approval of freezer, factory and reefer vessels and the implementation of the official controls of such vessels.
5. The structure and organisation of the competent authority in the region visited during the audit are aligned with the description made in the country profile. This region is divided into three ASL (in the region visited it is designated as AUSL (*Azienda Unità Sanitaria Locale*)), which in turn are organised into different services – Areas A, B and C. As regards fishery products, the official controls are implemented by Area B concerning all registered and approved operators, except aquaculture farms. The latter are controlled by Area C for hygiene and food safety requirements (being those relevant for as regards Regulation (EC) No 852/2004).
6. As indicated in the MANCP and the country profile, the relations and coordination between the State (national level) and the regions are managed through the State-Regions Conference.
7. There are no official controls or official controls tasks delegated to entities or bodies, other than the designated authorities.

Powers, Independence, Transparency, Penalties and Supervision

8. In the region visited, and as regards the fishery products sector, all staff involved in the official controls are civil servants. They have the necessary powers to have access to premises, products and documentation relevant for their controls. These staff are required to

⁽⁸⁾ Available at: <https://ec.europa.eu/food/audits-analysis/country/profile/details/IT>.

⁽⁹⁾ Organigram available at: https://www.salute.gov.it/portale/ministro/p4_5_5_1.jsp?lingua=italiano&label=org&menu=organizzazione.

comply with a Code of Conduct (Republic President Decree No. 62 of 16 April 2023), which prescribes their obligations in terms of independence, absence of conflict of interest and involvement in other activities. Moreover, the public administrations also have the obligation to map their risks of corruption and have appropriate preventive measures in place. As consequence, there is a policy to rotate officials within a defined timeframe (every 3 years in the region visited during the audit) amongst the operators/facilities to be controlled.

9. The transparency of the official controls is ensured by the publication of the annual reports of the MANCP. At the same time, confidentiality of the information gathered during the official control tasks is ensured.
10. The necessary legal instruments are in place, Legislative Decree No. 193/2007, to impose penalties when infringements are detected in relation to EU food law.
11. The competent authorities avail of a range of mechanisms to check the implementation of the controls and adherence to the defined procedures. These include audits of the Regions carried-out by Office 3 of DGHFS, internal audits carried out by the regional services and supervision carried out by ASL staff of officials performing the official controls.
12. Office 3 provided the audit team with detailed information on the audits carried out from 2003 to 2023 ⁽¹⁰⁾, demonstrating that the national level carries out system and sectorial audits to the regional levels. Currently, and since 2018, the third cycle of audits is being implemented. The two previous cycles covered roughly 2003 to 2010, and 2011 to 2017. According to the information made available, system audits were completed for all regional levels in the first cycle ⁽¹¹⁾ and there are still five regional levels not covered in the second cycle. As regards the sectorial audits for fishery products, nine regional levels were audited in the first cycle, four in the second (two of which were also audited in the first cycle) and three are planned to be audited in the third cycle (during which one regional level will be audited for fishery products for the first time). Reports on these audits are drafted and include findings, recommendations, and action plans to address the recommendations.
13. In terms of supervision, the audit team noted in the region visited that all AUSLs had mechanisms in place to assess officials in terms of adherence to the procedures in place, knowledge relevant for the tasks assigned to the official and their ability to perform official controls adequately. This supervision is carried out every year of 33% (established target) of the officials, and it comprises a desk-based documentary assessment and shadow-visits (the supervisor accompanies the official during an official control visit). In the case where an official is assigned with several official control tasks (different sectors) it is envisaged that all tasks are covered by a supervision over a period of 5 years. This region also performs system audits to AUSLs once every 5 years and additional sectorial audits based on specific criteria.

⁽¹⁰⁾This information is also available for 2003 to 2022 at: https://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1556&area=sicurezzaAlimentare&menu=audit.

⁽¹¹⁾The system audits of the first cycle covered some of the local levels of a region and not the regional level *per se*.

Resources available, Training and Knowledge of official staff

14. The different levels of the authorities indicated that, in general, the number of staff available for the control tasks is adequate. However, in certain cases not all tasks are carried out as per the defined deadlines (in particular, those related to the approval of establishments and vessels, and official controls of approved vessels), mainly due to work overload linked with certification for exports and the displacement to international ports (for approved vessels).
15. Italy avails of a network of designated laboratories, the Zooprofilactic Institutes (*Istituti Zooprofilattici Sperimentali - IZS*) and associated field units, to perform analytical tests of official control samples. These IZS are also designated as the national reference laboratories for certain parameters and their work is coordinated/supervised by the National Health Institute (*Istituto Superiore di Sanità - ISS*), which is also the EU reference laboratory for parasites (e.g. *Anisakis*), *Escherichia coli* and chemical elements in food of animal origin.
16. As far as could be observed during the audit, official staff have appropriate and properly maintained facilities, means of transport and equipment that allowed them to perform their tasks adequately.
17. Italy has a robust and comprehensive training strategy in place for official control staff. It includes training provided within the services (e.g. by the national level on the guidelines and novelties on the EU-rules), by the IZS and by the Italian academia, as well as external training (e.g. the European Commission training initiative “Better training for safer food”). Official staff is required to attend training to achieve a defined number of credits within a fixed timeframe to ensure that they maintain their competencies. Staff interviewed by the audit team showed a good level of knowledge of the fishery products sector, the applicable legislation and the Italian procedures.

Documented procedures and Control Activities, methods and techniques

18. The national level has developed guidelines on the interpretation of the rules of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004. These concern the development of plans for the official controls, the frequency of controls, determined by a risk-based approach, and the need to use the adequate methods and techniques for official controls. This guidance is currently being updated to align with Regulation (EU) 2017/625 (which repeals and replaces Regulations (EC) No 854/2004 and 882/2004).
19. The national level also developed guidelines on the interpretation and application of Regulations (EC) Nos 852/2004 and 853/2004. This guidance is directed at both operators and official controls officials. The audit team noted certain unalignments of the guidelines with the EU requirements, which is described under paragraph 33 below.

20. Based on the requirements of the applicable EU food law and the guidance issued by the national competent authority, each region issues several documented procedures covering the registration/approval of establishments, development of the control plan of operators (inspections and audits), the control plan of fishery products (see paragraphs 69 and 70 below), supporting documents for the official controls (risk-based matrices, checklists, reports, follow-ups, non-conformity notices, etc.) and reporting procedures (to report the control numbers and results to the national authority). The audit team noted a shortcoming in the implementation of the procedures for registration/approval, which is described in section 5.2 below.
21. The audit team notes that Italy did not provide the information requested in the pre-audit questionnaire (e.g. lists of registered operators, training of staff, human resources available, documented procedures for official controls, and laboratories) for one of the regions, which also included the breakdown of the official controls carried out in that region (the Annual Reporting on Official Controls), neither did they provide the additional information requested for other four regions. This situation is in contravention with Article 119 of Regulation (EU) No 2017/625.

Conclusions on competent authorities

22. The designated competent authorities have a structure and organisation adequate for the implementation of the required official control systems (production chain and products).
23. Official control staff presented an adequate knowledge of the applicable requirements of the EU food law and avail of a laboratory network to test official control samples. The different levels of the competent authority have internal audits and mechanisms in place to supervise official control staff.
24. The official controls are carried out supported by, in general, adequate documented procedures. Certain shortcomings were noted concerning the implementation of the procedures for registration/approval and the interpretation of Regulation (EC) No 852/2004.

5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATOR ESTABLISHMENTS

Legal requirements

Article 6 of Regulation (EC) No 852/2004 of the European Parliament and of the Council.

Article 4 of Regulation (EC) No 853/2004 of the European Parliament and of the Council.

Article 10(2), 138(2)(j) and 148 of Regulation (EU) 2017/625.

Article 69 of Commission Implementing Regulation (EU) 2019/627.

Article 45 of Commission Implementing Regulation (EU) 2019/1715.

Findings

25. The registration/approval of establishments is carried out as described in paragraph 27 of the 2019 audit report. As indicated in that report, the procedures respect the applicable EU rules as follows: an approval is granted only after a successful on-site visit; a conditional approval may be granted (in accordance with the EU rules) and is valid for no more than 3 months for establishments on land and 6 months for vessels; the conditional approval may be extended following a new on-site visit for a maximum total period of 6 months for establishments on land and 12 months for vessels.
26. The lists of registered establishments, aquaculture farms, fishing vessels and landing sites, are available to the different levels of the competent authorities.
27. The list of approved establishments is managed in Italy through a centralised system, the Integrated System for Trade and Imports (*Sistema Integrato per gli Scambi e le Importazioni* - S.Inte.S.I.S.). Through this system Italy makes available the list of establishments approved in accordance with the EU food law, to all EU Member States. An approved establishment is placed in the list of approved establishments from the moment a conditional approval is granted. The information on the status of the approval (“conditional” versus “final”) is not visible on the list made available to the EU member states, but it is visible in the list available in S.Inte.S.I.S..
28. In this regard, the audit team noted that the information in S.Inte.S.I.S. shows that there are several establishments/vessels for which a conditional approval has been issued – according to the table provided there are currently 2 factory vessels, 52 freezer vessels, and 80 establishments on land which have a conditional approval. In 57 cases (establishment on land), those conditional approvals were issued more than 6 months ago. For 53 approved vessels, the conditional approval was granted more than one year ago. Therefore, the information existing in S.Inte.S.I.S. suggests that the deadlines applicable to the conditional approval to establishments on land and vessels were not respected.
29. For the region visited during the audit, the current S.Inte.S.I.S. list identifies two establishments on land and one freezer vessel with a conditional approval. One of the establishments on land was granted the conditional approval in January 2022 and the other in July 2023. The freezer vessel has a conditional approval since July 2020. However, only the establishment that was approved in July 2023 is actually conditionally approved. The other two cases result of incorrect records in the database, and both have a valid “final” approval.
30. The competent authorities indicated that some of the cases indicated in paragraph 28 above result of incorrect recording of the information in S.Inte.S.I.S., while others, in particular for approved vessels, result of difficulties in carrying out the official visits. In the case of the establishment on land of the region visited, the shortcoming was caused by a cessation of the activity of the establishment during the period of conditional approval, which led to an overlook of the 6 months period.

31. Further discussions with the competent authorities revealed that Italy does not currently adequately implement the procedure for granting a conditional approval. Actually, the 3 months initial period for the conditional approval is always extended to 6 months, even without an on-site visit to verify progress on the points that were not in compliance with the EU rules at the time of the first on-site visit. The priority is to conclude the approval process and to grant the “final” approval within the 6 months. A similar situation is applied to vessels, being that the 6 months period is also extended without an on-site visit. The competent authorities indicated that shortage of staff and the need to prioritise other tasks leads to the adoption of this practice. This approach is not in line with Article 148(4) of Regulation (EU) 2017/625.
32. In addition to the above the audit team noted that for freezer vessels the period of 6 months for the conditional approval is extended to 12 months without an on-the-spot assessment. In some cases, the conditional approval is also extended over the 12 months period. Both situations are not in line with Article 148(4) of Regulation (EU) 2017/625.
33. In respect of registration of establishments and activities subject to registration, the audit team noted that the guidance document on Regulations (EC) Nos 852/2004 and 853/2004, issued by the national competent authority both to assist operators requesting registration/approval of their facilities and to assist officials in the performance of their official tasks, is not aligned with the EU rules, as follows:
 - a. Contrary to point 4(b) of Section VIII of Annex III to Regulation (EC) No 853/2004, Italy considers the removal of skin of the fish (*Selachii* species) as an operation (associated operation) included in the primary production sector. This type of activity should only be allowed on approved vessels/establishments.
 - b. Contrary to point 4(b) of Section VIII of Annex III to Regulation (EC) No 853/2004, Italy considers that the associated operations allowed on board fishing vessels can also be carried out in an establishment of an aquaculture farm as a primary production activity and covered solely by the registration of the aquaculture farm. An establishment of an aquaculture farm can perform this type of activities only if that establishment has been approved as required by Article 4(1)(b) of Regulation (EC) No 853/2004.

Conclusions on registration/approval of food business operator establishments

34. The procedures adopted to register/approve establishments are broadly in line with the applicable rules of the EU food law. Nevertheless, the guidance issued by the national competent authority allows registered vessels to perform activities that can only be carried out in approved vessels and allows establishments of aquaculture farms to operate without the necessary approval (only being registered).
35. The procedures related to the approval of establishments are not implemented as required by Article 148(4) of Regulation (EU) 2017/625 in respect of the renewal of the period of time for conditional approval and in terms of respecting the maximum period of time for that conditional approval.

5.3 OFFICIAL CONTROLS

5.3.1 Official controls on the production and placing on the market

Legal requirements

Article 4 and 5 of Regulation (EC) No 852/2004.

Article 3, Annex II, and Section VIII of Annex III to Regulation (EC) No 853/2004.

Commission Regulation (EC) No 2073/2005.

Section I of Annex II to Commission Regulation (EC) No 2074/2005.

Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011

Articles 9 (1) and (4-6), 10(1), 13, 14, 15, 18(1) and 18(8)(f), 137 and 138 of Regulation (EU) 2017/625.

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

Findings

36. The national competent authority developed a guideline for the official controls required by the applicable EU rules (see paragraph 18 above). This guideline is currently being updated (the EU legal basis/references changed), but it can still be considered adequate as regards the fishery products sector (as indicated in the 2016 and 2019 audit reports).
37. The control system covers the entire production chain – from the (primary production) fishing vessels/aquaculture farms to the establishments on-land (before retail) – and it is implemented using several written procedures. These written procedures are developed by each regional competent authority and implemented by the local competent authorities.
38. For primary production fishing vessels, and for aquaculture farms, the control frequency is set, at national level, at one visit every 5 years. The controls of these operators are carried out by the local authorities.
39. As regards freezer vessels, the control frequency is also set at one visit every 5 years. However, these controls are carried out by the national competent authority.
40. The control frequencies for the establishments on land are defined by the regional authorities, following the national guidelines (see paragraph 36 above). In the region visited during the audit, the regional competent authority defined three risk categories (low, medium and high) and specified the frequency of the controls as follows:
 - a. Audits – once every 3 years, except for category 0 establishments (i.e. cold stores);

- b. Low risk establishments – 4 inspections per year, which must cover a complete assessment of all the relevant topics;
- c. Medium risk establishments – 8 inspections per year, which must correspond to 2 complete assessments of all the relevant topics;
- d. High risk establishments – 12 inspections per year, which must correspond to 3 complete assessments of all the relevant topics.

Primary production fishing vessels

- 41. The audit team visited one primary production fishing vessel and noted that the procedures for the controls have been correctly implemented and the control frequency has been respected. This vessel is also an approved freezer vessel, but currently only carries out primary production activities – fishing, addition of additives to fresh fishery products (crustaceans), chilling and unloading of fresh/chilled fishery products.
- 42. With regard to the addition of sulphites on board primary production fishing vessels, the audit team noted that the guidance document on Regulations Nos 852/2004 and 853/2004 (see paragraph 19 above) allows this practice under certain conditions: recording by the fisherman of the use of the additive; indication on the landing document of the use of the additive; and, existence of a label, or a specific indication, to be kept up to retail and sale to the final consumer.
- 43. During the visit to the vessel, as well as during the visit to the auction hall and other establishments on land, the audit team noted that products treated with additives (sulphites) were accompanied by documents indicating this treatment. Moreover, on board the vessels, there was a simplified written procedure on how the treatment should be done. Nevertheless, the audit team noted that the time for the treatment (immersion time) was not clearly defined in the simplified procedure (it was set as “a couple of minutes”), there were no records of the treatment itself (quantity of products treated and time of treatment), no availability of a device to measure the time, and no records of past analytical tests to demonstrate compliance of the products with the maximum allowed levels set in the EU rules. In addition, the audit team was not provided with evidence of the validation of the treatment procedure.
- 44. The audit team found the guidance document of the national authority as suitable for use by the local authorities to verify and enforce the rules of Regulation (EC) No 1169/2001, in particular its Article 9(1)(c) regarding labelling information. However, the measures in place do not allow for the verification and enforcement of the rules set in Regulation (EU) 1333/2008, regarding the maximum permitted levels.
- 45. The audit team also reviewed the information provided by the national competent authority with regard to controls carried out (annual report on official controls – see section 4.2 above). The global figures for Italy show that overall 19% of the primary production fishing fleet was controlled in 2022 (1 148 out of 5 964 registered fishing operators (mainly fishing vessels)), which can be considered as being equivalent to one control every 5 years).

However, taking also into account the EUROSTAT figures, this percentage of cover drops to less than 10%.

46. Moreover, for the region visited during the audit, the figures provided by the fisheries authorities (595 fishing vessels) do not match those provided by the regional authorities (337 fishing vessels). For this specific region, and based only on the figures of the annual report on official controls, 17% of the fishing vessels were controlled in 2022.
47. Despite the differences of data provided in the annual report on official controls with other sources of information (see 4.2 above), the figures show that, overall, Italy does not comply with the frequency defined for the control of fishing vessels. Excluding the six landlocked regions, the data from the annual report on official controls suggests that one third of the remaining regions achieve or exceed the frequency defined for the controls, and two thirds do not respect the frequency.
48. The lack of adherence to the frequency defined for the controls of primary production fishing vessels was already identified in the 2019 audit report, which contained a recommendation in this regard (recommendation No 1). This recommendation has not been adequately addressed.

Aquaculture farms

49. The audit team visited one aquaculture farm and noted that the procedures for the controls have been correctly implemented and the control frequency has been respected. Minor shortcomings in relation to the recording of fish mortality in ponds were discussed with the local competent authority. The remaining farm records were adequate and fit for purpose.

Freezer/factory vessels

50. The national competent authority indicated that the frequency for the controls of certain approved vessels (mainly freezer) is not respected due to the shortage of staff available for those controls, the remote location of the ports where the vessels may land, and the unpredictable working pattern of the vessels.
51. The fishing vessel visited during the audit is actually an approved freezer vessel. However, due to matters related to fisheries policy, the operator does not currently avail of enough raw materials to conduct freezing operations. This situation is a longstanding one and does not allow the operator to demonstrate compliance with all the applicable requirements that allowed the vessel to be approved as a freezer vessel – the audit team noted that, in principle, the structural conditions of the freezing room comply with the applicable EU requirements, but it cannot be established that the freezing equipment is operational and that it works as required. Consequently, the operator does not have production records showing adherence to the applicable rules.
52. The national competent authority did not control this freezer vessel as required by the Italian procedures and by Article 67(b)(i) of Regulation (EU) 2019/627. Moreover, this vessel changed ownership in 2020 and the approval was transferred to the new owner

without an on-the-spot visit to ascertain that the initial approval conditions are still respected and have not been changed.

53. The national competent authority indicated that the situation, described in paragraph 51 above, is shared by many operators of crustacean freezer vessels and that the Italian rules will preclude the option to suspend the approval. According to these rules, a suspension of the approval is limited to a certain amount of time, after which the approval is either reinstated or is withdrawn. While understanding the limitations of the Italian provision, the audit team also considers that the current situation is not in line with the EU rules, namely Article 67 of Regulation (EU) 2019/627 and Article 148 of Regulation (EU) 2017/625.

Landing operations, landing and first sales sites (auction hall)

54. The audit team visited one landing site and one auction hall (including the respective landing site) and found them adequate for the operations that take place there.
55. The competent authorities provided evidence of controls that take place at landing, which would include the controls foreseen in Article 67(a) of Regulation (EU) 2019/627. In general, the controls of landing take place when there is the unloading of fishery products from the vessels, therefore it is not possible to establish a set frequency. In the region visited, the local authorities provided the audit team with records of several controls performed each year for the past 3 years.
56. With regard to the auction hall, the audit team noted that it has been controlled following the defined frequencies (four visits per year, which covered all the relevant control subjects within that year) and by using the relevant written procedures (including checklists, report and follow-up on correction of deficiencies detected during the controls).

Facilities on land, handling fishery products

57. The audit team visited five establishments on land and found four of them to be broadly compliant with the applicable EU rules.
58. The audit team noted that the applicable written procedures were adequately implemented, the relevant documents were used (checklists) and issued (inspection reports). When deficiencies were detected, the inspection reports required their correction within defined deadlines. Where necessary, follow-up inspections were carried out. The competent authority also provided evidence of enforcement measures in case of repeated non-compliances, which included the update of the risk classification (triggering an increased frequency for the controls) and financial penalties (fines).
59. Despite good implementation of the official controls, the audit team found shortcomings with regards to the drafting and implementation by the operators of shelf-life studies for ready-to-eat products that are able to support the growth of *Listeria monocytogenes*, as required by Article 3 of Regulation (EC) No 2073/2005. At the same time, the different local authorities did not take the same approach for assessing those studies (see below).

60. In one of the three cases observed by the audit team, the operator had a shelf-life study for their products which was made in accordance with the applicable guidance and was adequate. In this case, the local competent authority official requested assistance from the relevant IZS to assess the shelf-life study. The IZS assessed the study and correctly concluded that the self-life study had been adequately developed and that the conclusions and proposed shelf-life were adequate and aligned with the applicable EU rules.
61. In two other cases, the shelf-life studies presented to the audit team were not satisfactory nor were the assessments made directly by the local competent authority officials adequate. The studies presented to the audit team (durability tests) were either incomplete or not suitable to validate the shelf-life of the products. Official control staff did not possess the expertise and specific knowledge for an in-depth assessment of the shelf-life studies to determine the adequacy of these studies.
62. In one of the five establishments visited, which had been relocated at the end of 2021, the audit team identified several non-compliances related to structures, equipment, hygiene, temperature records, HACCP and labelling. In this establishment, it was also confirmed that operators of primary production fishing vessel remove the skin of certain fish species (*Selachii* – see paragraph 33.a above), which should not be allowed for these registered operators. Following the audit visit, the local competent authority made a specific inspection to that establishment to make a detailed assessment, which allowed the identification of the deficiencies noted by the audit team and other additional shortcomings. A report of the inspection was issued to the operator, which included the request for the correction of all deficiencies within well-defined deadlines. Documentary evidence of this process was provided to the audit team by the competent authorities.
63. With the exception of the shelf-life studies, the audit team noted that the deficiencies associated with recommendation No 2 of the 2019 audit report have not been seen during the current audit and that those issues are actively checked during the official controls.

Conclusions on official controls on the production and placing on the market

64. Overall, the control system is implemented as planned, except for fishing (primary production) and freezer vessels.
65. The control procedures, on the use of sulphites by operators of primary production fishing vessels, do not cover all the relevant EU rules, in particular with regard to the maximum admissible levels for such additives, and are therefore not adequately checked by the competent authorities.
66. The control system, covering the establishments on land, presents gaps in relation to the ability to assess that operators have in place adequate shelf-life studies for ready-to-eat products that are able to support the growth of *Listeria monocytogenes*.

5.3.2 Official controls of fishery products

Legal requirements

Council Regulation (EC) No 2406/96.

Article 1 and Annex I to Regulation (EC) No 2073/2005.

Regulation (EC) No 1333/2008.

Commission Regulation (EU) 2023/915.

Article 18 of Regulation (EU) 2017/625.

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

Findings

67. During the official control activities, namely during the controls carried out at the landing of fishery products, the local competent authorities check fishery products to detect visible parasites and also perform organoleptic examinations. At the same time, a control is carried out to identify, and exclude from consumption, poisonous fishery products.
68. If the result of the organoleptic examinations reveals doubts on the fitness for human consumption of the fishery products, the officials can take samples and have access to the IZS laboratories to test those products for the freshness indicators.
69. The national level of the competent authority establishes an annual testing plan to be implemented by the regions and covering all the relevant parameters defined in the EU food law, such as environmental contaminants (heavy metals, dioxins, polycyclic aromatic hydrocarbons (PAH) and polychlorinated biphenyls (PCBs)), microbiological criteria (*Salmonella* and *Listeria monocytogenes*) and histamine.
70. This annual plan determines the total number of tests that each region must carry out on fishery products. The total number of tests is divided as follows: 45% of tests performed from samples taken from the production sector and 45% from the distribution sector. The remaining 10% are, by default, to be taken from the distribution sector, but each region decides the best allocation of these 10%.
71. From the total number of tests allocated to each region, their regional authorities decide the actual distribution by the relevant parameters. Different tests can be performed on the same sample.
72. With regard to environmental contaminants, following the entry into force of Commission Implementing Regulation (EU) 2022/931 of June 2022 and Commission Implementing Regulation (EU) 2022/932, Italy submitted its control plan for 2023 to the Commission services and it will soon submit the plan for 2024, which will already include sampling of fishery products to be tested for perfluoroalkyl substances.

73. The competent authority of the region visited provided the audit team with the regional sampling plan stemming from the national plan. The samples assigned to the region are then distributed by the different ASLs. The audit team noted that, in cases that could not be justified by the small number of samples, or the specificity of the parameter (e.g. environmental contaminants), the national instruction to distribute 45% of the samples at production and 45% at distribution, has not been followed. As examples, testing for histamine is only carried out on samples from the distribution sector, and the same for testing for *Listeria monocytogenes* in ready-to-eat food.

Conclusions on official controls of fishery products

74. The competent authorities implement adequately an annual testing/sampling plan that covers all the relevant parameters of the EU food law applicable to fishery products.
75. However, the non-adherence by the regional authorities to the distribution of samples defined by the national authority casts doubt on the complete adequacy of the regional control plan to achieve the objectives of the official controls set in the EU food law (verification of compliance with the applicable rules).

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.

Articles 1(a), 2, 4, 12 to 22 and 25 of Implementing Regulation (EU) 2019/1715.

Findings

76. The Office 8 of DGHFS is the national contact point in Italy for the iRASFF notifications. Each region/province is required to have its own contact point. The contact point at ASL level is decided upon following an instruction from the regional/provincial level.
77. The national level issues guidelines on the handling of iRASFF notifications and management of the network in Italy. These guidelines were last issued within the Conference State/Regions in May 2021. The guidelines describe the responsibilities of each authority level, as well as the flow of communication and actions to be taken following a notification.
78. The authorities of the region visited indicated that, in addition to having access to the iRASFF portal, they also use their own information systems to manage the notifications and to record additional information. The use of this information system allows the competent authorities to expedite the exchange of relevant information and to better handle the follow-up of notifications.

79. During the audit visits, the competent authorities provided information showing how the iRASFF notifications have been handled and what measures were taken to address them. The competent authorities requested the relevant operators to investigate the possible causes for the notification and how the reoccurrence of such notifications could be prevented. Where necessary, the measures taken by the relevant operators included product recall and withdrawal from the market. The competent authorities would then assess if the investigations were adequately performed and, if necessary, would impose additional measures (such as additional sampling and/or control visits). The cases showed to the audit team were adequately handled both by the authorities and the operators involved.

Conclusion on follow up of iRASFF notifications

80. Italy has adequate procedures in place to create and to handle iRASFF notifications, as required by the EU rules and respecting those rules.

5.5 LABORATORIES

Legal requirements

Annex I to Regulation (EC) No 2073/2005.

Commission Regulation (EC) No 333/2007.

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

Commission Regulation (EU) 2017/644.

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

Findings

81. Italy has a laboratory network of ten IZS and one ISS capable of testing official control samples. Additionally, laboratories of the Regional Environmental Protection Agencies can be used to test official control samples for dioxins and polychlorinated biphenyls.
82. The IZS laboratories have been designated for testing official control samples. ISS supervises the IZS laboratories and carries out confirmatory analytical tests. ISS is the EU reference laboratory for parasites (in the case of fishery products the most relevant one is Anisakis) and the Italian national reference laboratory for metals and nitrogen compounds in food.
83. The ten IZS cover one or more regions of Italy. They consist of central laboratories (one for each IZS) and associated peripheral sections (at province level).

84. According to the information provided by Italy in the response to the pre-audit questionnaire ⁽¹²⁾ nine of the ten IZS can test official samples of fishery products for the parameters defined in Annex VI to Regulation (EU) 2019/627, as follows:
- For cadmium, lead and mercury – nine IZS and three IZS sections;
 - For tin – five IZS and one IZS section;
 - For PAH – six IZS;
 - For dioxins and PCBs – three IZS;
 - For histamine – seven IZS and three IZS sections;
 - For microbiological criteria (*Listeria monocytogenes* and *Salmonella*) - nine IZS and four IZS sections.
85. IZS laboratories are accredited to ISO/IEC 17025, the scope of which accreditation includes the relevant analytical testing methods, and they participate regularly in proficiency tests with satisfactory results.
86. With regard to the analytical methods for testing official control samples for the quantification of the level of heavy metals, the audit team noted that for one IZS the limit of detection of the method for cadmium does not respect the EU rules, in particular table 5 of point C.3.3.1 of Part C of the Annex to Regulation (EC) No 333/2007. The same finding was noted for another IZS in the case of the limit of detection for the method for lead.
87. The analytical methods used by the different laboratories to test fishery products for histamine are always internal methods and include: ELISA methods for screening tests; HPLC-UV; HPLC-DAD; HPLC-TL; and LC-MC/MS. This information will be included in a future control of DG Health and Food Safety designed specifically to assess the implementation of the requirements of the food law concerning the control of histamine in fishery products. Therefore, no further conclusions and/or recommendations will be included in the current audit report.
88. For the IZS covering two regions, the audit team did not receive the information requested in the pre-audit questionnaire (see paragraph 21 above).

Conclusions on laboratories

89. Italy uses a network of designated laboratories for testing official control samples, capable of ensuring, by and large, the reliability of the test results.
90. However, and specifically for the testing of fishery products for cadmium in one IZS and for lead in one IZS, that reliability can be compromised by EU rules not being respected in relation to the EU rules on the limits of detection of the analytical methods used for that testing.

⁽¹²⁾The initial information provided was supplemented with the information from the Italian accreditation body, Accredia, which is available at: https://services.accredia.it/accredia_labsearch.jsp?ID_LINK=1734&area=310&dipartimento=L&desc=Laboratori.

5.6 FOLLOW-UP

The table below summarises the follow-up to the relevant recommendations made in report reference number DG(SANTE) 2019-6747:

| <i>No</i> | <i>Previous recommendation</i> | <i>Assessment</i> |
|-----------|--|---|
| No 1 | <p>While performing the official controls of primary production fishing vessels, the competent authority should ensure adherence to the frequencies set in the official control plans, drafted and adopted in accordance with the applicable EU rules, in particular Article 3(1) of Regulation (EC) No 882/2004.</p> <p>Recommendation based on conclusion No 48.</p> <p>Associated finding Nos 31 and 33.</p> | <p>Not addressed.</p> <p>See findings Nos. 45 to 48 above.</p> <p>See recommendation No. 3 of the current audit report.</p> |
| No 2 | <p>The competent authority should verify effectively that approved establishments comply with relevant requirements of Regulation (EC) No 852/2004 and Annex II of Regulation (EC) No 853/2004, in particular, cold stores equipped with temperature recording devices, hygienic ice production on board vessels and applicable microbiological criteria.</p> <p>Recommendation based on conclusion No 49.</p> <p>Associated findings Nos 34, 40 and 41.</p> | <p>Partially addressed.</p> <p>See finding No. 63 above.</p> <p>See recommendation No. 6 of the current audit report.</p> |

6 OVERALL CONCLUSION

Overall, the organisation and operation of the official control system put in place by the Italian competent authorities largely meet the requirements of the relevant EU law, it is correctly implemented in the vast majority of the cases and it is effectively enforced.

The official control system in place is well organised, risk based, covers completely the

production chain and it is supported by extensive and detailed written instructions/guidance. The guidance document for fishery products is not fully aligned with the EU rules in certain particular aspects related to primary production.

The control system is implemented by and large adequately as required by the EU rules, by knowledgeable staff, in accordance with the adopted procedures and the defined frequencies.

However, the control frequencies for primary production fishing vessel and for approved fishing vessels are not respected. Moreover, the procedures for granting the conditional approval and subsequent “final” approval are not always correctly implemented. The approach on the assessment of shelf-life studies is not consistent between the local authorities within the same Region – one of the approaches can be considered the most appropriate one.

The situation observed during the audit suggest that the weaknesses identified above have a limited impact in the overall objective of the official control system governing the production and placing on the market of fishery products.

7 CLOSING MEETING

During the closing meeting held by video conference on 13 March, the audit team presented the main findings and preliminary conclusions of the audit to the competent authorities.

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

8 RECOMMENDATIONS

The competent authority should provide Commission services with an action plan, including a timetable for its completion, within 25 working days of receipt of the translated draft report, intended to address the shortcomings identified and, in particular, the following recommendations:

| No. | Recommendation |
|------------|--|
| 1 | The national competent authority should ensure that the national guidance for fishery products as regards Regulations (EC) Nos 852/2004 and 853/2004 is fully aligned with those regulations. In particular, that it respects Article 4(b) of Section VIII of Annex III to regulation (EC) No 853/200, in relation to the operations that are allowed to be carried out by registered operators (primary production fishing vessels and aquaculture farms) in order to support adequately operators and officials when registering, and controlling, those registered operators. |

| No. | Recommendation |
|-----|--|
| | <p><i>Recommendation based on conclusions Nos 24 and 34.</i></p> <p><i>Associated findings Nos 19, 20 and 33.</i></p> |
| 2 | <p>The competent authorities should ensure that the approval procedures are implemented as planned and that the requirements of Article 148(4) of Regulation are fully respected and implemented.</p> <p><i>Recommendation based on conclusions Nos 24 and 35.</i></p> <p><i>Associated findings Nos 14, 20, 28 to 32.</i></p> |
| 3 | <p>The competent authorities should ensure that primary production fishing vessels are controlled regularly as required by Article 67(b) of Regulation (EU) 2019/627, and in accordance with the frequencies defined in the Italian control programme.</p> <p><i>Recommendation based on conclusion No 64.</i></p> <p><i>Associated findings Nos 45 to 48.</i></p> |
| 4 | <p>The competent authorities should ensure that the control over operators of primary production fishing vessels covers all the relevant aspects to verify that operators guarantee compliance of fishery products with the maximum permitted level for additives (sulphites) defined in Regulation (EC) 1333/2008.</p> <p><i>Recommendation based on conclusion No 65.</i></p> <p><i>Associated findings Nos 42 to 44.</i></p> |
| 5 | <p>The national competent authority should ensure that freezer vessels are controlled regularly as required by Article 67(b) of Regulation (EU) 2019/627, and in accordance with the frequencies defined in the Italian control programme. This control should also ensure that, as required in Article 148(3) of Regulation (EU) 2017/625, the vessels are approved, and maintain the approval, only if the food business operator has demonstrated that it complies with the relevant requirements of food law.</p> <p><i>Recommendation based on conclusion No 64.</i></p> <p><i>Associated findings Nos 14, 50, 52 and 53.</i></p> |
| 6 | <p>The competent authorities should ensure that, during the official controls to verify compliance of the operators with the applicable requirements, the shelf-life studies required under Article 3 of Regulation (EC) No 2073/2005 are assessed adequately and by staff in possession of the specific knowledge necessary for that</p> |

| No. | Recommendation |
|-----|---|
| | <p>assessment.</p> <p><i>Recommendation based on conclusion No 66.</i></p> <p><i>Associated findings Nos 59 to 61.</i></p> |
| 7 | <p>The competent authorities should ensure that the distribution of the official control samples is carried out in accordance with the guidelines issued by the national competent authority, which were adopted based on a risk assessment and to verify compliance of fishery products with the applicable EU rules.</p> <p><i>Recommendation based on conclusion No 75.</i></p> <p><i>Associated findings Nos 70 and 73.</i></p> |
| 8 | <p>The competent authorities should ensure that the laboratories designated to test official control samples use analytical methods that comply with the EU rules concerning the performance criteria of the methods, defined in table 5 of point C.3.3.1. of part C of the Annex to Regulation (EC) No 333/2007, in order to guarantee the reliability of the test results.</p> <p><i>Recommendation based on conclusion No 90.</i></p> <p><i>Associated finding Nos 86.</i></p> |

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2024-8018

ANNEX 1 - LEGAL REFERENCES

| Legal Reference | Official Journal | Title |
|-----------------|--|---|
| Dir. 2020/2184 | OJ L 435, 23.12.2020, p. 1-62 | Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) |
| Reg. 2406/96 | OJ L 334, 23.12.1996, p. 1-15 | Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products |
| Reg. 178/2002 | OJ L 31, 1.2.2002, p. 1-24 | Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety |
| Reg. 852/2004 | OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3 | Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs |
| Reg. 853/2004 | OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22 | Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin |
| Reg. 2073/2005 | OJ L 338, 22.12.2005, p. 1-26 | Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs |
| Reg. 2074/2005 | OJ L 338, 22.12.2005, p. 27-59 | Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 |
| Reg. 333/2007 | OJ L 88, 29.3.2007, p. 29-38 | Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs |

| Legal Reference | Official Journal | Title |
|------------------------|--------------------------------|--|
| Reg. 1333/2008 | OJ L 354, 31.12.2008, p. 16-33 | Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives |
| Reg. 931/2011 | OJ L 242, 20.9.2011, p. 2-3 | Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin |
| Reg. 1169/2011 | OJ L 304, 22.11.2011, p. 18-63 | Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 |
| Reg. 2017/625 | OJ L 95, 7.4.2017, p. 1–142 | Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) |
| Reg. 2017/644 | OJ L 92, 6.4.2017, p. 9–34 | Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014 |

| Legal Reference | Official Journal | Title |
|------------------------|--------------------------------|---|
| Reg. 2019/627 | OJ L 131, 17.5.2019, p. 51–100 | Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls |
| Reg. 2022/931 | OJ L 162, 17.6.2022, p. 7–12 | Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food |
| Reg. 2022/932 | OJ L 162, 17.6.2022, p. 13–22 | Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation |
| Reg. 2023/915 | OJ L 119, 5.5.2023, p. 103–157 | Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 |