FINAL REPORT OF AN AUDIT
CARRIED OUT IN
TUNISIA
FROM 17 SEPTEMBER 2019 TO 26 SEPTEMBER 2019
IN ORDER TO
EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF FISHERY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN UNION
Executive Summary

This report describes the outcome of an audit in Tunisia carried out from 17 to 26 September 2019, as part of the published Directorate-General for Health and Food Safety audit programme.

The objectives of the audit were to evaluate whether the official controls put in place and implemented by the competent authority can guarantee that the conditions of production of fishery products in Tunisia destined for export to the European Union are in line with the requirements laid down in European Union legislation, and in particular with the health attestations contained in the model health certificate of Appendix IV to Annex VI to Regulation (EC) No 2074/2005. In this context, the audit team also assessed the extent to which the corrective actions submitted to the Commission services in response to the recommendations following the previous 2011 fishery products audit, were implemented, and the effectiveness of these actions in addressing the identified deficiencies.

The audit concluded that the official control system developed by the competent authority is based on adequate procedures and legislation aimed at providing the guarantees required by the European Union model export health certificate. The system as designed covers the entire production chain as well as the associated European Union food safety requirements, and can also ensure that imported raw materials for processing are equally eligible for the European Union. However, and in terms of its implementation in practice, the audit team found that the controls are not consistently carried out in line with the established frequencies, and moreover did not identify and/or record relevant and systemic deficiencies at facilities listed for European Union exports.

These shortcomings impact, to a certain extent, on the ability of the competent authority to provide consistently, and in full, the guarantees as set out in the European Union health certificate.

In respect of the follow-up to the two recommendations made following the 2011 audit and relevant for this audit, the audit team found that the announced corrective measures were satisfactorily implemented and effective for one, but not for the other concerning the assurance that only fully compliant establishments should be listed as eligible for exports to the European Union.

The report contains recommendations to the Tunisian competent authorities to address the identified shortcomings.
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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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<tr>
<td>APA</td>
<td>Arrondissement for Animal Husbandry - <em>Arrondissement de la Production Animale</em></td>
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<td>CN</td>
<td>Combined Nomenclature</td>
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<tr>
<td>CRDA</td>
<td>Regional Commissariat for the Rural Development - <em>Commissariat Régional au Développement Agricole</em></td>
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<tr>
<td>DG SANTE</td>
<td>Directorate-General for Health and Food Safety</td>
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<tr>
<td>DGSV</td>
<td>Directorate General for Veterinary Services - <em>Direction Générale des Services Vétérinaires</em></td>
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<tr>
<td>EC</td>
<td>European Community</td>
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<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EU health certificate</td>
<td>Model health certificate for imports of fishery products intended for human consumption, as defined in Appendix IV to Annex VI to Commission Regulation (EC) No 2074/2005</td>
</tr>
<tr>
<td>EU-listed establishments</td>
<td>Establishments included in lists (EU-lists) made in accordance with Article 12 of Regulation (EC) No 854/2004 and available at <a href="http://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en">http://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en</a>, from which imports into the EU are permitted</td>
</tr>
<tr>
<td>EUROSTAT</td>
<td>The statistical office of the European Union</td>
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<tr>
<td>FBO/s</td>
<td>Food business operator/s</td>
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<tr>
<td>HACCP</td>
<td>Hazard analysis and critical control points</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>TRACES</td>
<td>Trade Control and Expert System</td>
</tr>
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</table>
1 INTRODUCTION

The audit took place in Tunisia from 17 to 26 September 2019, as part of the audit programme of the European Commission’s Directorate-General for Health and Food Safety. The audit team comprised two auditors from the Directorate-General.

An opening meeting was held in Tunis on 17 September with the competent authority, the Directorate General for Veterinary Services (DGSV - Direction Générale des Services Vétérinaires) of the Ministry of Agriculture, Water Resources and Fisheries (Ministère de l'Agriculture, des Ressources Hydrauliques et de la Pêche). At this meeting, the audit team confirmed the audit objectives and itinerary, and requested additional information on specific elements of the control system in place. Representatives from the competent authority accompanied the audit team throughout the audit.

2 OBJECTIVE AND SCOPE

The objective of the audit was to assess whether the official controls put in place and implemented by the competent authorities can provide adequate assurance that the conditions of production of fishery products in Tunisia and destined for export to the European Union (EU) are in line with the relevant requirements laid down in EU legislation, and in particular that it can attest to the requirements contained in the model health certificate for fishery products intended for the EU (as defined in Appendix IV to Annex VI to Commission Regulation (EC) No 2074/2005, hereafter: “the EU health certificate”).

In this context, the audit team also assessed the extent to which the corrective actions submitted to the Commission services in response to the recommendations following the previous 2011 fishery products audit (hereafter: "the 2011 audit") (1), were implemented, and the effectiveness of these actions in addressing the identified deficiencies.

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 (2) intended for export to the EU, and the operation of export certification procedures. Accordingly, relevant aspects of the EU legislation (3) listed in Annex 1 to this report were used as a technical basis for the audit.

In pursuit of the audit objective, the itinerary comprised the following visits:

<table>
<thead>
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<th>COMPETENT AUTHORITY</th>
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</thead>
<tbody>
<tr>
<td>Main headquarters</td>
</tr>
</tbody>
</table>

(2) Fishery products from wild caught fish and including all edible forms, parts and products of such animals, intended for EU export.
(3) EU legislation available at: http://eur-lex.europa.eu/homepage.html. Full legal references to EU legal acts quoted in this report are provided in the Annex 1 and refer, where applicable, to the last amended version.
Regional office 2

**PRIMARY PRODUCTION**

- Fishing vessels 5
- Auction halls 2

**FACILITIES HANDLING FISHERY PRODUCTS**

- Freezer vessels 5
- Processing Plants 7

### 3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, and in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

### 4 BACKGROUND

#### 4.1 GENERAL

Tunisia is included in Annex II to Commission Decision 2006/766/EC which sets out the list of third countries and territories from which imports of fishery products are permitted. It is also listed in Annex I of that Decision, for bivalve molluscs, and in the Annex to Commission Decision 2011/163/EU as having an approved residue monitoring plan for aquaculture products. The latter two categories of products were not within the scope of the audit. EU Member States are authorised to import fishery products from Tunisia from 320 EU-listed facilities (130 processing establishments and 190 freezer vessels). According to the competent authority 41 landing sites and 24 active auction halls are involved in the fishery products export chain.

The report of the 2011 audit made three recommendations to the competent authority, two of which are relevant to the scope of this audit. In response, the competent authority provided an action plan containing corrective actions to address them. These corrective actions were deemed, at the time and on paper, as satisfactorily addressing the recommendations. This report describes, where applicable and for these recommendations, the implementation of the corrective actions in the relevant sub-sections of Section 5.

#### 4.2 PRODUCTION AND TRADE INFORMATION

Data from EUROSTAT indicate that between 2013 and 2018, the EU imported 90,344 tonnes of fishery products (Combined Nomenclature (CN) codes 0301, 0302, 0303, 0304, 0305, 0306, 0307 and 1604) from Tunisia – roughly 15,000 tonnes/year. These imports included:

- 34.4 % cephalopods (0307 – mainly frozen);
- 32.3 % crustaceans (0306 – mainly frozen);

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(4) Establishments included in lists made in accordance with Article 12 of Regulation (EC) No 854/2004 and available at [http://ec.europa.eu/food/safety/international_affairs-trade/non-eu-countries_en](http://ec.europa.eu/food/safety/international_affairs-trade/non-eu-countries_en), from which imports into the EU are permitted – hereafter: “EU-listed establishments”.

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10.6% processed products (1604 – mainly anchovies); and, 5.3% live blue fin tuna (0301). The main importing EU Member States were Italy (63.7%) and Spain (26.7%). Live blue fin tuna was imported by Malta. For the same years and same CN codes, TRACES data suggest that the EU imported around 83,187 tonnes of fishery products from Tunisia. The audit team noted that the imports of live tuna (0301), around 4,800 tonnes, were not recorded in TRACES. This difference largely explains the discrepancy between the two data sources.

The audit team noted that, although mainly using the TRACES system for certification of exports to the EU, the figures provided by the competent authority for 2017 and 2018 do not match those of EUROSTAT or of TRACES. The competent authority pointed out that manual certification rarely takes place. Moreover, the audit team also noted that the competent authority did not issue certificates for live tuna (there is no such requirement under EU rules) and some consignments had been rejected at EU borders without the issuance of a RASFF notification. All of these factors contribute to explaining the discrepancies.

The Tunisian authorities stated that each year they imported approximately 1,200 tonnes of anchovies (mainly salted) from EU Member States for further processing and subsequent export to the EU.

### 4.3 Rapid Alert System for Food and Feed (RASFF) Notifications

Members of the RASFF network (5) issued 30 notifications for Tunisian fishery products between 2016 and mid-2019, as follows:

<table>
<thead>
<tr>
<th>Short description</th>
<th>Notifications</th>
<th>Product/issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heavy metals above the EU maximum admissible level in crustaceans</td>
<td>13</td>
<td>10 border rejections (cadmium in shrimps) 2 alerts (cadmium in crab, mercury in live lobster) and 1 information notice (mercury in chilled lobster).</td>
</tr>
<tr>
<td>Undeclared sulphites in crustaceans</td>
<td>1</td>
<td>1 information notice (sulphites in pink shrimp).</td>
</tr>
<tr>
<td>Heavy metals above the EU maximum admissible level in fish</td>
<td>8</td>
<td>3 border rejections (2 for lead, 1 for mercury) 5 information notices (4 for mercury, 1 for lead).</td>
</tr>
<tr>
<td>Histamine levels above the regulatory limits</td>
<td>6</td>
<td>1 border rejection (chilled sardines) 2 alerts (canned sardines) and, 3 information notices (chilled/vacuum packed sardine fillets).</td>
</tr>
<tr>
<td>Incorrect certification</td>
<td>2</td>
<td>2 border rejections (dispatch from a suspended establishment, and inconsistency between the EU health certificate and the products label.</td>
</tr>
</tbody>
</table>

Section 5.5 describes how the competent authority handled these RASFF notifications.

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(5) European Commission, EFSA, EFTA Surveillance Authority, EU Member States, Iceland, Liechtenstein, Norway and Switzerland.
5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements


Findings

1. The competent authority stated that, from the moment that Tunisia applied to export fishery products to the EU and its inclusion on the list of third countries from which EU Member States could import such products (6), that they have strived to draft, implement and maintain national legislation aligned with the EU rules for that sector.

2. The reports of the previous 2006 (7) and 2011 fishery products audits to Tunisia provide a short description and information concerning the Tunisian legislation applicable to fishery products to be exported to the EU.

3. The situation has not changed since the 2011 audit, and, as such, the different Ministerial Orders published in November 1995 and the Decree No 2001-622 of March 2001, as well as their subsequent amendments, are still valid. They cover both the requirements applicable to products to be exported to the EU and to their production chain and also the rules/principles to be followed by the competent authority while setting up and implementing an official control system. In addition, Tunisia also adopted other legal acts with updates/additional rules related to the official control system and the approval (as applicable) of production facilities (e.g. Ministerial Order of 26 May 2006).

4. The competent authority also publishes, as necessary, Service Notes that update or clarify the elements covered by the legal texts mentioned in paragraph 3.

5. The competent authority provided the audit team with a comprehensive list of the legal acts and Service Notes. The audit team noted that, the list matches the references made in the Manual of Procedures (19) for the official control of fishery products (hereafter: "the Manual of Procedures").

6. From the cursory assessment made to certain selected legal acts and the Manual of Procedures, the audit team noted that they encompass and are aligned with the relevant EU provisions.

(6) Commission Decision 97/296/EU.

Conclusions on Legislation

7. Tunisia adopted legislation encompassing the vast majority of the EU requirements applicable to fishery products to be exported to the EU.

8. These legal acts, which cover fishery products and their production chain, are appropriate for the implementation of an official control system aimed at providing the guarantees that are required by the EU health certificate.

5.2 COMPETENT AUTHORITY

Legal requirements

Article 46(1) of Regulation (EC) No 882/2004, in particular points (b) to (e).

Findings

Structure and organisation

9. The main competent authority is still the DGSV within the Ministry of Agriculture, Water Resources and Fisheries. Its structure and organisation has not changed since the 2011 audit.

10. DGSV organises, plans and provides instructions/guidance for the implementation of the official control system. This control system is implemented by the Arrondissement for Animal Husbandry (APA – Arrondissement de la Production Animale) of the Regional Commissariat for the Rural Development (CRDAs – Commissariat Régional au Développement Agricole). DGSV also has the duty to follow-up (supervise) and assess the implementation of the control system implemented by the APAs and participates in the approval of establishments (see paragraph 29). Each coastal CRDA (relevant for fishery products) has at least one veterinarian in charge of the fishery products chain in every APA.

11. The information contained in the reports of the 2006 and 2011 audits in relation to both the structure and the organisation of the competent authority remains valid.

Powers, Independence and Supervision

12. The audit team did not note any significant changes with regard to the powers of the competent authorities and official staff since the 2011 audit. The description on this point in that audit report remains valid.

13. In relation to control staff independence, the competent authority informed the audit team that this is ensured by the “Code of Conduct” of civil servants and the obligation of an official to declare any situation of possible conflict of interest. Official staff interviewed confirmed these arrangements.
14. Regarding supervision, the competent authority has minimal supervisory arrangements, and which are implemented in a way that does not allow them to detect and/or quantify the shortcomings indicated in sections 5.4.1 and 5.4.2 of the current report (mainly in relation to the frequencies of controls). These arrangements include quarterly and annual reports from APAs to DGSV on the official control tasks performed, and joint visits to establishments, in particular at the time of the initial approval. However, these reports are not checked/assessed at DGSV and, as a consequence, the latter does not detect that the controls are not being carried out at the planned frequencies.

Training – Knowledge of EU requirements

15. The competent authority provided information on training provided since 2017 which covered amongst others: (1) official controls (HACCP, EU regulations and Manual of Procedures); (2) official certification; (3) TRACES system; (4) control of fishery products (sampling, analytical methods and interpretation of results); (5) Prerequisite Programmes, Operational Prerequisite Programmes and Critical Control Points; and, (6) TAIEX – Management of environmental contamination by heavy metals.

16. Staff met had adequate general knowledge on food safety and EU hygiene requirements, as well as regarding the attestations contained in the EU model health certificate.

Resources available to the competent authority

17. Official control staff have equipment, means of transport and access to adequately equipped offices. They also have access to an official network of laboratories.

18. It was flagged to the audit team that there is a trend towards a reduction of staff (non-replacement of staff when they retire and/or leave) which does not allow for the proper implementation of the control system in terms of frequency of control visits, and the number of samples taken in the framework of controls.

Documented control procedures

19. The competent authority continues to use a comprehensive Manual of Procedures which is updated regularly. The latest version (August 2019) was provided to the audit team. This Manual provides instructions and guidance covering all tasks related to the official controls of fishery products for EU export and their production chain. The Manual is considered as a reference tool for official control staff as well as aiming to harmonise and facilitate the implementation of official controls.

20. The Manual includes procedures covering: (1) requirements applicable to products and their production chain, legal references, guidance/instructions for checking those requirements and control plan; (2) control plan of products (sampling plan); (3) approval; and, (4) management of food alerts (e.g. RASFF notifications). To support the implementation of the procedures, the Manual also contains checklists and a series of templates forms for sampling, registration and approval.
21. The audit team found that the Manual adequately covers the activities carried out within the official controls for EU exports. However, in the case of the approval of freezer vessels, the Manual's instructions are incomplete (see paragraph 34).

**Conclusions on competent authority**

22. The competent authorities have a structure, organisation and powers adequate to perform their tasks. Official staff met presented a good knowledge of the applicable rules and procedures, are impartial and have no conflict of interest.

23. The supervisory mechanisms in place do not allow the detection and/or quantification by the competent authority of gaps in the implementation of the official control system.

24. The implementation of the official control system in terms of frequency of visits and official sampling is hampered by a reported shortage of human resources.

25. Provided that the relevant procedures would be correctly implemented and the available guidance contained therein would be used as intended, the control arrangements in place would allow the competent authorities to provide the requisite guarantees in terms of EU compliance.

5.3 National provisions and procedures for listing establishments exporting fishery products to the EU

**Legal requirements**

Article 12(1), (2) and (3) of Regulation (EC) No 854/2004.

Parts I.8., I.11. and I.28. of the EU health certificate.

**Findings**

26. The competent authority has a procedure in place to manage the list of facilities authorised to export to the EU (hereafter: "the EU-list"). This procedure is well defined in the Manual of Procedures and it is adequately supported in law (Ministerial Order of 26 May 2006).

27. In summary, only the facilities approved (with an agrément sanitaire vétérinaire) and specified in the list of Annex 2 to Service Note No 100/2767 of 3 November 2006 (as amended) can be included in the EU-list.

28. Primary production fishing vessels, landing sites and auction halls are under the official control of the competent authority which compiles lists of those that are authorised to participate in the EU export chain.

29. The administrative and technical proceedings to include a facility in the list of Annex 2 to Service Note No 100/2767 are implemented by DGSV and APA and include:
a. Submission to APA of a request for granting the approval, by the food business operator (FBO), together with an administrative file (e.g. blue-prints, construction plans, equipment description).

b. Desk assessment of the request and administrative file by APA and DGSV.

c. On-site visit by APA and DGSV in order to confirm the information submitted and to assess whether the conditions are in line with the applicable requirements. At this stage the competent authority may require additional information and/or corrective actions should they detect deficiencies or non-compliances. If necessary, follow-up visits will be made.

d. Invitation to the FBO to submit a technical file (written procedures based on the HACCP principles and pre-requisite programmes) to APA, following a successful outcome of an on-site visit.

e. Desk assessment by APA and DGSV of the technical file. Eventually, this process will conclude with the approval of the HACCP plan (formal approval is given by signing, stamping and dating the cover of the HACCP document).

f. Another on-site visit to assess whether the implementation of the technical file is in line with the applicable requirements. As before, additional information and/or corrective actions may be required, and follow-up visits may be carried out.

g. The proposal for approval is prepared by the APA veterinarian (see paragraph 10) and passed to DGSV, which submits it to the specific National Commission. This Commission usually convenes twice per year and informs DGSV of the resulting approval endorsements (the octroi de l'agrément sanitaire vétérinaire).

h. Assignment of an approval number and inclusion in the list of Annex 2 to the Service Note No 100/2767.

i. A notification is sent to the FBO.

30. Once the process above is concluded, and following the expression of interest by the FBO, DGSV submits a request to the EU Commission services to include the facility in the EU-list. At this stage the FBO is informed that it can begin to manufacture products for EU export but the dispatch of such products and subsequent export certification can only proceed after the updated EU-list has been published.

31. The above approval process is applied to establishments on land (facilities handling fishery products including auction halls) as well as to freezer vessels. For the latter, one visit is carried out to assess, at the same time, the administrative and technical files.

32. The audit team noted that the list in Annex 2 to the Service Note No 100/2767 includes facilities that export directly to the EU as well as facilities that export to other markets. This information is clearly indicated in the Annex.

33. The audit team noted that the Manual of Procedures clearly indicates all the steps to be followed by officials (and FBOs), provides guidance and includes templates of checklists and forms to be used during the approval process. The audit team also noted that the Ministerial Order of 26 May 2006 indicates that any modification of the establishment (e.g. beginning the manufacture of new products, setting up of new
equipment, changes to the current manufacturing processes or to the products being produced), of its location or ownership, leads to a new approval process; during this process, as an exception to the service note, the on-site evaluation can be limited to one visit. The Ministerial order also describes the conditions that may lead to withdrawal of approval.

34. The audit team noted that the Manual of Procedures indicates that in the case of freezer vessels the FBO must submit, together with its HACCP plan, an annex containing the relevant written records of a "trial" fishing trip. These records must include, amongst others, the HACCP records, temperature records and analytical test results (in particular sulphite tests in the case of crustaceans). However, they are insufficient for the FBO to demonstrate that the manufacturing process guarantees that the products will respect the regulatory limits for additives.

35. Neither the legal acts nor the Manual of Procedures indicate a validity period for the approval. However, the competent authority stated that the approvals are valid for six months, which is the maximum period between two consecutive official controls (i.e. audits carried out in establishments and freezer vessels – see section 5.4.1). In the case of freezer vessels, two additional months of tolerance can be granted taking their activity and the fishing seasons into consideration.

36. The audit team noted that all primary production fishing vessels visited were included in a list of vessels handled by the fisheries authorities (an updated list was provided to DGSV during the audit). This list is passed to DGSV and allows them to implement the official controls over these vessels (see section 5.4.1).

37. The audit team also noted that the competent authority followed the approval procedure in all facilities and freezer vessels visited (see table in section 2). In general, the administrative procedure was correctly followed in all cases. However, in two establishments on land and in all freezer vessels (seven cases out of twelve) the technical assessment carried out by the authorities either overlooked or did not consider relevant EU rules, as described below.

38. One recently approved establishment presented significant shortcomings related to structural requirements (broken floors, condensation present on ceilings in several areas, incorrect location of probe in a cold storage room (for frozen products) and with many windows opened and insect screens broken and doors not pest proof); at the time of the visit there was a large presence of insects in all production areas. The audit team also noted shortcomings with the HACCP based procedures: (1) incomplete hazard identification and incomplete process diagram (band saw to cut frozen fish was not considered); (2) critical control points not established by using a logical approach; (3) critical limits contravening the applicable legal requirements (acceptance of frozen fish at -18°C ± 3°C). These are not incidental shortcomings and, if they had been detected/identified by the competent authority, would not approve the establishment and would not require its inclusion in the EU-list.
39. In another establishment, which recently changed its activity to include a new product, the competent did not identify that a cold storage room was not equipped with a temperature recording device and, as a consequence, no temperature records were available. Moreover, the existing probe was not placed in the area where the temperature in the room is the highest, as required in the EU rules. These deficiencies, if they had been detected, would have prevented the re-approval of this establishment for activities involving frozen fishery products. The audit team also noted that during an official control, after to the re-approval, the absence of temperature records was indicated as a failure, but no corrective actions had since been taken by the FBO and the next official control was not yet due.

40. In relation to the approval of freezer vessels, some of them approved for the first time in the last two years, the audit team noted that systematically the competent authority did not detect/identified shortcomings related to HACCP based procedures, evidenced as follows: (1) in all cases seen the critical control points have not been established by using a logical approach; (2) the limits for the use of metabisulphite (additive) in crustaceans were defined but the process implemented was not validated to demonstrate its compliance with the set limits; (3) in one case, the records produced on-board the vessel were not made using the applicable forms and were later transferred to permanent records which are always kept at the land office; (4) absence of instruments/devices to measure the duration of the different production steps, although the step duration was indicated in the HACCP manual; (5) information notices to workers were not consistent with the specifications defined in the HACCP manual; and, (6) unclear definition of the freezing step (e.g. duration of freezing time) and insufficient understanding of this process by the workers of the freezer vessel in charge if this operation.

41. The audit team noted that all freezer vessels presented good structural and equipment conditions, storage holds were equipped with temperature recording devices, temperature records were available and also results of own-check tests (of both internal and external laboratories).

42. In relation to the "validation" of the use of the additive, the competent authority expressed the view that this had been a key issue in the past, but somehow it had become overlooked. Another contributing factor for this oversight was the incomplete guidance provided in their Manual of Procedures (see paragraph 34).

43. Despite the presence of the deficiencies mentioned above, the competent authority approved the HACCP plans, granted an approval and requested the inclusion of such vessels in the EU-list. The approval and the EU-listing of those freezer vessels should have not occurred prior the correction of these deficiencies.

44. As a result, in several instances the competent authority did not fully respect the requirement of Article 11(2)(a) of Regulation (EC) No 854/2004.
45. At the closing meeting the competent authority announced, and provided written evidence to the audit team, the suspension of approval of and EU exports from the establishments mentioned in paragraphs 38 and 39.

46. The 2011 audit report required the competent authority to guarantee that only establishments compliant with the EU rules would be included in the EU-list. That report identified as shortcomings the absence of control on the use of sulphites and HACCP based procedures with incoherent description of control measures. To address this recommendation the competent authority announced a complete review of the approval of EU-listed facilities, removing those that were non-compliant, and training of official control staff.

47. Based on the findings described above, the audit team notes that, despite of the biannual audits for renewing the approval, the implementation of the proposed actions did not prevent the reoccurrence of the issues identified during the 2011 audit.

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

<table>
<thead>
<tr>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>48. The procedures in place for listing establishments for EU exports are, in general, correctly implemented and can be considered adequate.</td>
</tr>
<tr>
<td>49. However, in nine cases examined, the audit team noted two where approvals were granted/extended to facilities that did not comply with the relevant standards. Additionally, an approval was granted to five freezer vessels that did not fully comply with the requirements related to HACCP procedures (validation of the use of additives).</td>
</tr>
<tr>
<td>50. These shortcomings, in particular the one related to freezer vessels, calls into question the ability of the competent authority to provide in full the guarantees required by Article 11(2)(a) of Regulation (EC) No 854/2004.</td>
</tr>
<tr>
<td>51. The measures implemented to address recommendation No 1 of the 2011 audit report did not preclude the reoccurrence of the deficiencies identified during that audit.</td>
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5.4 OFFICIAL CONTROLS

5.4.1 Official controls of production and placing on the market

Legal requirements

Article 11(4) and 12(2) of Regulation (EC) No 854/2004.

Article 46(1)(g) and (h) of Regulation (EC) No 882/2004.

Point II.1 of the EU health certificate, and in particular the controls laid down in Annex III, Chapter I of Regulation (EC) No 854/2004.
Findings

Official control system in place

52. The competent authority has a control system in place based on Tunisian legislation and covering the entire production chain. This system is well described in the Manual of Procedures (see paragraph 20) and aims to guarantee that products exported to the EU have been manufactured in compliance with the applicable EU rules (including the requirements for facilities).

53. This control system is primarily implemented by the APAs which avail of lists compiled (or gathered) by DGSV of all facilities involved in the EU export chain for fishery products.

54. Primary production fishing vessels are inspected by the APAs at least once per year. The remaining facilities, which are subject to approval, are also audited by the APAs at six-month intervals (linked to the validity of the approval – see paragraph 35). The landing operations are controlled systemically by the APAs. The control of means of transport is covered during the control of EU-listed facilities.

55. All controls are carried out with the support of checklists (included in the Manual) and official records/reports are issued. A copy of the report is provided to the FBO.

56. The above reports include a clear indication of deficiencies, deadlines for their correction, the outcome of the control visit and the validity of the "renewed" approval.

57. In addition to the controls mentioned above, the competent authority also carries out visits to EU-listed facilities for official sampling, export certification and investigation of RASFF notifications.

Primary production fishing vessels and landing operations

58. The audit team visited two auction halls, which serve as a base for the controls of fishing vessels and landing operations, and noted that lists of primary production fishing vessels were available to APAs in order to allow them to implement the annual controls.

59. The audit team selected a sample of vessels from the above lists and noted that they were inspected within the set frequency. Completed checklists were available for all these inspections and in general no deficiencies were noted. For shortcomings identified during the inspections, corrective actions were requested. The audit team also found that the competent authority verified whether the corrective actions had been satisfactorily implemented and effectively addressed the non-compliance(s).

60. The audit team visited five primary production fishing vessels and found them to be compliant with the EU rules, except in two cases due to unhygienic storage of ice.

61. The audit team did not witness any unloading but the three places visited had the necessary elements to allow hygienic unloading operations.
**Freezer vessels handling fishery products**

62. The audit team visited five freezer vessels and noted that the audits had been carried out in accordance with the set procedures and respecting the defined frequencies.

63. However, as already indicated in paragraph 40, none of these vessels' FBOs could demonstrate the correct use of additives (sulphite): the operational criteria for their correct use was not clearly defined in many cases; there was no validation/demonstration that the manufacturing practices can ensure adherence to the EU regulatory limits; the measuring instruments were not available; and, instructions for workers were also missing.

64. The audit team also noted in one instance where of an ice machine was placed in an unhygienic location and another instance where the workers on board did not understand how to complete the form used to demonstrate that freezing was being carried out in accordance with their procedures. These deficiencies also have not been detected by the competent authority in their controls.

65. The audit team noted one case where the competent authority suspended a freezer vessel from EU exports due to its unavailability for a scheduled audit.

**Establishments on land handling fishery products**

66. The audit team visited seven establishment and two auction halls. Both of the auction halls visited complied with the EU rules for structures and records. In one of the auction halls, in operation at the time of the visit, the audit team observed adequate hygiene conditions for the handling of fishery products. Both auction halls had been audited by the competent authority. However, the control frequency was not respected for one of them – in one instance the visit took place 77 days after the expiry of the approval and in another after 45 days.

67. One of the seven establishments visited by the audit team was found not compliant with the EU rules (see paragraph 38). Another establishment was performing activities for which it could not demonstrate compliance with the relevant EU rules for that activity (see paragraph 39).

68. In the remaining five establishments the audit team noted several non-compliances with the EU rules, in particular: (1) HACCP based procedures not adequately applying principles 1, 2 and 3 (e.g. hazards not identified and not using a logical approach to identify critical control points, critical limits not respecting the EU rules); (2) inability to demonstrate adherence to operational criteria for freezing (e.g. unreliable and questionable temperature records); (3) lack of demonstration on the correct use of additives (sulphite) (see paragraph 63); (4) frozen products with a temperature above the EU regulatory limit in two establishments (e.g. products showing temperatures between -10°C and -13°C while the display of the cold store indicated -25°C).
69. In addition to these deficiencies the audit team found other shortcomings during the assessment of EU health certificates for exported products (see paragraphs 116 and 117). These oversights, impact on the ability of the competent authority to guarantee that EU-listed establishments comply consistently and in full with the EU rules, as required by Article 12(2)(a) of Regulation (EC) No 854/2004, and to certify with confidence the attestations of the EU health certificate.

70. The audit team noted that, in four out of six cases the frequency of the audits to establishments was followed (not more than two months delay was observed in the two cases mentioned). In all cases the administrative control procedures were adequately followed, reports were issued and transmitted to the FBOs and follow-up to verify correction of deficiencies was carried out where necessary.

Checks on the EU eligibility of imported raw materials

71. The competent authority highlighted that there is a procedure in place regarding to the handling of imported raw materials used for manufacturing products for EU exports.

72. That procedure requires that FBOs obtain their imported raw materials from countries authorised to export to the EU and from establishments included in the EU-lists for those countries. Additionally, the imported consignment must be accompanied by an attestation that the products comply, and were produced in compliance, with the EU rules.

73. The audit team could not assess the implementation of this procedure, as in the establishments visited all imports were from EU Member States only.

Conclusions on official controls of production and placing on the market

74. The official control system covers the entire production chain and it is implemented in accordance with the set procedures. However, the audit team noted in three out of eight establishments that the specified frequencies were not followed.

75. Despite of the correct implementation of the control plan, official control staff did not identify certain deficiencies which were present at the establishments visited, that should have been detected. This oversight weakens the ability of the competent authority to guarantee that EU-listed establishments comply with the applicable EU rules, as required by Article 12(2)(a) of Regulation (EC) No 854/2004.

76. The current arrangements covering the sanitary imports of raw materials used for the manufacture of products for EU export can adequately guarantee their EU eligibility.

5.4.2 Official controls of fishery products

Legal requirements
Point II.1 of the EU health certificate, and in particular official controls laid down in Annex III, Chapter II of Regulation (EC) No 854/2004.

Findings

77. The plan for the official control of fishery products for export to the EU is included in the manual of procedures which defines the parameters to be checked, the frequency of checks (including sampling size), maximum allowed limits and the designated laboratory(ies). The legal framework for this control plan is the Service Note No 300/229 of 31 January 2011.

78. The audit team noted that the control plan covers the relevant requirements of EU legislation, in particular those of Chapter II of Annex III to Regulation (EC) no 854/2004.

79. In this regard, the audit team noted that fishery products are checked/sampled at landing sites/auction halls and EU-listed facilities for organoleptic checks, freshness indicators, histamine, environmental contaminants (i.e. heavy metals (cadmium, lead and mercury), poly-aromatic hydrocarbons, dioxins and polychlorinated bisphenols), parasites and poisonous species. This control plan also includes testing of fishery products for sulphite levels. In addition, water and ice is sampled to be tested for microbiological and physico-chemical parameters.

80. The audit team also noted that sampling and testing fishery products for inorganic tin is not included in the control plan. The audit team could not ascertain the relevance of this oversight because no cannery exporting fishery products to the EU was visited during this audit.

81. Supplementary to the official control plan the competent authority also performs sampling and testing of fishery products for heavy metals and histamine for imported and exported consignments. In this regard, the competent authority informed the audit team that since 2017 to date approximately 408 samples were taken and tested for histamine and approximately 185 for heavy metals.

82. In relation to the implementation of the control plan the audit team noted that APAs generally performed the check and/or took samples of products and water/ice at the relevant locations. As indicated in paragraph 14 the APAs submit to DGSV reports on the number of samples taken per location and any non-compliant results. A yearly report is also compiled and submitted to DGSV.

83. However, the audit team noted that in three out of five establishments the established control frequencies (mainly sampling for histamine in fishery products and sampling for the control of water) were not adhered to. This situation was more evident in one of the APAs visited. Staff interviewed during the audit stated that the reduction of staff numbers contributed significantly to the non-adherence to the control plan.
84. The audit team noted that this failure to fully adhere to the prescribed frequencies occurred in different calendar years. However, the audit team could not find measures taken or defined by DGSV to ensure that APAs implement adequately the control plan (this issue is also linked with the issues raised in relation to supervisory mechanisms – see paragraph 14).

85. With regard to the control plan for the levels of sulphite in fishery products, the audit team noted that the plan was fully applied in 2017 but not in 2018 and had, so far, a low level of sampling in 2019.

86. All the analytical results observed by the audit team were in line with the EU rules. The competent authority informed the audit team that measures are foreseen in the case where analytical results present non-compliant results. These measures include the assessment of the case in order to establish the reasons for non-compliance and, if necessary, the recall of products and eventual suspension of export certification.

Conclusions on official controls of fishery products

87. The official control of fishery products covers the EU requirements, an annual sampling programme is prepared and it is implemented by the regional levels.

88. However, the annual sampling programme is not implemented as planned (i.e. the defined frequencies are not respected) which impacts on the guarantees provided by the competent authority with regard to the health attestations contained in the EU health certificate.

5.5 FOLLOW UP OF RASFF NOTIFICATIONS

Legal requirements


Findings

89. Since 2016 there have been 30 RASFF notifications related to Tunisian fishery products covered by the scope of this audit (see section 4.3).

90. The competent authorities presented to the team the actions taken to follow-up on these notifications. The audit team followed the implementation of these actions at the establishments visited that were involved in those notifications.

91. The audit team noted that the actions taken by the competent authorities were satisfactory for the notifications discussed.

92. The measures taken resulted from thorough investigations into all cases and included suspension of exports by the concerned establishment, re-enforced official sampling, additional official testing of the concerned batch (or similar products), additional pre-
export testing (heavy metals in crustaceans), improvement of the relevant FBO’s procedures (e.g. strengthening of incoming raw materials controls, traceability, strengthening of sampling plans in terms of frequency, fine tuning recall procedures, updating of the HACCP plan, improvement of labelling procedures, and, staff training), and, withdrawal of approval (with consequent withdrawal from the EU-list).

**Conclusion on follow up of RASFF notifications**

93. The competent authority carried out a satisfactory follow-up of the RASFF notifications reviewed by the audit team.

### 5.6 Laboratories

#### Legal requirements


#### Findings

94. The competent authority avails of a network of three Tunisian laboratories to test official control samples of fishery products and water/ice.

95. One of these laboratories is accredited against EN ISO/IEC 17025:2005 and carries out testing of official control samples for heavy metals, sulphites, dioxins, poly-aromatic hydrocarbons and histamine in fishery products, as well as for microbiological and chemical parameters in water/ice.

96. This laboratory regularly participates in proficiency tests, having achieved a satisfactory Z-score in the last test they completed. Laboratory staff informed the audit team about the quality controls to ensure the reliability of analytical test results. The audit team found these controls to be adequate.

97. The audit team also found that the performance criteria of the methods used to test fishery products for heavy metals and poly-aromatic hydrocarbons are aligned with the EU rules. The method used for histamine testing is an internal validated HPLC method, aligned with the ISO 19343:2017. The remaining analytical methods used are the methods that are indicated in the EU rules.

98. A second laboratory, also accredited to EN ISO/IEC 17025:2005, carries out testing of fishery products for histamine and total volatile basic nitrogen. This laboratory also tests...
fishery products for parasites but this test is not included in the scope of its accreditation.

99. This laboratory uses a method based on the ISO 19343:2017 for histamine testing and uses the EU reference method to test for total volatile basic nitrogen. The laboratory also participates in proficiency tests; their last results presented a questionable Z score with regard to the histamine testing. The laboratory suspended this testing until corrective measures were implemented and after verification that these measures addressed the issue. The audit team received limited information on the measures in place (quality controls) to ensure the reliability of the analytical test results – only quality charts for the recovery were provided (these charts were satisfactory).

100. The third laboratory is not currently accredited to EN ISO/IEC 17025:2005 and is mainly involved in total volatile basic nitrogen testing, microbiological testing of canned products, and water/ice testing. The competent authority informed the audit team that this laboratory has not carried out any water/ice testing since the beginning of 2019.

101. The competent authority established written agreements with the laboratories performing official control testing. These agreements define the obligations of both the authority and the laboratory. They include requirements concerning the samples (identification and integrity), confidentiality and also prescribe the methods to be used. The agreements also define the maximum time afforded to the laboratory to provide test results; in one case observed that time was 21 working days (for the laboratory indicated in paragraph 95) and in another it was 10 working days (for the laboratory indicated in paragraph 100). Considering that, as indicated in paragraph 81, part of the official controls are carried out within the framework of EU exports, the audit team is of the view that this agreed delay is excessive and may preclude the competent authority from taking the necessary measures if a test presents results above the EU regulatory limits. The competent authority informed that this never occurred to date.

102. The audit team noted, in four cases out of seven, that the analytical results for samples of fishery products taken between January-July 2019 for heavy metals testing have not yet been issued/received. In an additional case the results were issued 44 days after sampling. A similar situation was observed regarding the testing for sulphites (three cases of more than 60 days for the results to be reported), for histamine (one case of 35 days) and also for the testing of water (two cases of more than 21 days).

103. These cases illustrate the non-adherence to the written agreements. This issue was already signalled by the competent authority to one laboratory in early 2019 and it was requested that the laboratory respect the deadlines agreed in the agreement.

104. With regard to recommendation No 2 of the 2011 audit report the audit team noted that the measures proposed to address the recommendation were satisfactorily implemented.

Conclusions on laboratories
105. The competent authority avails of an adequate network of laboratories for the testing of official control samples in terms of parameters covered, analytical methods used and demonstration of the reliability of the test results.

106. However, as detected by the competent authority, the excessive delay that occurs sometimes between the sampling and the reporting of the test results does not allow the competent authority to take timely measures to prevent the export to the EU of products containing levels of sulphite, histamine and heavy metals above the regulatory limits.

107. The measures to address recommendation No 2 of the 2011 audit report were satisfactorily implemented.

5.7 OFFICIAL CERTIFICATION

Legal requirements


Article 6 of Regulation (EC) No 2074/2005, and in particular the EU health certificate.

Article 6 of Council Directive 96/93/EC.

Findings

Issuance of EU export certificates

108. The competent authority mainly uses the TRACES system for issuing EU health certificates. Certifying officers are designated regularly by a Decision issued by DGSV (the last decision, dated 1 February 2019, was provided to the audit team).

109. The competent authority has a procedure in place for the issuance of EU health certificates which describes the steps to be followed by the FBO and the documentation to be submitted.

110. For each certification request submitted to the APA, the FBO must provide the commercial invoice, packing list, relevant production records and the control document issued at the time of unloading of the raw material. This documentation is checked by the certifying officer and a physical check of the consignment is also carried out.

111. Subject to the satisfactory outcome of the documentary and physical checks, the EU health certificate is completed in TRACES, printed, signed and stamped. This certificate is then provided to the FBO for it to accompany the consignment to be exported.

112. The procedure also foresees the steps to be followed for the replacing and/or cancellation of EU health certificates.
The competent authority informed the audit team that sometimes, albeit rarely, certificates are issued manually. Nevertheless, the procedure described above is equally followed and certifying officers have access to the necessary certificate models.

Checks of EU export certification of products exported to the EU

The audit team assessed a selection of EU health certificates issued in 2018 and 2019 and found that the certification procedure indicated above had been adequately followed.

In all cases the documentation supporting the export certification was available and it demonstrated that, in general, the products had been manufactured with eligible raw materials and that the production process respected the EU rules.

However, in two separate instances the audit team noted that the application of the labels containing the identification mark (the approval number of the manufacturing facility) and the indication of the freezing date did not refer to the manufacturing establishment (a freezer vessel) but instead to the EU-listed establishment that dispatched the consignment. Moreover, the comparison between the catch certificate and the declared freezing date showed that the latter was incorrect.

After assessing the issue the audit team established that, in certain cases, frozen products are supplied by freezer vessels in unmarked carton boxes, without an indication of the freezing date; it is the FBO of the EU-listed establishment receiving these products (to be stored before dispatch to the EU) who marks the products (with the approval mark of the freezer vessels) and indicates the freezing date as the date of arrival of the products into its premises. This contravenes the requirements of Sections I and IV of Annex II to Regulation (EC) No 853/2004.

Conclusion on official certification

The procedures in place for the issuance of the EU health certificates are in line with the EU requirements.

The majority of the traceability exercises carried out by the audit team allowed to verify that products have been adequately produced and correctly certified. However, the audit team noted, in some instances, that products were not labelled by the production facility and the freezing dates were incorrectly indicated.

6 Overall Conclusions

The official control system developed by the competent authority is based on adequate procedures and legislation aimed at providing the guarantees required by the EU model export health certificate. The system as designed covers the entire production chain as well as the associated EU food safety requirements, and can also ensure that imported raw materials for processing are equally eligible for the EU. However, and in terms of its implementation in practice, the audit team found that the controls are not consistently
carried out in line with the established frequencies, and moreover did not identify and/or record relevant and systemic deficiencies at facilities listed for EU exports.

These shortcomings impact, to a certain extent, on the ability of the competent authority to provide consistently, and in full, the guarantees as set out in the EU health certificate.

In respect of the follow-up to two recommendations made following the 2011 audit and relevant for this audit, the audit team found that the announced corrective measures were satisfactorily implemented and effective for one, but not for the other concerning the assurance that only fully compliant establishments should be listed as eligible for exports to the EU.

7 CLOSING MEETING

At the closing meeting held in Tunis on 26 September 2019, 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.

Moreover, the competent authority provided the audit team with evidence of: (1) the suspension of the approval and EU exports from the establishments mentioned in paragraphs 38 and 39; (2) the creation of a supervisory mechanism to ensure that the official sampling plan is respected in terms of frequency; (3) a communication to the APAs providing instructions related to, as well as clarification of, the applicable rules and how the controls should be carried out in relation to the use of additives (sulphites is crustaceans), storage of frozen products (including the temperature of products); (4) labelling of products in terms of identification mark, freezing dates and additives used; (5) assessment of HACCP based procedures; and, implementation of the official control plan in terms of the frequency of visits. DGSV gave a deadline of one month to APAs to implement these corrective measures.

The competent authority is invited to detail and provide an update regarding the measures mentioned above when replying to the recommendations of this report under section 8 below.

8 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 public health guarantees set out in the EU health certificate (as defined in Appendix IV to Annex VI to Regulation (EC) No 2074/2005) 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.
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<tr>
<td>1.</td>
<td>The competent authority should improve/establish and implement supervisory mechanisms to oversee the work of controlling officers, both in terms if adherence to the established frequencies and ability to detect non-compliances, in order to guarantee that all EU-listed establishments comply with those rules, as required by Article 12(2)(a) of Regulation (EC) No 854/2004 and to be in a position to provide reliable guarantees to the requirements set out in the EU health certificate. Recommendation based on conclusions Nos 23, 75, 88 and 119. Associated findings Nos 14, 68 to 70, 83 to 85, 116 and 117.</td>
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<tr>
<td>2.</td>
<td>Within their next re-approval visits, the competent authority should review in detail the HACCP based procedures of all EU-listed facilities, in particular the freezer vessels, and provide guarantees that only facilities that comply with the applicable structural and hygiene EU rules are included in the list of establishments authorised to export to the EU, as required by Article 11(2)(a) of Regulation (EC) no 854/2004. Recommendation based on conclusions Nos 48 and 49. Associated findings Nos 38 to 44.</td>
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<td>3.</td>
<td>The competent authority should ensure adherence to its control plan, in particular with regard to frequencies, in order to be in a position to provide adequate guarantees in relation to the health attestations of the EU health certificate. Recommendation based on conclusions No 74. Associated findings No 70.</td>
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<tr>
<td>4.</td>
<td>The competent authority should ensure adherence to its annual sampling plan, in order to provide consistent guarantees that fishery products exported to the EU have satisfactorily undergone the official controls laid down in Chapter II of Annex III to Regulation (EC) no 854/2004, as provided for in the EU health certificate. Recommendation based on conclusions Nos 87 and 88. Associated findings Nos 83 to 85.</td>
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<td>5.</td>
<td>The competent authority should ensure that the test results of the official control samples are made available in a way that allows for timely measures to be taken in case of non-compliant results, and to provide continued assurance that products exported to the EU have satisfactorily undergone the official controls laid down in Chapter II of Annex III to Regulation (EC) no 854/2004. Recommendation based on conclusions No 106. Associated findings Nos 101 and 102.</td>
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<td>6.</td>
<td>The competent authority should ensure that frozen products bear the correct freezing date on their labels or that the correct information on the freezing date is passed on to allow for accurate labelling, as required by Section IV (2) and (3) of Annex II to Regulation (EC) No 853/2004. Recommendation based on conclusions No 119. Associated findings Nos 116 and 117.</td>
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<td>7.</td>
<td>The competent authority should ensure that the identification mark for products for EU export, is applied in accordance with the rules of Articles 5(2) and 6(c)(i) of Regulation (EC) No 853/2004. Recommendation based on conclusions No 119. Associated findings Nos 116 and 117.</td>
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The competent authority's response to the recommendations can be found at:

## ANNEX 1 – LEGAL REFERENCES

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<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
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<td>Regulation</td>
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