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 Denmark carried out from 12 to 21 June 2019, as part of its programme of audits in Member States.

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

The audit found that the system of official controls largely covers the production, processing and distribution stages applicable to fishery products placed on the market. Tools to support staff in performing their tasks are readily available, allowing the control arrangements and associated follow-up activities overall to be met, as planned.

However, the effectiveness of the system is negatively affected by shortcomings in the subsequent enforcement of corrective actions by food business operators, allowing non-compliances to persist.

The audits to ascertain the fitness for purpose of food business operators’ HACCP-based procedures demonstrated a number of deficiencies.

With regard to the approval of establishments, there are some shortcomings in the system concerning the assessment of compliance of particular types of establishments with the general and specific requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004. The deficiencies concern both the granting of the initial approval, as well as the subsequent verification during official controls that the conditions of the original approval continue to be met.

The report contains recommendations addressed to the competent authorities aimed at rectifying the identified shortcomings.
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### Abbreviations and Definitions Used in This Report

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<tr>
<td>CA(s)</td>
<td>Competent Authority(ies)</td>
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<td>CCP</td>
<td>Critical control point</td>
</tr>
<tr>
<td>DFA</td>
<td>Danish Fisheries Agency of the Ministry of Foreign Affairs</td>
</tr>
<tr>
<td>DVFA</td>
<td>Danish Veterinary and Food Administration of the Ministry of Environment and Food</td>
</tr>
<tr>
<td>EC</td>
<td>European Communities</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FBO(s)</td>
<td>Food Business Operator(s)</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
</tr>
<tr>
<td>PAH</td>
<td>Polycyclic aromatic hydrocarbons</td>
</tr>
<tr>
<td>PCBs</td>
<td>Polychlorinated bi-phenyls</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>RTE</td>
<td>Ready to eat</td>
</tr>
<tr>
<td>TMA-N</td>
<td>Trimethylamine nitrogen</td>
</tr>
<tr>
<td>TVB-N</td>
<td>Total volatile basic nitrogen</td>
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1 INTRODUCTION

The audit took place in Denmark from 12 to 21 June 2019 and was undertaken as part of the Directorate-General for Health and Food Safety audit programme. The audit team comprised two auditors from the Directorate-General. An opening meeting was held in Copenhagen on 12 June 2019 with the Competent Authorities (CAs): the Danish Veterinary and Food Administration (DVFA) under the Ministry of Environment and Food and the Danish Fisheries Agency (DFA) under the Ministry of Foreign Affairs.

At this meeting the audit team confirmed the objectives of, and itinerary for the audit. The CAs provided additional information required for the satisfactory completion of the audit.

2 OBJECTIVES AND SCOPE

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

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

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

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITY VISITS/METINGS</th>
<th>CENTRAL LEVEL</th>
<th>REGIONAL LEVEL</th>
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<tbody>
<tr>
<td>Opening and closing meeting</td>
<td>2</td>
<td>1</td>
</tr>
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<table>
<thead>
<tr>
<th>PRIMARY PRODUCTION FACILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landing sites/ports</td>
</tr>
<tr>
<td>Fishing vessels</td>
</tr>
<tr>
<td>Collection centre</td>
</tr>
<tr>
<td>Auction</td>
</tr>
<tr>
<td>Aquaculture Farm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FOOD PROCESSING FACILITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing establishments</td>
</tr>
<tr>
<td>Cold store</td>
</tr>
</tbody>
</table>

*Some establishments visited had more than one activity in place.
3 Legal Basis

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

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

4 Background

4.1 General

The previous audit in Denmark on fishery products took place in 2015 (ref. DG(SANTE)/2015-7460). The report for that audit is accessible at:


The report highlighted some weaknesses in relation to the implementation of official controls and the unauthorised use of certain additives and recommendations were made in respect of the action required by the DVFA.

4.2 Production Data

Denmark is a major fishery products producer in the EU. DFA provided the following data as regards the landings of fishery products and aquaculture production for 2017 and 2018.

<table>
<thead>
<tr>
<th>Type of fish at landing</th>
<th>2017 (in tonnes)</th>
<th>2018 (in tonnes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish for industrial use (fish meal and fish oil production)</td>
<td>918,933</td>
<td>856,431</td>
</tr>
<tr>
<td>Fish for human consumption</td>
<td>280,444</td>
<td>287,123</td>
</tr>
<tr>
<td>Bivalve molluscs</td>
<td>83,917</td>
<td>70,059</td>
</tr>
<tr>
<td>Fish from aquaculture</td>
<td>37,488</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1,320,782</td>
<td>1,213,613</td>
</tr>
</tbody>
</table>

Further statistical data on fishery products production in Denmark are accessible at:

https://fiskeristyrelsen.dk/english/fishery-statistics/

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

Since 2016 to date, there were 18 RASFF notifications concerning fishery products from Denmark; eight in 2016, two in 2017 and eight in 2018. These RASFF notifications concerned the following:

- *Listeria monocytogenes*: four notifications (three in 2016 and one in 2018)
- *Salmonella enterica*: one (in 2017)
- High bacterial counts: one (in 2017)
- Histamine: one (in 2018)
- Leucomalachite green: two (in 2016)
- Parasitic infestation (Anisakis): two (in 2018)
• Foreign bodies: two (in 2018)
• Undeclared ingredients: two (in 2016)
• Absence of health mark: one (in 2018)
• Unauthorised placing on the market: one (in 2016)
• Unauthorised operator: one (in 2018)

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements


Findings

1. An overview about the arrangements put in place by the Danish CAs for the implementation of certain requirements of Regulation (EC) No 882/2004 is provided in chapter one of the country profile of Denmark, which has been drawn up by DG Health and Food Safety on the basis of information supplied by Denmark. The country profile, which was updated in January, 2018, reflects the current structure and organisation of the CAs and is accessible at: http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=DK

Designation of competent authorities

2. DVFA and DFA share responsibilities for food safety along the production chain of fishery products in Denmark.

3. In summary, DFA is responsible for official controls on primary production at sea, including the hygiene of fishing vessels and landing operations up to the point of first sale. DVFA is responsible for official controls of fishery products after the point of first sale and of establishments, facilities and equipment (including freezer and factory vessels).

4. Primary production in aquaculture is under the responsibility of the Veterinary Inspection units of DVFA.

Power, independence and supervision

5. DVFA and DFA staff have the necessary powers to enter vessels, establishments and premises to carry out official controls (inspections and sampling) and impose, where necessary, enforcement measures.

6. Independence of the staff is covered in the Danish Public Administration Act. In any case, the management of the CAs ensure that members of staff do not engage in activities which are in conflict with their employment. Staff are obliged to inform their management of potential situations of conflict of interest.
7. Regional offices, both of DVFA and DFA have a system of internal supervision in place. The system comprises of assessments of inspectors' reports by the team leaders as well as the shadowing of inspectors during the performance of official controls.

8. To prevent staff from becoming familiar with an establishment and perhaps biased, DVFA staff is rotated (changing the food business operators (FBOs) under their responsibility) every three to four years.

9. At central level, DVFA coordinate regularly with the regional offices through meetings organised by the headquarters. The verification on the ground of performance of inspectors from different regional offices in order to assess whether the different regional offices perform at similar standards is achieved through internal audits. The last internal audit on official controls of fishery products establishments took place in 2012. According to DVFA, areas where specific problems were previously identified, including areas in relation to the recommendations included in the report of the said internal audit, have been included in the scope of subsequent internal audits.

Resources

10. In 2018, DVFA availed of a total of 349.5 full time equivalents of food inspectors. In the same year, DFA had 102 full-time inspectors for fisheries, and five part-time.

11. The audit team noted that the CAs have adequate numbers of inspectors and equipment to allow them to perform official controls.

12. The regional DVFA office visited has, according to a representative of the office, in total 62 inspectors of which nine are dedicated exclusively to fishery products. Five of the nine dedicated fishery products inspectors visit also Greenland two to three times per year, in order to carry out official controls on fishery products there.

13. Inspectors are organised in teams, which are under the responsibility of a team leader; a team leader can be responsible for more than one team.

14. In order to be able to carry out official controls in the establishments dispersed across the area under the responsibility of the office in an efficient manner, DVFA inspectors work in many cases from home. For the purpose of co-ordination, inspectors meet every two weeks at the regional DVFA office.

15. The audit team noted that both DVFA as well as DFA inspectors are provided with several information technology tools that enable them to effectively plan and implement their official control programme and monitor the progress in its execution.

Training

16. The DVFA team leaders supervise the work of the inspectors in the team and determine also their training needs.
17. The audit team noted that the regional offices visited, both of DVFA and DFA maintained, in a user-friendly electronic form, a matrix of competencies for the inspectors. Any training needs for each inspector were identified and recorded and provisions were made to cover the training needs.

18. Inspectors met were familiar with the relevant legal requirements.

Cooperation and Coordination

19. Based on information provided both by DVFA and DFA, regular meetings or communications take place for co-ordination purposes or for addressing problems or answering any questions that arose in the course of the official controls.

Enforcement measures

20. There are different levels for escalating enforcement measures in cases on non-compliance by the FBOs. These included, for minor non-compliances, verbal advice and, for more serious cases and depending on the severity of the non-compliance, the issue of a warning, injunction, administrative fine, the withdrawal of approval or prosecution.

21. The audit team noted that in case of warnings, inspectors do not set a specific deadline for the FBO to rectify the identified non-compliance. According to DVFA, although no deadline is set, non-compliances sanctioned with a warning are followed up during subsequent inspections, which normally take place within three months.

22. The audit team noted that enforcement measures were not proportionate.

23. All the examples seen by the audit team during the audit were rated by the inspectors either as minor (verbal advice given), or, in some cases, more significant than minor, in which cases warnings were issued. The audit team noted that in the processing establishments visited, enforcement measures for non-compliances identified by the DVFA inspectors during official controls were never rated beyond a warning although, in some cases, these could pose a serious risk for food safety (see paragraphs 24, 25 and 39 below).

24. An FBO for instance, who had breached the obligation to notify to DVFA the intention to engage in additional activities and started producing ready to eat (RTE) foods without informing the CA, without adequate facilities or equipment and without having developed HACCP-based procedures for the newly introduced product, was only sanctioned with a warning (see also paragraph 48)(1).

25. On another occasion, a FBO was also sanctioned with a warning although the DVFA inspector identified significant non-compliances including contamination of exposed smoked fishery products. The audit team noted that following the advice of the legal

(1) After the audit and during the drafting of the report, the DVFA provided the audit team with a summary of the enforcement measures imposed on the FBO following the audit visit. The FBO was subject to a sanction (a written warning) in relation to a) protection of food from contamination, including that from food contact materials and b) the need for a written risk analysis covering the activities of the establishment (RTE food).
service of DVFA, the inspector withdrew the warning on the basis that the FBO had a maintenance plan in place, which included addressing the non-compliances referred to above, to be rectified at some stage (2).

26. At the same time, the audit team noted that an inspector issued a warning to a FBO due to a mismatch of the approval number indicated on the product and the approval number indicated on the accompanying documents. FBOs selling food grade products for animal feed are required by the CA to request and obtain an approval number for feed. The mismatch, which most probably was unintentional, concerned documents indicating the approval number for feed while the label on the product (food grade material destined for pet food) indicated the approval number of the food establishment.

27. During the closing meeting, DVFA informed the audit team that a new 'Uniformity strategy' was introduced in 2019 with the aim, amongst others, to harmonise the way inspectors assess and deal with non-compliances. According to the document provided, outlining the strategy, the objectives are that:

   a. the customers (FBOs) perceive the service of DVFA as uniform;
   b. DVFA serves the customers uniformly;
   c. DVFA acts and responds to customer needs.

**Conclusions on competent authority**

28. Both DVFA and DFA avail of sufficient adequately trained staff and resources to allow them carry out official controls efficiently, meeting or even exceeding the planned arrangements.

29. The enforcement measures most frequently applied by DVFA, namely verbal advice and warnings are not sufficiently effective and do not set clear deadlines by which the FBOs should address any identified non-compliances.

30. Enforcement measures applied by DVFA are not proportionate to the degree of the non-compliance and its significance on food safety. Non-compliances with potentially significant negative impact on food safety are sanctioned in a similar manner as those with minimal or no direct public health consequences.

### 5.2 REGISTRATION AND APPROVAL OF ESTABLISHMENTS AND VESSELS

**Legal requirements**


(2) In their response to the draft report, DVFA clarified that they did not withdraw the warning concerning contamination of exposed fishery products but the warning concerning maintenance since there was a maintenance plan in place.
Findings

31. Fishing vessels are all registered by DFA. Factory and freezer vessels requiring approval are approved by DVFA.

32. FBOs are obliged to apply to DVFA before they engage in the production of food. Following an assessment of the FBO’s own-checks system, including HACCP as well as an on-the-spot control of the facilities and equipment, an FBO is initially granted a conditional approval, which is then converted to a final approval if DVFA considers that the requirements are met and the HACCP plan and own-checks systems are fit for purpose.

33. The audit team noted that the approval process failed to correctly assess whether or not all conditions for approval were met, before granting approval, contrary to the requirement of Article 31(2)(c) of Regulation (EC) No 882/2004.

34. According to information provided, DVFA inspectors use a specific checklist during the assessment and on-the-spot inspections of establishments to be approved.

35. The audit team noted that the checklist used is detailed as regards the general hygiene requirements, however, less detailed in relation to the assessment of the HACCP plan. In relation to the assessment of HACCP, DVFA explained that the inspectors are expected to be aware of the relevant requirements and use the Guidance on own-checks in food establishments (version February 2012), which provides detailed information, guidance and examples about own-checks systems and HACCP.

36. The audit team noted that although certain topics are explained in detail in the above-mentioned guidance document, the inspectors carrying out the approval controls did not adhere to the guidance provided in relation to HACCP. In relation to the process flow diagrams the guidance explains under Title VIII, section ‘Preparation of process diagrams (flow charts)’, "...the chart shall contain an overview and a review of all production steps, including the waiting time at each step of the production and between the production steps. ...The process diagram shall describe all activities that involve the product. That is to say not only the processing itself but also parallel activities, as may be the case, to waste leaving the production line, additives or packaging used to pack the product.” The guidance provides an example of a flowchart in Annex I of that guidance document.

37. In one establishment visited, which was also marinating fish, the process flow diagram of the establishment was limited to naming the processes without any further information on the parallel activities. The FBO explained that they are now in the process of updating the HACCP manual as they intend to apply for certification by a third-party assurance scheme. The audit team was shown an example of an updated process flow diagram, which now provides at a glance, information about all the processes and the materials used or added to the fishery product.
38. In the same establishment, the audit team noted that the only critical control point (CCP) identified by the FBO was related to parasites, namely the treatment for killing parasites. However, the physical hazard of foreign bodies, in particular, metal fragments from the blades operating in the fully automated filleting and cutting operations and the risks arising therefrom, was not taken into account.

39. As a result, the establishment was approved without having any metal detectors installed or any other measures in place to prevent fishery products containing metal fragments from being placed on the market. The audit team noted that many of the blades were damaged to a greater or lesser extent, ranging from dents to missing fragments from the cutting surface. The implication being that small fragments of metal could potentially remain in the fishery products as foreign bodies putting consumers’ health at risk. The DVFA inspector correctly identified the absence of a metal detector as an issue. However, he accepted the statement of the FBO about the difficulties faced in finding on the market a metal detector that could scan the 20 kg packages produced in the establishment. The audit team noted that the particular risk could have been addressed at a different stage of the processing line, e.g. immediately before the packaging stage, where the product volumes were smaller and could readily be subject to metal detection.

40. In another example noted by the audit team, an establishment was approved for the production of fish oil for human consumption although neither the HACCP plan, nor the arrangements in place to meet the specific requirements applicable to the production of fish oil for human consumption as laid down in Annex III, Section VIII, Chapter IV, point B of Regulation (EC) No 853/2004 as regards the raw materials, were fit for purpose.

41. The HACCP plan did not contain a description of the products produced namely, fish oil and, a product called “Graks”. The latter product is essentially a solid phase after the extraction of the fish oil (frozen in blocks), in which the FBO also mixed the stick-water coming out of the three-phase separator decanter centrifuge (tri-canter) along with an antioxidant. While the FBO considered “Graks” as food, it was not adequately stored or handled. For example, frozen blocks were piled unwrapped on old dirty wooden pallets and with several loaded pallets piled on top of each other with the bottom of the pallets in direct contact with the frozen blocks underneath.

42. In addition, the HACCP plan identified the heat treatment as a CCP to control microbiological hazards. The critical limit identified a particular temperature requirement but did not indicate how long the product should be heated at this temperature. However, irrespective of what the HACCP plan was describing, the staff responsible for monitoring the production process (and contrary to what was described in the HACCP plan), did not consider the heat treatment as a CCP and as a consequence they did not have to monitor the temperature during the heat treatment.

43. In relation to the raw materials used, these were sourced from two fishery products establishments and were transported, in particular from the establishment located further away, through a dug-in-earth pipe, which could only be cleaned by "blowing" a metallic
object through the pipe to clear any blockages. This practice of the establishment sourcing raw materials also from a second supplier and using transporting conditions inadequate to consider the raw material as (remaining) fit for human consumption, were not assessed by DVFA inspectors before granting the approval for the production of fish oil for human consumption.

44. After the audit, DVFA provided the audit team with a summary of the enforcement measures imposed on the FBO following the visit. The FBO was sanctioned with a prohibition order against the production of food for human consumption for the following reasons:

   a. problems with hygiene during handling of food;
   b. problems with maintenance of production equipment;
   c. problems with the own checks; and
   d. problems with labelling and information.

The audit team noted that the fact that the fish oil producing establishment was receiving raw materials from another nearby establishment transported through pipes which were impossible to clean and disinfect and therefore should not be regarded as food grade, was not taken into account for reviewing the approval of the establishment.

45. In another establishment producing frozen fishery products, the audit team noted that the establishment has been approved in 2016 although it was not in compliance with the requirements of Annex III, Section VIII, Chapter I, part I.C, point 2 of Regulation (EC) No 853/2004. The establishment did not avail of continuous temperature-recording devices in their cold store. In April 2019, the FBO has installed a data logger for temperature recording in the cold store inside the establishment, following a recommendation on the part of a third party assurance provider.

46. The audit team noted that the competent authority did not keep, as required by Article 31(2)(e) of Regulation (EC) No 882/2004, the approval of establishments under review when carrying out official controls.

47. In the establishment mentioned in paragraph 45, due to insufficient capacity, the FBO was using refrigerated shipping containers to store frozen products. The containers were parked in an open space in the yard of the establishment. The DVFA inspector accepted the use of refrigerated shipping containers as a storage arrangement to address the lack of adequate cold storage capacity inside the establishment. According to the DVFA, under certain conditions, the use of such containers as a cold store in an establishment could be
acceptable (3). However, the audit team noted that DVFA had not yet defined these conditions. The audit team noted that, because these containers are not designed to function as a cold storage facility, the first in – first out principle cannot be implemented without exposing all products in the container to large temperature fluctuations. The same applies during loading and unloading these containers, especially if these are detached from the establishment and accessible only from outside. In the containers concerned, the audit team noted that the temperature was recorded manually once a day, on weekdays only, contrary to what is required in Section VIII, Chapter I, point A(2) of Annex III to Regulation (EU) No. 853/2004. In some examples seen by the audit team, the temperatures recorded ranged from -2.1°C to -20°C. On other occasions the temperatures recorded were far above -18°C for several days in a row. The above reinforces the point that such refrigerated containers cannot replace a proper cold storage facility and should not be considered an acceptable equivalent thereto. The increase in the production volumes of an establishment subject to approval should be a function of availability of sufficient proper cold storage facilities, either on- or off-site, and this in turn should be subject to review during official controls in order to verify that the conditions of the original approval are still met, which was not the case in this establishment. According to the FBO, all its products were sold frozen.

48. In another establishment visited, the FBO started producing RTE foods without informing the DVFA, without adequate facilities and equipment and without having developed HACCP-based procedures for the newly introduced RTE product. The situation was identified by a DVFA inspector in May 2018, who requested the FBO to stop the activity until it was included in the HACCP plan. Nonetheless, the establishment was allowed to resume the production of the RTE food. Since then, the production of RTE foods in the establishment is ongoing, although the DVFA inspector is still not satisfied with either the HACCP plan and the own-checks system or the facilities and equipment. In an effort to assist the FBO in complying with the rules and make the necessary amendments of the HACCP plan and the own-checks system, the DVFA inspector provided advice.

(3) In their response to the draft report DVFA indicated that DVFA has not specified the conditions for use of containers as a cold storage, as it will always depend on a concrete assessment of the own-checks programme of the establishment, if it is possible to use a container for the purpose of cold storage. DVFA further explained, that as the “containers” are rooms in the establishment, they must be mentioned in the approval document. Containers can in fact be used as cold stores, in the opinion of DVFA. It is then required that the container is fit for purpose and that the establishment has own-check procedures which ensure hygienic loading and unloading of the products from the container. According to DVFA, the products must not be exposed to temperature fluctuations during loading and unloading by ensuring, according to the example given, that the container is not filled to such a degree that products cannot be accessed without almost emptying the container and that the door is kept closed as far as possible during loading and unloading.
Conclusions on registration and approval of establishments

49. There are procedures in place, which are followed by DFA and DVFA for registration of vessels and approval of establishments and vessels requiring approval respectively. However, the practical implementation of the system - in particular the assessment and verification of compliance - shows weaknesses, which resulted in the granting of approval to some establishments although these were not in full compliance with the relevant general and specific requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004.

50. The approval of establishments is not subject to review by DVFA in cases where official controls reveal that the conditions of approval are no longer met.

5.3 OFFICIAL CONTROLS

Official controls on the production and placing on the market

Legal requirements


Findings

51. DVFA official controls are categorised in three groups; the basic inspections, the prioritised inspections and the inspection campaigns. The first constitute the regular official controls, the second group constitutes an extension of the coverage of the basic inspections, while the latter group constitutes targeted controls based on identified or emerging risks.

52. Official controls are carried out on the basis of a risk categorisation of the establishments and vessels. DVFA uses a point system to calculate the risk score of an establishment, which will determine the frequency of the ordinary inspections with fixed frequencies. The audit team noted though that freezing at sea is categorised differently from freezing at land as it is harder to visit vessels. DFA uses also different tools to calculate the risk for each vessel, which is related to fisheries policies but also to the hygiene conditions. As explained to the audit team, hygiene related issues lead to vessels being included into a local risk list and are subject to more frequent controls for three months after their inclusion in the list.

53. The DVFA frequencies for official controls in establishments range from “when needed” in very low risk establishments, to four times a year in high risk establishments. The frequency can also be reduced or increased depending on the past records of compliance.
of a FBO. The frequency of official controls can also be reduced under certain conditions for establishments which are certified members of a third party assurance scheme.

54. FBOs can obtain a so-called "Elite" status if the last four inspection reports were without any sanctions, and all inspection reports of the last 12 months were without sanction as well. The frequency of official controls in Elite status establishments is reduced.

55. The topics covered by DVFA inspectors during their official controls fall within 12 legislative areas and include e.g. food hygiene (handling of food, cleaning and maintenance), HACCP and own-checks systems, approvals, labelling, contaminants, publication of inspection report, packaging materials and product standards. For each establishment, DVFA keeps an Excel spreadsheet indicating which of the legislative areas and their subtopics are relevant, and which topics have been covered by the official controls. According to DVFA, all relevant legislative areas and subtopics must be subject to at least one official control within a three-year cycle.

56. The audit team noted that from the examples seen, the planned inspections with fixed frequencies are generally met and supplemented e.g. by follow-up inspections, prioritised inspections and campaign inspections.

Primary production – vessels

57. Official controls on primary production vessels are carried out by DFA. Factory and freezer vessels are covered, as regards the primary product (fish), by DFA, and, as regards the facilities, equipment and the transformed fishery products, by DVFA.

58. Based on an agreement between DVFA and DFA, the latter is expected to carry out hygiene controls of at least 10% of the landings. According to DFA, in 2018 the hygiene controls covered 13.5% of the total quantities of fish landed.

59. The audit team noted that DFA inspectors who are "on call" around the clock in shifts receive information about landings of fish so they can select (on the basis of risk criteria) which vessels should be inspected during landing. Vessels are also inspected by a special DFA team while they are at sea.

60. The vessel visited during the audit pre-notified the landing to the DFA inspectors two hours in advance. The exact landing time was communicated with a subsequent notification sent by the vessel. Such notifications are received on the mobile phones of the DFA inspectors immediately.

61. DFA inspectors observed the entire landing process and then accessed the vessel to check the hygiene conditions on board the vessel. Organoleptic checks on the fishery products were carried out in the auction hall where the fish was transported immediately after landing.

62. DFA inspectors recorded their findings in a database used to store all official control results. DFA inspectors communicate to DVFA the official control reports on hygiene
only in cases of non-compliance, in which case, depending on the seriousness of the non-compliances they contact DVFA either by email or by telephone.

**Aquaculture farms**

63. Official controls on aquaculture farms are carried out by the veterinary units of DVFA.

64. The audit team noted that official controls are mainly focused on animal health. Elements related to public health, e.g. use of antibiotics and the respect for withdrawal period were not checked and verified by the inspectors. According to a veterinary inspector met, a question was sent a year ago from the regional office to the DVFA headquarters in relation to whether veterinary inspectors should carry out controls on the use of veterinary medicinal products in aquaculture, but to date no answer has been received.

65. The audit team noted that no guidelines have been prepared for the veterinary inspectors in relation to public health and food safety issues relevant specifically to aquaculture that need to be covered during official controls.

66. In the land-based aquaculture farm visited, the audit team noted that certain ponds were used to keep the so called "back-weighters" (all fish which did not pass through the last sizing and grading step meaning that they were undersized). Due to the fact that there has been an overall increase in the numbers of "back-weighters", there has been an associated increase in the density of fish (now very high) of different sizes and vitality state. According to the veterinary inspector, checks on the density of fish in ponds and animal welfare are carried out only in organic aquaculture farms.

**Landing sites, collection centres, auctions**

67. The landing operations observed were carried out quickly and efficiently. The fish arrived gutted and sorted in boxes and stored on melting ice. The transportation from the vessel to the auction hall was also rapid.

68. The audit team noted that the boxes used to store the fishery products had drain holes on their bottom part so that the melt water from a box placed on the top of a pile of boxes would drain all the way down through all the boxes positioned underneath, irrigating and potentially contaminating fishery products stored in boxes underneath. According to DVFA and DFA, the boxes should be constructed that way, because it is the running melt water which keeps the fish cold (\(^4\)).

\(^4\) In their response to the draft report, DVFA pointed out that as melt water has a larger surface, it is more efficient for chilling than ice. DVFA acknowledged that the boxes seen by the audit team had holes in the bottom, explaining further that these were constructed precisely this way in order to allow melting ice to pass from one box to the next. As DVFA explains, it is a prerequisite for the use of this system that there are efficient own-check procedures in place to ensure that the boxes are always clean when they are used, so that contamination is not passed between the boxes. DVFA make also reference to their response to recommendation no. 7.
69. The boxes with the fish unloaded from the vessel were placed directly on the ground on the quay, where some cleaning with pressurized water took place before the landing activities commenced. The audit team noted that the bottom box, which was touching the ground and as such was contaminated underneath, could in the auction hall, (due to regrouping of the boxes according to species and size, or check weighing) be relocated above other boxes. Contamination from the ground on the quay and the floor in the auction hall would drip with the melt water through all boxes below, contaminating some or all of the fish.

70. Collection centres are facilities which receive unsorted and/or ungraded fish from the vessels, which they then sort and grade before this is transferred to the auction hall.

71. The hygiene controls on fishery products both in collection centres and auction halls (before the first sale) are under the responsibility of DFA; the equipment and facilities are under the responsibility of DVFA.

72. With the exception of the placing of the boxes with fishery products on the floor, as described above, the hygiene conditions in the collection centre and auction hall visited were satisfactory.

73. The audit team noted that the auction hall visited did not have lockable facilities for the refrigerated storage of detained fishery products nor separate lockable facilities for the storage of fishery products declared unfit for human consumption, as required by point 2(a)(i) of Chapter II, Section VIII, Annex III to Regulation (EC) No 853/2004. According to the FBO, non-compliant fish would be immediately sent to a close-by located ABP processing plant. The DFA inspector explained this by the fact that, unlike it in the past and due to the rules on fisheries and the quotas, fishermen are interested in maximizing their profit by delivering smaller quantities of fresher, high quality fish, rather than large quantities of old, lower quality fish. The FBO explained also that in the past, it was quite regular to have old, low quality fish landed as the focus was on the quantity; the last couple of years the FBO could not remember an occasion of low quality fish received.

74. The audit team noted that the FBO used special transportation equipment, developed following a request from the DVFA inspector. This equipment was designed to allow the transportation of the boxes of sold fish from the auction hall, to the trucks of the buyers, without the fishery products being exposed to birds and/or weather conditions.

75. The audit team found the traceability of the products in the auction hall to be effective, readily allowing the tracing back to the vessel and forward to the purchaser of the fish.

Establishments

76. The audit team noted that official controls were carried out regularly. In the establishments visited, planned arrangements were always met irrespective of whether the establishments were in a standard or reduced frequency regime (Elite status) of
official controls. Follow-up inspections to verify compliance were carried out, but with a questionable degree of effectiveness (see paragraphs 79 and 88).

77. In a stand-alone cold store visited, the audit team noted that the facilities were kept at a very high level state of maintenance, tidiness and hygiene; a detailed hazard analysis assessed the risks arising from the possible hazards. It was also noted that all products stored were labelled, and accurate information was available about the location within the cold store of each product. The traceability of all products, including the intermediate products sent to the Ukraine for filleting and returned to Denmark post-processing, was possible, both backwards up to the vessel and forward to the customer receiving the goods.

78. The audit team noted that temperatures in the cold chambers were continuously monitored and recorded by means of data loggers; the FBO could demonstrate that the temperature in the cold store (and in the fishery products) was maintained at all times below -18°C Celsius.

79. In one establishment visited the audit team noted that condensation was dripping from the ceiling over exposed smoked fishery products. The audit team also noted that the DVFA inspector identified this issue during an official control in January 2019 (see paragraph 25). However, the fact that there was no condensation on the ceiling during the follow-up inspection was sufficient for the inspector to conclude that the non-compliance has been addressed. It was not clear from the report whether the inspector assessed the measures taken by the FBO or whether, during the follow-up inspection, freshly smoked products were present in the chiller (a situation which would generate the condensation on the ceiling) or not. The substantial condensation present on the ceiling of the chiller during the audit demonstrated that the actions taken by the FBO, if any, had not been effective in preventing the build-up of condensation (5).

80. The audit team also noted that official controls tend to overlook non-compliances in relation to the HACCP plans and own-checks systems. In one establishment visited, approved for the production of fish oil for human consumption, the audit team noted a number of deficiencies in the HACCP plan, which had been overlooked by DVFA inspectors (see paragraphs 40, 41, and 42). In addition, inspectors had not identified the fact that in practice, the HACCP plan was not implemented as described in the plan, especially as regards the heat treatment. To note is that there was no subsequent step in the production chain capable of eliminating the microbiological hazards.

81. In another establishment visited, DVFA inspectors overlooked the fact that reception, storage and dispatch of live lobster was not covered in the establishment’s HACCP plan.

(5) After the audit and during the drafting of the report, the DVFA provided the audit team with a summary of the enforcement measures imposed on the FBO following the audit visit. The FBO was sanctioned with an administrative fine of 15,000 DKK in relation to the risk of contamination of salmon (in the shock chill room, rinsing room and in the section for raw materials). The FBO was also issued a warning due to a) the absence of documentation of corrective actions to address temperature deviations in the freezer container and b) the absence of commercial documents that should accompany animal by-products dispatched from the establishment.
82. In another establishment visited, producing smoked products, the audit team noted that polycyclic aromatic hydrocarbons (PAH) had been assessed as “low risk” and no sampling was taking place; the hazard analysis justified this on the basis that consumers are aware of the risk of PAH arising from the smoking process. The audit team also noted that the maximum permitted limit for PAH indicated in the HACCP plan was 5 micrograms per kg, which was the limit legally valid until 2014. The establishment in question was approved in 2016.

83. In another establishment visited, processing mainly herring, the audit team found that there was no clear procedure in the FBO’s own-checks system as to what was to be sampled, or what constituted a sample. In particular, it was not clear whether the nine samples (for histamine testing) consisted of nine fish taken on a particular day of a month, or whether the nine samples were taken on nine different days in a particular month. It was also not clear whether a sample consisted only of one fish or whether several fishes were pooled together to a composite sample.

84. In addition, in the same establishment the audit team also noted that not only the limits indicated in the own-checks system were ten times higher than the maximum permitted levels indicated in Regulation (EC) No 2073/2005 (100mg/100gr instead of 100mg/kg indicated in the Regulation), the interpretation of the results was also not in line with the above-mentioned Regulation. According to the procedure described, if the average of the nine samples together is below 100mg/100gr, then the samples, according to the FBO’s procedure, are considered compliant.

85. The audit team noted that the risk from physical hazards, in particular in the form of metal fragments from the machinery and equipment was not adequately managed. Although these non-compliances had been identified by the DVFA inspectors, corrective measures were not enforced. One highly automated establishment filleting and cutting herring, did not avail of metal detection equipment because, according to the FBO, there was no metal detector available that would be able to detect metal pieces in the 20 kg bags the establishment produced. The DVFA inspector was satisfied with this statement of the FBO, despite alternatives being available. See also paragraphs 38 and 39.

86. In the establishment in question, the FBO indicated that a metal detector would also be useless to install because the sliced fishery products are placed on a metal-coated tray, rendering use of a metal detector impossible. However, there are alternative foreign body detection methods, which could be assessed for that purpose. Nonetheless, the FBO had at least established a procedure to check, before and after production, the condition of the blades and to block products produced on a particular day, if the checks revealed that any metal fragments are missing from the blades.

87. The audit team had the opportunity to witness the effectiveness of the cleaning programme and maintenance of the establishment concerned. It was noted that the facilities, equipment and machinery were meticulously cleaned, despite the high level of automation with associated complex installations. However, the washed blades, which
were left to air-dry, developed rust along the edges, in places which could come into contact with the fishery products.

88. The general hygiene and cleanliness in the establishments visited varied, as did the good hygiene practices implemented by the FBOs. The audit team noted some general hygiene issues as well as poor hygienic practices whose regularity suggested that they were either overlooked by the DVFA inspectors or not subject to effective enforcement of corrective measures:

a. In two of the establishments visited, shovels used to distribute ice over the fishery products and paddles used to stir fishery products were in contact with cleaning equipment for other purposes (brooms).

b. In one establishment, a large number of old wooden pallets were stored inside the production hall. Products, which the FBO considered to be food were in direct contact with these wooden pallets. In the same establishment, chemicals were also stored freely accessible inside the production hall. In another establishment, wooden pallets were in use inside the filleting room.

c. In one establishment, finished products were stored in the same chiller as the raw materials. In the same establishment, staff were using a high-pressure washer while raw materials, ice and mussels were being exposed to the dirt which was being dislodged with the water jet from the floor.

d. Staff sitting outside the establishment wearing the same clothes they wore while processing fishery products.

e. Racks used for fishery products were placed directly on the floor.

f. In one establishment, staff training and knowledge about basic hygiene requirements, good hygiene and good manufacturing practices were insufficient. Staff were also having their break outside wearing the same clothes used in the production, aprons were in contact with the scrappers used to clean the floor, staff were not wearing hair-covers or, where necessary, beard-covers.

89. In two establishments visited, the audit team noted that fishery products were neither labelled, nor traceable (lobsters and live crayfish kept in water tanks in one of the establishments visited) or unlabelled and poorly identified, with one “post-it” label on a full pallet of otherwise unlabelled, packed and packaged fishery products.

90. In one establishment visited, the audit team noted that, although the FBO considered the cooling phase after the heat sterilization of the products as the most important phase for product safety, no effective measures were taken to prevent contamination of the cans in the cooling phase. Instead of being protected by being stored in a dedicated area, cans were allowed to cool down in metal crates in different parts of the factory.

91. In one establishment visited the audit team noted that the flow of the clean equipment was crossing the flow of the dirty one. While the DVFA inspector identified this issue, existing arrangements were accepted as the FBO was planning to extend the facilities of the establishment in the near future and could address the issue with the additional space.
created (6). In the same establishment, the position of the drains in relation to the position of the equipment was inadequate and resulted in the entire floor of the processing room being covered in process water and trimmings from the filleting process.

92. In three of the establishments visited, the audit team noted that animal by-products were not identifiable as required by Article 4 of Regulation (EC) No 1069/2009; as a consequence, they were not distinguishable from the fishery products destined for human consumption. In some instances, animal by-products were stored together with raw materials and finished products. The audit team also noted that animal by-products from these establishments were dispatched without the commercial documents required by Article 21 of the aforementioned Regulation.

93. Two of the establishments visited were obtaining ice from external independent ice producers. The audit team noted that such independent ice producers are out of the scope of DVFA and are not subject to official controls because, according to DVFA, ice used to chill fishery products does not constitute (a) food (ingredient) as defined in Regulation (EC) No 178/2002, and ice producers therefore are not food business operators and, as such, do not fall within its responsibility. Nonetheless, where ice is used for chilling, DFVA requires FBOs to ensure that the ice is safe and does not pose any risk to the fishery products.

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

94. Both the DVFA and DFA have a system in place of risk-based official controls, with the calculated frequency of official control being adjusted to take account of the past compliance history of the FBO.

95. Both CAs have tools available which enable them to keep track of the progress of the implementation of the official controls and the follow-up activities. The planned control frequencies are overall met and supplemented by other types of inspections.

96. However, official controls failed to verify and/or ensure FBOs’ compliance with the requirements for auction and wholesale markets, and in traceability of fishery products. The scope of official controls carried out by DVFA in aquaculture farms is limited to matters relating to animal health. Issues related to contamination and cross-contamination of fishery products through contact with dirty surfaces or (contaminated) melt water were also overlooked by both CAs.

97. The assessment of the HACCP plans and own-checks systems of food establishments is not carried out to an extent which would allow DVFA to ascertain that FBOs apply such procedures both continuously as well as correctly, and to determine whether these procedures guarantee, to the largest extent possible, that the fishery products comply

(6) In their response to the draft report DVFA agreed that the solution implemented by the establishment for separation between the dirty and clean flow was not optimal and indicated further that considering that this was a temporary solution, DVFA found that it could be accepted. DVFA also informed that the rebuilding of the establishment to avoid cross of dirty and clean flow will be completed by 1 April 2020.
with the microbiological criteria laid down in Regulation (EC) No 2073/2005 and the maximum permitted levels of certain contaminants such as PAH in foodstuffs laid down in Regulation (EC) No 1881/2006 and, that they do not contain physical hazards, such as foreign bodies, as required respectively by Articles 4(5), 4(5)(a) to 4(5)(c) of Regulation (EC) No 854/2004 (7).

98. Official controls failed to verify correctly, and therefore enforce, compliance of FBOs with the EU animal by-products legislation in respect of the identification, handling (including separation) and dispatch of ABP generated during the production of fishery products.

**Official controls on fishery products**

**Legal requirements**


**Findings**

99. Organoleptic checks are under the responsibility of DFA. Official controls mainly take place during landing operations, on vessels, in collection centres, or in the auction halls. According to DVFA and DFA, the organoleptic checks carried out on fishery products in recent years did not raise any doubts that would require checks of the freshness indicators, i.e. total volatile basic nitrogen (TVB-N) and Trimethylamine nitrogen (TMA-N).

100. During the audit, in an auction hall which was visited, DFA inspectors verified the hygiene conditions of the fishery products landed by a vessel, as well as their freshness and the size categories. The control was concluded by checking the discrepancy between the weights indicated on the boxes by the FBO and the actual weight of the fishery products, which should be below the permitted level of 5%.

101. DFA inspectors regularly carry out the official controls of fish landings, up to the place of first sale. In cases where the fish is sold directly from the vessel to an establishment, DFA inspects the fish either directly at the establishment receiving the fish or at the cold store receiving and storing the fish for the purchaser.

102. The audit team noted that one FBO visited had appointed a private company (ISO 17020 accredited) to monitor the landing operations and the weight of the fish (including by-catch), and to perform the organoleptic checks; both were documented in detail.

(7) In their response to the draft report DVFA stated that they consider the conclusion to be a generalisation, indicating that only singular cases of establishments with non-conformities with regards to histamine and *Listeria monocytogenes* testing were found. In this respect, DVFA made also reference to the response provided in relation to recommendation no. 8. DVFA stressed out that despite the lack of a description of a procedure for testing of the shelf-life of products for *Listeria monocytogenes* in one establishment, the testing was actually being carried out correctly.
103. Microbiological samples, samples for residues and contaminants (heavy metals, dioxins and Polychlorinated bi-phenyls (PCBs)) are collected and analysed as part of the official controls or of particular campaigns and projects developed and run by DVFA. According to DVFA, the projects are adapted -or new projects developed- to cater for any emerging situations or the need to investigate particular issues.

104. As regards official controls on parasites and poisonous fishery products, DVFA indicated that this is to a large degree covered by audits of the FBO’s own-check system, as it is the FBO’s responsibility to have procedures in place to ensure compliance with legislation so that only products fit for human consumption are placed on the market.

105. In relation to the shelf life of smoked fishery products, the audit team noted that the FBOs visited regularly carried out verification of the shelf-life, and testing for *Listeria monocytogenes* (daily and weekly sampling). In one of the establishments visited, however, the procedure followed for the shelf-life tests was not described in the own-checks system or HACCP plan. This was overlooked by the official controls.

106. The audit team noted in the establishments visited that the sampling and testing of finished products by FBOs for *Listeria spp.* was supplemented with sampling and testing for *Listeria* in raw materials, as well as in the environment of the establishments.

**Conclusions on official control on fishery products**

107. Official controls on fishery products are largely carried out in line with the requirements of Annex III, Chapter II to Regulation (EC) No 854/2004.

**5.4 FOLLOW UP OF RASFF NOTIFICATIONS**

**Legal requirements**


**Findings**

108. DVFA does not generate any RASFF notifications if the fishery products concerned did not leave Denmark.

109. DVFA provided the audit team with details about the handling of, and the actions taken in response to, the above-mentioned RASFF notifications.
Conclusions on follow-up of RASFF notifications

110. The DVFA has an adequate system in place for dealing with RASFF notifications.

6 Overall Conclusions

The system of official controls largely covers the production, processing and distribution stages applicable to fishery products placed on the market. Tools to support staff in performing their tasks are readily available, allowing the control arrangements and associated follow-up activities overall to be met, as planned.

However, the effectiveness of the system is negatively affected by shortcomings in the subsequent enforcement of corrective actions by food business operators, allowing non-compliances to persist.

The audits to ascertain the fitness for purpose of food business operators’ HACCP-based procedures demonstrated a number of deficiencies.

With regard to the approval of establishments, there are some shortcomings in the system concerning the assessment of compliance of particular types of establishments with the general and specific requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004. The deficiencies concern both the granting of the initial approval, as well as the subsequent verification during official controls that the conditions of the original approval continue to be met.

7 Closing Meeting

The closing meeting was held in Copenhagen on 21 June 2019. During the meeting, the audit team presented the audit's main findings and preliminary conclusions to DVFA and DFA. DVFA provided further information about the scoring system for risk categorisation of the establishments and informed the audit team about the new 'Uniformity strategy', which was introduced in 2019 with the aim, amongst others, to harmonise the way inspectors assess and deal with non-compliances.
## 8 RECOMMENDATIONS

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| 1.  | The DVFA should ensure that enforcement measures ensure that food business operators correct the non-compliances found, as required by Article 54(1) of Regulation (EC) No 882/2004, and that sanctions imposed are proportionate and effective, as required by Article 55(1) of the same Regulation.  
  *Recommendation based on conclusions: 29 and 30*  
  *Associated findings: 21, 23-26 and 79* |
| 2.  | The DVFA should ensure that establishments, and in particular those producing fish oil for human consumption and frozen fishery products, are approved for these activities only if the food business operator has demonstrated that these comply with the relevant requirements of food law, as required by Article 31(2)(c) of Regulation (EC) No 882/2004. For fish oil producing establishments this concerns in particular the requirements of Section VIII, Chapter IV, points B.2 and 3 of Annex III to Regulation (EC) No 853/2004. For establishments producing frozen fishery products, this concerns notably the requirements of Section VIII, Chapter III, point B of Annex III to Regulation (EC) No 853/2004.  
  *Recommendation based on conclusion: 49*  
  *Associated findings: 33 and 37-45* |
| 3.  | The DVFA should ensure that the approval of an establishment is kept under review when carrying out official controls, as required by Article 31(2)(e) of Regulation (EC) No 882/2004.  
  *Recommendation based on conclusion: 50*  
  *Associated findings: 46-48* |
| 4.  | The DVFA should ensure that the requirements of point 2(a)(i), Chapter II, Section VIII, of Annex III to Regulation (EC) No 853/2004, are enforced.  
  *Recommendation based on conclusion: 96*  
  *Associated finding: 73* |
| 5.  | The DVFA should ensure that official controls covering public health aspects of fishery products take place at all stages of production, processing and distribution, including aquaculture farms as required in Article 17(2) of Regulation (EC) No 178/2002.  
  *Recommendation based on conclusion: 96*  
  *Associated findings: 64-66* |
| 6.  | The DVFA should ensure that the food business operators' obligations regarding traceability as laid down in Articles 18(1) and (4) of Regulation (EC) No 178/2002, are enforced.  
  *Recommendation based on conclusion: 96* |
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| 7.  | The DVFA and DFA should ensure that the requirements concerning avoidance of (cross-)contamination of fishery products, and in particular the provisions set out in point 1(b) of Chapter II, and point A(4) of Chapter III of Section VIII, Annex III to Regulation (EC) No 853/2004, are enforced.  
*Recommendation based on conclusion: 96*  
*Associated findings: 68 and 69* |
| 8.  | The DVFA should ensure that audits of HACCP-based procedures verify that food business operators apply such procedures continuously and properly and determine whether the procedures guarantee, to the extent possible, that the fishery products comply with the requirements of Union legislation on microbiological criteria of foodstuffs, on maximum levels for certain contaminants in foodstuffs and, do not contain physical hazards, such as foreign bodies, as required respectively by Articles 4(5), 4(5)(a) to 4(5)(c) of Regulation (EC) No 854/2004.  
*Recommendation based on conclusion: 97*  
*Associated findings: 80-85* |
| 9.  | The DVFA should ensure that official controls verify compliance of food business operators with the requirements of Regulation (EC) 1069/2009, as required by Article 4(2)(c) of Regulation (EC) No 854/2004, in particular with regard to the identification, handling and dispatch of animal by-products generated during the production of fishery products.  
*Recommendation based on conclusion: 98*  
*Associated finding: 92* |

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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