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 an audit carried out in Denmark from 11 to 22 June 2018 as part of the published Directorate General for Health and Food Safety’s audit programme.

The objective of the audit was to assess the arrangements put in place by the competent authorities to verify compliance with European Union food hygiene requirements applicable to ready-to-eat food.

The report concludes that the official controls over production of ready-to-eat food are organised and implemented on a risk basis using comprehensive documented procedures and guidance, covering relevant aspects of the legislation and supported by IT systems.

Certain shortcomings and weaknesses are mainly related to approval of establishments, to auditing Good Hygiene Practices and procedures based on the HACCP principles, in particular food business operator procedures to prevent cross-contamination and to reporting audit findings.

Several measures to facilitate compliance and reduce food-borne outbreaks are in place addressing competent authorities and food business operators.

The report contains recommendations to the competent authorities to address the identified shortcomings.
### Abbreviations and Definitions Used in This Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<tr>
<td>DANAK</td>
<td>Danish Accreditation Found</td>
</tr>
<tr>
<td>DG Health and Food Safety</td>
<td>Directorate-General for Health and Food Safety of the European Commission</td>
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<td>DVFA</td>
<td>Danish Veterinary and Food Administration</td>
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<tr>
<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>EU</td>
<td>European Union</td>
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<td>EURL</td>
<td>EU Reference Laboratory</td>
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<tr>
<td>FBO</td>
<td>Food Business Operator</td>
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<td>FIU</td>
<td>Food Inspection Unit</td>
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<td>GHP</td>
<td>Good Hygiene Practice(s)</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Points</td>
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<td>KOR</td>
<td>Control Object Register</td>
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<td>MANCP</td>
<td>Multi-Annual National Control Plan</td>
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<td>MID</td>
<td>Meat Inspection Department</td>
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<td>MS</td>
<td>Member State/s</td>
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<tr>
<td>RASFF</td>
<td>Rapid Alert System for Feed and Food</td>
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<td>RTE</td>
<td>Ready-To-Eat</td>
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1 INTRODUCTION

This audit took place in Denmark from 11 to 22 June 2018 and was undertaken as part of the planned audit programme of Directorate-General for Health and Food Safety's (DG Health and Food Safety).

The audit team comprised two auditors from DG Health and Food Safety and was accompanied throughout the audit by representatives from the central competent authority (CCA) which for this audit was Danish Veterinary and Food Administration (DVFA).

An opening meeting was held in Glostrup on 11 June 2018 with the representatives from the CCA. At this meeting, the audit team confirmed the objective and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit.

2 OBJECTIVES AND SCOPE

The objective of the audit was to assess the arrangements put in place by the competent authorities (CAs) to verify compliance with European Union (EU) food hygiene requirements applicable to ready-to-eat (RTE) food\(^1\).

In terms of scope, the audit focused on the official controls performed by the CA in registered and approved establishments producing\(^2\) RTE food, in particular those that according to the data\(^3\) currently available represent the highest microbiological risk\(^4\), as well as RTE food that is increasingly common on the market and may have the potential for posing health risks.

The audit team, in this context, also took note of any challenges encountered in (the controls over) the implementation of EU food hygiene requirements in this particular area, as well as any measures to address these challenges, to support the implementation of the EU requirements, and/or aimed at reducing the number of food-borne outbreaks caused by the consumption of this category of food.

In pursuit of this objective, the following sites were visited:

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1 ‘Ready-to-eat food’ means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern (Article 2, point (g) of Regulation (EC) No 2073/2005)

2 Primary production and associated establishments are excluded from the scope of the audit.

3 The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016 - EFSA (European Food Safety Authority) Journal 2017;15(12):5077, 228 pp, the EFSA scientific opinion "Listeria monocytogenes contamination of ready-to-eat food and the risk for human health in the EU" - EFSA Journal 2018;16(1):5134, the data emerging from Rapid Alert System for Feed and Food (RASFF) alerts were considered as well as CAs classification for RTE food and associated microbiological risks/hazards considered important and taken into consideration in the organisation of the risk-based official controls.

4 See chapters Background and National context.
### Table 1: audit visits and meetings

<table>
<thead>
<tr>
<th>COMPETENT AUTHORITIES</th>
<th>No.</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>Competent Authorities</td>
<td></td>
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</tr>
<tr>
<td>Central level</td>
<td>1</td>
<td>Opening, closing and clarification meeting with the CCA</td>
</tr>
<tr>
<td>Regional level</td>
<td>5</td>
<td>Food Inspection Units (FIUs) (4) and Meat Inspection Department (MID) (1)</td>
</tr>
</tbody>
</table>

#### FOOD PRODUCTION ACTIVITIES

<table>
<thead>
<tr>
<th>Activity</th>
<th>No.</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat products establishments</td>
<td>3</td>
<td>One of them produces minced beef (&quot;tatar&quot; beef)</td>
</tr>
<tr>
<td>Fishery products establishments</td>
<td>1</td>
<td>Smoked and gravad (cured) fish</td>
</tr>
<tr>
<td>Dairy establishments</td>
<td>1</td>
<td>Producing cheese from raw milk</td>
</tr>
<tr>
<td>Salads and sandwiches producers</td>
<td>2</td>
<td>One of them also supplies to catering</td>
</tr>
<tr>
<td>Sushi establishments</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Catering establishment</td>
<td>1</td>
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</table>

### 3 LEGAL BASIS FOR THE AUDIT

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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the EU acts quoted in this report are given in Annex 1. Guidance documents which are relevant to the subject of this audit are listed for information in Annex II.

### 4 BACKGROUND

"The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016" issued by the European Food Safety Authority (EFSA) and the European Centre for Disease Control highlights that:

- The highest fatality rate and the highest number of deaths in 2016 were due to listeriosis, followed by salmonellosis. There has been a statistically significant increasing trend of confirmed listeriosis cases in the EU/European Economic Area (EEA) during the period 2008–2016. Non-compliance estimates in the different RTE food categories were consistently higher at the processing stage. The highest level of non-compliance was observed in the food category ‘fish and fishery products’ followed by ‘meat products other than fermented sausages’.

- Most of the outbreaks reported, for which the causative agent was known, were associated with bacterial agents, in particular *Salmonella* and *Campylobacter*. For the strong-evidence outbreaks, the implicated food vehicles were mostly of animal origin.

The summary of reported strong-evidence food-borne outbreaks caused by *Listeria monocytogenes* in the EU/EEA, as reported in the zoonoses database (2008–2015) -
published in the EFSA scientific opinion on *Listeria monocytogenes* contamination of ready-to-eat food and the risk for human health in the EU – reveals that the highest number of human cases were caused by consumption of mixed foods (like sandwiches and composite meals), followed by meat products, dairy products and fishery products, while the highest number of hospitalised cases and deaths were caused by meat products, dairy products and fishery products.

While the topic of the current audit has not been, as such, specifically targeted in any previous DG Health and Safety audit, the official controls over the production of different foods, some of them also RTE food, were covered within the scope of a number of audits and fact-finding missions, the reports of which can be found on the EU Commission website at: [http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm](http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm).

The overview reports on "*the state of implementation of HACCP in the EU and areas for improvement*" and on "*microbiological criteria for food*" are published at [http://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm](http://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm).

### 4.1 National Context

The CCA highlighted that the types of RTE food that cause listeriosis outbreaks in Denmark are mainly meat products (cold cuts), cold smoked fish and cured (*gravad*) fish. This is related to the relatively long shelf life of these types of products and their possible contamination by production equipment.

In 2017, one listeriosis outbreak of seven cases was caused by cold cuts of meat (Danish produced), which was recalled from the Danish market.

In recent years most food-borne outbreaks due to RTE food are caused by buffet meals served either in working place canteens or in restaurants. *Norovirus* has caused most of these outbreaks.

According to the CA data in 2016 and in 2017, 271 and 505 persons respectively became ill from *Norovirus* due to consumption of buffet meals. The most common route of transmission was ill kitchen staff or healthy carriers of virus among kitchen staff (six outbreaks in 2016, seven outbreak in 2017), or an ill person/guest attending the buffet (four outbreaks in 2016, one outbreak in 2017).

The CA highlighted also the risk related to consumption of imported frozen berries (especially raspberries and strawberries) and green salads (lettuce) which are often contaminated with *Norovirus* (see also paragraph No 2).

In 2016 and 2017, Denmark notified two (one each year) rapid alerts in the Rapid Alert System for Food and Feed (RASFF) due to *Listeria monocytogenes* in Danish produced RTE food. There were no reports of illness linked to these RASFF notifications. The audit team noted a decreasing trend in the number of RASFF notification for Denmark related to *Listeria* since 2015.
There were 10 product recalls in 2016-2017 related to RTE products (50% of them due to *Listeria* contamination in cold cuts).

No special consumer behaviours have been identified by the CA which may pose increased risk in relation to RTE food. The audit team noted that minced beef is consumed raw as “*tatar* beef”.

Nonetheless, the CA highlighted that long time, low temperature heat treatment of meat (e.g. roast beef) may pose a risk if this type of meat is not handled properly at the restaurant. In 2016 there was an outbreak linked to this type of food where 50 people got sick caused by *Clostridium perfringens*.

After the Danish outbreak in 2014 where 19 people died and 90 became sick due to the consumption of food contaminated with *Listeria monocytogenes*, the CA put in place several measures to address the causes and to prevent a reoccurrence of the situation (see paragraph No 110).

5 FINDINGS AND CONCLUSIONS

5.1 NATIONAL MEASURES

Legal requirements


Findings

1. Although no specific national legislation or further guidance have been put in place in addition to the definition laid down in Regulation (EC) No 2073/2005 regarding what foods are considered to be RTE, some of the national legislation contains measures which are relevant to the RTE food sector. For example:

2. Order No. 1354 (29 November 2017) on Food Hygiene ("Food Hygiene Order") requires that frozen raspberries must be heat treated for at least one minute if they are to be an ingredient in RTE food. The same Order specifies as a general rule that “heat treatment and reheating of food must be made by such a combination of time and temperature that the food is safe”. A table describing the effect from different temperature/time combinations considered equivalent to heat treatment at 75°C for one second has been developed by the National Food Institute (DTU Food), and was presented to the audit team.

3. Guidance No. 9236 of 29 April 2014 on food hygiene ("Hygiene Guidance") further explains the provisions of the above mentioned Order and lists some exemptions when heat treatment at 75°C (or equivalent) is not required (e.g. for fish 60°C for one minute is sufficient (killing parasites) or for whole meat pieces where the characteristics of the meal exclude thorough cooking (e.g. roast beef rare inside).
4. The Food Hygiene Order also establishes temperature requirements additional to those in the Hygiene Package for storage and transport of food. Some of these requirements are relevant to RTE food (e.g. mayonnaise, salads and remoulades with a pH above 4.5 should be stored at not more than 10°C).

5. DVFA established a website "All about Listeria" to help FBOs to better control hazards related to Listeria in their products and support CA officials in their controls. The website provides guidance on e.g.

- how to categorise products in relation to Regulation (EC) No 2073/2015 (whether they can support Listeria growth);
- how to perform risk assessment for Listeria and to set up own-check systems (including examples of sampling plans);
- how to react when Listeria is detected (corrective actions – including efficient cleaning and disinfection).

6. On the same website there are links to different Danish guidelines: e.g. Guidelines on microbiological criteria for food and Guidelines on shelf life studies.

7. The CCA informed the audit team that an FBO may choose to take single samples over a period (e.g. each day for a week), and evaluate the results together instead of taking five sample units on the same day. The FBO can also use a "Moving window5" and continuously assess whether the criterion is met on the basis of the latest five results. These solutions are primarily relevant for frequent, e.g. daily or weekly sampling. The CA requires the FBO to prove that the selected sampling plan provides the same guarantees as the ones laid down in EU legislation.

8. The audit team saw an example of implementation of the "Moving window" principle in a dairy establishment visited. In this establishment, the FBO tested one sample unit per batch (instead of five sample units at a time) and assessed the last five test results against the relevant criteria.

9. The CCA informed the audit team about the available specific guidelines prepared by different food business sectors and relevant for RTE food. The audit team noted that most of them are relevant for the retail or primary production sectors (e.g. retail butchers, honey production, fishmongers, supermarkets, restaurants, cheese at retail, etc.).

Conclusion on national measures

10. Several measures are in place supporting FBOs in addressing the microbiological hazards and control the production process of RTE food, as well as CA in performing the related official controls.

5 See: Principles and guidelines for the establishment and application of microbiological criteria related to foods (Codex Alimentarius Commission CAC/GL 21 – 1997 4.9)
5.2 COMPETENT AUTHORITY

Legal requirements


Findings

11. Detailed information on the structure and organisation of the Danish CAs can be found in the country profile for Denmark at:
   http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=DK

12. DVFA, an agency of the Ministry of Environment and Food, as the CCA has the overall responsibility for food safety. Official controls in the area of food safety (including in the RTE sector) are carried out by four DVFA Food Inspection Units (FIUs) and the Meat Inspection Department (MID).

13. The FIUs adapt national control programmes to local needs. Their responsibilities, inter alia, include approval/registration of food businesses, auditing of establishments, follow up of non-compliances and imposing sanctions, official sampling for laboratory analyses (including follow up of non-compliant results), providing guidance to FBOs, investigation of food-borne outbreaks and follow up of recalls, etc.

14. The CCA informed the audit team that in total, 226 full time inspectors in FIUs and 14 official veterinarians in MID are involved in official controls of RTE products as a part of their tasks. The total number of food businesses in Denmark (April 2018) was 63,604 of which 33,735 are involved in the production of RTE food (32,632 retailers and 1,103 wholesalers with production). The audit team did not note any issue related to availability of staff or equipment.

Training

15. The CCA informed the audit team that the heads of FIUs are responsible for ensuring that all employees are qualified and to determine the training needs for the staff.

16. Training can be provided through courses, job swapping, on the job training or participation in Danish or international seminars or workshops.

17. The audit team saw evidence of training particularly relevant for CA staff carrying out official controls on production of RTE food. Two Listeria specialisation courses were conducted in January and November 2016 with a total of 57 participating food inspectors from all FIUs. Two HACCP courses were held in November 2017 (one for technicians and one for official veterinarians and the audit team noted that mainly focused on USA HACCP requirements). There were several training courses on the relevant microbiological requirements for CA control staff (in 2016 and in 2017). The audit team saw evidence of CA staff participation in the relevant BTSF courses.

18. The audit team noted that no specific training courses were organised on audit. In this
respect the CCA informed the audit team that new inspectors follow an experienced inspector during several audits before they perform audits themselves as part of their induction programme. The CCA highlighted that experienced inspectors participated in BTSF courses on auditing of HACCP.

19. When observing the official controls carried out by the CA inspectors in the establishments visited, the audit team noted that that the inspectors are knowledgeable, competent and identified issues which were also found by the audit team.

**Internal audit**

20. The DFVA internal audit unit carried out 9 internal audits between 2015 and 2017 (three each year). The CCA provided the audit team with information on the internal audit carried out in 2015 on microbiological criteria which is relevant for RTE food. The main recommendations (which had already been addressed by the CA) were as follows:

- More risk based approach is needed for choosing relevant establishments and products for sampling;
- Focus on FBO own-check analysis whether the correct analytical method is used;
- Training of official sampling staff (from 2018 sampling is accredited);
- Sanctions in case of non-compliances (now central guidance from the legal team included in the sampling project manual).

<table>
<thead>
<tr>
<th>Conclusions on competent authority</th>
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<tbody>
<tr>
<td>21. The CA responsible for the official control system over the production of RTE food is clearly designated. The CA's structure and organisation are adequate for the performance of its task.</td>
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<tr>
<td>22. A training system, also covering issues related to RTE food sector, aimed at ensuring that official staff can execute their tasks effectively is in place.</td>
</tr>
<tr>
<td>23. An internal audit system is in place in line with the requirements of Article 4(6) of Regulation (EC) No 882/2004 which covers aspects relevant to the official controls carried out over the production of RTE food.</td>
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</tbody>
</table>

### 5.3 REGISTRATION/APPROVAL OF FBOs

**Legal requirements**


**Findings**

24. The approval/registration system is described in the country profile for Denmark (see paragraph 11).
25. The CA informed the audit team that there is a CA guidance document specifically dealing with the approval and registration of food establishments ("Approval Guide"). The document is intended to provide guidance both for FBOs and CAs.

26. Establishments for which approval is not required must be registered. FBOs can perform registration on the website of the CA. Registration is followed by an on-site visit by the CA within one month.

27. According to the approval procedure in place where all infrastructure and equipment requirements are complied with, conditional approval for three months is granted for the establishment, and the establishment is given an approval number. Within the three month period, the FIU or the MID revisits the establishment to evaluate the performance of the own-check system and the production process, and final approval is granted if everything is found to be in compliance with all the requirements of the food law. The FIU or the MID issues approval numbers and updates lists of establishments.

28. The audit team noted that the above-mentioned approval procedure is followed only in the case of new establishments. If a new activity is added by the FBO to the existing ones, final approval is granted by the CA as regards the new activity without a prior conditional approval.

29. The audit team noted several discrepancies between the activities indicated on the list of approved food establishments, the activities mentioned in the approval certificates and the activities actually carried out in the establishments visited.

30. In some of the establishments visited the audit team noted that:

- the establishments had not been approved for all the activities which were actually carried out (e.g. fishery products establishment producing fried chicken skin was not approved as a poultry meat products establishment; a catering establishment cooking fish (among other activities) was not approved as a fishery products establishment).
- the establishments were listed under several activities which were not being carried out, or for which they have not been approved.
- one of the establishments visited was approved as a meat products establishment, but was not on the published list of approved food establishments.

31. These findings are not in compliance with the requirements of Article 31(2)(c) and (e) of Regulation (EC) No 882/2004 which requires that the CA shall approve an establishment for the activities concerned and shall keep the approval under review when carrying out official controls.

32. The CCA informed the audit team that in line with the provisions of the "Approval Guide" FBO must notify the CA only if there are significant changes in the activities carried out in the establishment (e.g. processing meat in an establishment which is
approved for fishery products, mentioned by the CA inspectors as an example). There is an exhaustive list of examples in the “Approval Guide” as to what should be considered as significant changes. The audit team noted that the examples provided in the guidance document are not supportive as regards what changes (and in which cases) the FBO should report to the CA in the RTE food sector. Moreover, the scenario mentioned above is not included in the list of examples.

33. The audit team also noted that if an establishment already has an approval for meat products (e.g. producing fermented salami), the FBO is not required to inform the CA when another type of meat product (e.g. heat treated meat product) is produced in addition to the existing one, even if the way of controlling the hazards associated with these types of products are significantly different. This neither facilitates the effectiveness of official controls nor the individual risk characterisation of the establishments (see paragraph No 37) as the CA inspector will become aware of the new activities during the subsequent visits only.

34. The audit team noted that in the approval certificate, intermediate processing steps (e.g. cutting of meat for the preparation of meat products; mincing meat for the production of meat preparation) are included in the approved activities and the establishment is listed as a cutting plant in addition to a meat products establishment (although meat cuts are not the final products). The CCA informed the audit team that according to the CCA's interpretation of the relevant EU legislation meat products establishments should be approved also as cutting plants and cold stores (even though they store their own final products only). According to the CCA this approval is needed for the CA in order to be able to enforce the temperature requirements applicable for cutting plants and cold stores.

35. Although the CA inspectors are required to verify the maintenance of approval conditions at least annually during inspection and the inspectors should update the relevant information in the KOR system (Control Objects Register –the main database used by the CA for individual risk characterisation of each establishment), the audit team noted that it is not consistently carried out. As the published list of approved establishments obtains the information from KOR, the list is not up to date.

**Conclusion on registration/approval of food business operators**

36. Procedures are in place for registration and approval of establishments handling or producing RTE food. However, there are shortcomings in their implementation which result in the list of approved establishments not being up-to-date and approval of establishments does not accurately reflect the actual activities carried out.
5.4 **OFFICIAL CONTROLS OF FBOs PRODUCING RTE FOOD**

5.4.1 *Organisation and implementation of Official Controls*

**Legal requirements**


**Findings**

5.4.1.1 *Risk based official controls*

37. DVFA has implemented a system for planning the risk-based frequency of official controls using an individual risk characterisation for each establishment (to be updated annually). Based on the calculated risk each FBO is placed in one of the five risk groups (from “very high” to “very low”) to determine the standard frequency of inspection.

38. The system was introduced at the beginning of 2017 and is described both in the Country profile of Denmark and in the report of a fact-finding mission carried out in Denmark in order to gather information on the arrangements put in place for risk-based planning of official controls on food safety. The mission report (2017-6035) can be found at: [http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3873](http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3873)

39. Risk characterisation of establishments, inspection planning and report writing are supported by several IT applications (more details can be found in the above mentioned audit report).

40. The KOR system captures the details of all registered and approved establishments including the main activities carried out. As the risk characterisation system is based on activities and not on the type of products, there is no specific category for establishments handling or processing RTE food.

41. The audit team noted that production of RTE products does not automatically involve a higher score in the risk characterisation system. Risks points are allocated to processes and some of them are relevant to RTE products: e.g. heat treatment, smoking, handling of unwrapped goods that require cooling, etc. The highest risk points are allocated to products of animal origin (handling food of animal origin at wholesale) and to production of sprouts.

42. Wholesale establishments producing food of animal origin, regardless of the fact that they produce RTE food or not, will in general be inspected four times annually as they fall in the highest risk category (e.g. cutting fish or smoking fish are in the same category).

43. The audit team was informed by the CA that 51% of the 1,103 wholesale establishments producing RTE food are placed in the very high risk (four ordinary inspections
annually), 39% in the high risk (two ordinary inspections annually) and 9% in the medium risk group (one ordinary inspection annually). All RTE food establishments visited by the audit team were categorised as “very high risk” establishments.

44. Inspections are, with few exceptions, carried out unannounced.

5.4.1.2 Procedures for official controls

45. The Control Frequency Guidelines for Food and DVFA’s General Inspection Manual provide guidance to CA staff to plan and implement official controls. Annex I of the General Inspection Manual contains Guidelines on Audits. However, the audit team noted that this guideline currently covers audits on the FBOs' procedures based on the HACCP principles. The CCA informed the audit team that they plan to revise the Guidelines on Audit by June 2019 to also cover the audits of Good Hygiene Practices (GHPs).

46. The DVFA distinguishes between three main types of inspections – basic inspections (including: ordinary inspection according to fixed frequencies; follow up inspections after an inspection resulting in sanctions; other inspections: e.g. related to certain subjects; and approval inspection), prioritised inspections and campaign inspections, which are targeting specific issues.

47. Basic inspections are the most numerous type of inspection and are those whose frequency at particular operators is determined according to the individual risk-based frequency.

48. Prioritised inspections allow additional inspections to be carried out at particular establishments, due for example to specific problems with compliance or activities considered to be of relatively higher risk. In 2016, there were approximately 6,000 prioritised inspections and this has more than doubled to 13,300 in 2017 (13,000 retail and 300 wholesale). Examples of prioritised inspections in 2017 include the targeting of low compliance establishments, controls on food additives and Listeria at wholesale operators.

49. Inspection campaigns, of which there are approximately 15 per year, represent the third type of risk-based inspection activity undertaken by DVFA (see paragraph No 75).

50. Standard inspection frequency can be reduced:

- to reflect the FBO's history of compliance (e.g. FBOs with "Elite" status),
- for FBOs with Third Party Certification,
- for FBOs forming part of a chain.

51. The audit team noted that the number of official controls actually carried out in RTE food production establishments ("wholesale with processing") exceeded the planned targets (e.g. 2,102 official controls were planned for 2017 and 3,306 were carried out). These latter numbers include all types of inspections carried out (ordinary, follow-up,
prioritised and inspection campaigns).

52. The audit team noted in all establishments visited that the planned inspection frequency for each establishment was followed. The DVFA has made an inspection plan for all wholesale establishments covering an inspection period of three years.

53. After each inspection an official control report is prepared on the spot and is given to the FBO. Each inspector has a “Digital bag” (digital tools) including a printer. Individual inspection reports are publicly available on the DVFA website (except for establishments where more than 12 reports are prepared annually: in those cases a monthly summary report is published).

54. Although according to the CA’s procedure all non-compliances should be recorded in the official control report, the audit team noted that non-compliances considered by the CA inspectors as minor ones (i.e. usually non-compliances related to the requirements of Annex II of Regulation (EC) No 852/2004) were not recorded in the report, especially in the cases when the FBO made a verbal commitment to rectify them.

55. The audit team noted when deciding on the significance of non-compliances that the CA does not routinely take into account the specific risks linked to RTE food products. For example: in a catering establishment visited peeling silicone sealer and rusty grids of the chilling unit above partially protected/exposed products were considered by the CA inspector as “too minor maintenance issues” to mention them in the report. In a fishery products establishment visited the FBO had no written procedures for parasite testing (as found by the CA inspector), this non-compliance was not recorded in the official control report.

56. The audit team noted in a dairy establishment visited which was registered as third party certified by DVFA not long before the audit team visit and had several non-compliances related to maintenance and GHPs (Annex II of Regulation (EC) No 852/2004), that the establishment – in line with the CA procedures - would remain with reduced number of CA inspections even though the results of controls by third party organisations were not satisfactory.

5.4.1.3 Scope/coverage of official controls

57. While the content of each basic inspection is dependent on the risk associated with the specific FBO, the systemic scope for basic inspections is designed to ensure that all relevant food legislation is checked over a specific time period, normally as spot checks. For most wholesale operators (including RTE production establishments) all relevant area of food legislation (e.g. hygiene, own-checks, approval, training, labelling, additives, etc.) must be checked each year or at least every other year (in the case of “elite” establishments; third party certified establishments or establishments controlled as chains). During each inspection it is the inspectors’ decision which elements of the relevant legislation (within the main areas) will be covered (spot checks). All elements should be covered within three years.
58. The audit team found that in all establishments visited, the above mentioned procedures were followed by the CA.

59. However, the audit team noted that in establishments with several activities the control system does not ensure that each activity carried out is checked for the different aspects of the legislation. In a fishery products establishment visited (with several other activities) deficiencies related to the number of sample units to be taken for own-checks (i.e. the FBO took one sample from fishery products instead of the required five for microbiological analysis or the required nine for histamine) had not been detected during previous inspections as, according to CA inspector this aspect of the relevant legislation (Regulation (EC) No 2073/2005) had, in line with the procedures, not been checked previously.

60. The audit team also noted that the allocated time by the IT system (i.e. 1h 55 min) for the inspection of this particular establishment does not support comprehensive checks to be carried out (especially in establishments with multiple activities). In this respect, the CCA informed the audit team that the time allocated for inspections is an average value and inspectors can use additional time if needed and can manually adjust the required inspection time in the IT system. One FIU official confirmed that in their unit, each inspector responsible for official controls of RTE food production establishment has an extra 100-hour time credit annually.

61. According to national requirements, FBO procedures related to GHPs are not required to be documented in writing unless these procedures are in place to avoid cross-contamination of food. In the establishments visited the audit team saw in several instances that the layout of the establishments and/or the flows of products/personnel did not ensure avoidance of cross-contamination. For example: final (RTE) products go through the area where raw products are handled; transporting semi-finished products (cheese) for further ripening through the courtyard of the establishment in a way that did not avoid cross-contamination.

62. Although the CA informed the audit team that the FBOs concerned have put in place procedures (e.g. time separation) to ensure that cross-contamination is avoided, the audit team noted non-compliances (see above). Moreover, no such procedures were available in writing and, in most cases the CA inspector accepted them without having the opportunity to verify (e.g. to observe) their implementation. The CA stated that the official controls in relation to these procedure consisted of interviews with the FBO. Similar findings were noted during an audit carried out by the Commission services in 2014 and a recommendation was made regarding this issue. To address this recommendation the CCA included this issue in the training courses for inspectors highlighting that FBOs must have written procedures for measures to prevent cross-contamination.

63. The CA informed the audit team that there are no national measures (i.e. legislation or guidelines) or specific training on flexibility (e.g. separation of processes in time to avoid cross-contamination). It is up to the individual inspector's professional judgement to accept or not to accept the measures put in place by the FBO.

64. The audit team noted that inadequate FBO procedures related to possible contamination from persons (e.g. clothing, hair, etc.) are not considered by the CA as non-compliances. For example: personnel with beard, handling exposed RTE product (salad with dressing) without wearing beard net; flow of personnel in street clothes through the establishment premises to reach the changing rooms; entrance to the establishment directly from the yard.

65. In one of the meat products establishments visited, the audit team noted that after a *Listeria monocytogenes* outbreak linked to a product which was manufactured in this establishment, as a corrective action, the FBO made changes to the product flow in order to avoid cross-contamination of the products. Nevertheless, the audit team frequently noted in establishments visited cross-flows which pose risks for cross-contamination of products.

66. In all establishments visited, the HACCP-based procedures were checked by the officials according to the procedures in place and documented accordingly.

67. In one meat products establishment visited producing fermented meat products (salami) the HACCP plan did not contain measures to control if the hazard related to *Listeria* was eliminated. The pH check performed by the FBO was only a part of quality control to verify if the fermentation took place properly. This was not identified as non-compliance by the CA.

68. In the same establishment the shelf-life study for RTE products able to support the growth of *Listeria monocytogenes* and involved in food incidents was not carried out by using the temperature conditions laid down in the EU Reference Laboratory (EURL) guidance. This was not noted by the CA inspector.

69. FBOs own-check sampling plans for *Listeria* testing seen by the audit team included both final products and environmental samples.

70. The audit team noted in all establishments visited that verification of FBO's compliance with microbiological sampling and testing requirements of Regulation (EC) No 2073/2005 is part of the official controls. However, in accordance with the "spot check" approach, not all aspects of the relevant legislation is checked or not for all type of products/activities (see also paragraph 59) during CA inspection.

71. In one establishment visited producing minced beef, including minced "tatar beef" (to be eaten raw), the audit team noted that the FBO pooled five 10g samples of minced beef into a 50g sample for *Salmonella* testing in line with a procedure approved by the CCA for minced meat. However, the CCA confirmed that if minced beef is intended to be eaten raw (e.g. "tatar beef") the FBO should take 5X25g samples for *Salmonella*
testing and no approved CCA procedure exists which would allow pooling of individual sample units. This non-compliance has never been detected by the CA inspector as specifically the "tatar beef" production was not checked during past official controls. A similar deficiency was noted during the audit in 2014 (see footnote No 6 of this report).

72. In line with Regulation (EC) No 2073/2005, CA requires FBOs to use reference or validated methods for microbiological analyses of own-check samples. On DVFA website information is provided to the FBOs which alternative methods are recognised by the CA as validated methods.

73. The audit team noted that during official controls inspectors verified FBO compliance with the requirement regarding the analytical methods used and asked for evidence of validation if the FBO used alternative methods other than the ones listed on the CCA website. However, in two establishments visited no such verification has been carried out during the previous inspections. In one case, at the time of the audit team visit, the FBO could not provide the CA inspector with evidence that the analytical methods used by the laboratory had been validated against the reference method (the only evidence provided was that the laboratory is accredited).

74. The audit team noted that, as a result of the recent training courses related to RTE food for official staff (microbiological criteria, *Listeria*, mathematical modelling of bacterial growth, etc.) CA inspectors put a greater emphasis on FBOs compliance with Article 3(2) of Regulation (EC) No 2073/2005 (studies to verify compliance with microbiological criteria throughout the shelf-life).

75. Establishments can be inspected as a part of inspection campaigns, which are targeted controls, based on identified risk(s): e.g. type of establishment, activity, product or a combination of different factors. There are usually 15 food inspection campaigns annually. The CCA provided the audit team with information (summary) of some of these campaigns which are relevant to RTE food. For example:

- *Listeria* in institutional kitchens (2016),
- Capacity issues in catering establishments in relation to their production (2016),
- *Listeria* control in establishments handling fish (2017),
- Correct heat treatment of food (2017),
- *Listeria* control in high risk establishments (2018),
- Instruction of staff in food establishments (2018).

76. According to the information provided, during the 2017 campaign (fish) all Danish establishments producing RTE smoked or/and cured (gravad) fish were inspected (31 establishments in total). Six establishments were given enjoining orders (19%). In addition, 55 batches of finished products were tested for *Listeria*, of which two batches tested positive. Overall, the CCA concluded that there has been an improvement in the
overall FBO compliance level compared to the campaign carried out in 2015 where one third of the FBOs were imposed sanctions. The guidance materials and tools provided to the FBOs by the CA also have contributed to the improvement.

77. The audit team noted that FBOs’ traceability systems are checked at least annually by the CA. Official controls over FBOs compliance with traceability, labelling and identification marking were satisfactory.

5.4.1.4 Official sampling and laboratory analysis

78. The CCA informed the audit team that all planned official samples are part of specified sampling projects. Samples taken due to previous non compliances, disease outbreaks and consumer complaints are registered on specified projects related to the issues mentioned. When deciding on sampling projects CCA follows a risk based approach and takes into account different data (e.g. number of human cases in food-borne outbreaks, findings in foodstuffs, RASFF notifications, data needed for risk assessment, etc.).

79. For each project a project group is established to prepare the project details with participants from central DVFA, food inspectors, official laboratories and the Danish Technical University. Results of the projects are published on the DVFA website and used to assess whether new risk management measures should be applied (e.g. legislation, guidance, consumer information, etc.). Although the projects are decided and co-ordinated at central level, FIUs decide in which establishments samples are taken.

80. The CCA informed the audit team that in 2016 9 out of 60 and in 2017 12 out of 58 sampling projects were related to RTE food. Verifying FBOs’ compliance with microbiological criteria is part of a project every year. The audit team noted that in the latter case CA takes five sample units (n=5) for microbiological analyses whilst for follow up of alerts or recalls or for surveillance purposes, they take one sample unit (n=1). Nonetheless, non-compliant results are always followed up by the CA.

81. The audit team noted that when official samples are taken to follow up product recalls or food-borne outbreaks, the CA follows the EURL *Listeria monocytogenes* guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes* (i.e. samples are also taken during processing).

82. The audit team noted that in general, the planned number of samples was taken by the CA (except where e.g. import product sampling was planned but the import did not take place). For example in 2017 22,000 samples were planned but 19,800 were taken.

83. The following table was provided by the CCA and describes the official sampling carried out in the RTE food sector from 2016 to 2017.

<table>
<thead>
<tr>
<th>Type of RTE food</th>
<th>Testing parameters</th>
<th>Number of official samples tested 2016</th>
<th>Number of non-compliant results 2016</th>
<th>Number of samples tested 2017</th>
<th>Number of non-compliant results 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Category</td>
<td>Pathogens</td>
<td>Sample Size</td>
<td>Positive</td>
<td>Total</td>
<td>Non-Compliance</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-------------</td>
<td>----------</td>
<td>-------</td>
<td>----------------</td>
</tr>
<tr>
<td>Meat products</td>
<td>Listeria, Salmonella</td>
<td>350 (sliced meat products)</td>
<td>10</td>
<td>512</td>
<td>2</td>
</tr>
<tr>
<td>Dairy products</td>
<td>Listeria, Salmonella, Staphylococcus enterotoxin, Enterobacteriaceae, coagulase positive Staphylococcus, E. coli</td>
<td>500</td>
<td>0</td>
<td>445</td>
<td>2</td>
</tr>
<tr>
<td>Egg products</td>
<td>Listeria, Salmonella, Enterobacteriaceae</td>
<td>100</td>
<td>5</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>Fish products</td>
<td>Listeria</td>
<td>300</td>
<td>0</td>
<td>163</td>
<td>2</td>
</tr>
<tr>
<td>Fruit and vegetables</td>
<td>Listeria, Salmonella, E. coli, STEC, Campylobacter, Norovirus</td>
<td>1,200</td>
<td>4</td>
<td>653</td>
<td>2</td>
</tr>
<tr>
<td>Other products (including RTE meals)</td>
<td>Listeria</td>
<td>650</td>
<td>7</td>
<td>335</td>
<td>3</td>
</tr>
<tr>
<td>Heat treated food</td>
<td>Clostridium perfringens, Bacillus cereus</td>
<td>Not tested</td>
<td>0</td>
<td>1,776</td>
<td>0</td>
</tr>
<tr>
<td>Production environment</td>
<td>Listeria</td>
<td>400</td>
<td>34</td>
<td>Not tested</td>
<td>0</td>
</tr>
</tbody>
</table>

84. All official samples are analysed in DVFA laboratory which is accredited to ISO/IEC 17025 by the Danish Accreditation Found (DANAK).

85. The CCA informed the audit team that in addition to accreditation of the official laboratory, the official sampling is accredited since 2018.

5.4.2 Measures in case of non-compliance

Legal requirements


Findings

86. The General Inspection Manual provides guidance to CA staff on the measures to be
taken in case of non-compliance detected (including sanctions).

87. The CA informed the audit team that no deadlines are given to the FBO for correcting non-compliances as legally the FBO is expected to be in compliance with the requirements at all times. If non-compliance is considered by the CA as minor, the inspector can provide the FBO with guidance instead of imposing sanctions. As an example the audit team was informed and also saw evidence in establishments visited that if an FBO carries out an activity which is not included in the approval certificate, unless it poses a food safety concern, no sanction is imposed by the CA but guidance.

88. If there is a risk for direct product contamination, the corrective action should be immediate. The audit team saw evidence during the visits when the inspector ordered immediate corrective actions: e.g. due to condensation above exposed product. For other deficiencies related to maintenance issues, the audit team noted that if the FBO has a maintenance plan, its implementation was accepted by the CA inspector without imposing specific deadlines.

89. Correction of non-compliances without sanctions is usually followed up by the CA during the next ordinary inspection, which may take place within a few month or one year.

90. If non-compliances are detected and sanction is imposed (e.g. a formal warning) the follow up inspection must be carried out within two months and the CA will charge an inspection fee to the FBO.

91. When the CA inspector detects that the FBO breaches food law, several enforcement instruments are available:
   - Admonition/Enjoining order
   - Injunction/Prohibition order
   - Administrative fines
   - Reporting to the police
   - Withdrawal of registration/approval

92. According to the guidance on enforcement measures, the inspectors should impose the sanctions deemed necessary to ensure that the FBO corrects the non-compliance. If the FBO still fails to comply, the enforcement measure is escalated to a more severe sanction.

93. During the establishment visits, the audit team saw several examples when the inspector imposed warning and/or enjoining orders due to non-compliance. As a result, establishments’ “Elite” status were withdrawn. Three of six “Elite” establishments visited lost their “Elite” status after the audit team visits.

94. The audit team saw an example of imposing an administrative fine by the CA when there was an unjustified delay in an FBO’s action in response to a product withdrawal
95. The CCA informed the audit team that in case of product withdrawals, recalls and RASFF notifications, the Alert Unit for Food and Feed within DVFA is responsible for the co-ordination of all DVFA actions. In accordance with established procedure, having received a notification (from FBOs, RASFF, official control or laboratory results, etc.) FIU performs official control at the FBO concerned (“first FBO level”) and collects all the necessary information including identification and traceability of all food involved and documentation of any actions taken by the FBO. Official control at first FBO level is always supplemented with checks carried out at randomly selected second and subsequent FBO levels (e.g. FBOs who received the food concerned from the first level FBOs).

96. There is a guide, publicly available on the DVFA website, “how to perform food recalls” which is a national guide on food recalls and withdrawals both for FBOs and for CA staff. In addition, a special, extended version of the guide is available for DVFA employees only, describing in detail how to perform official controls following a food recall.

97. In case of a recall of food (including RTE food) consumers will be informed through multiple channels. The recall will be published on the DVFA webpage and a newsletter will be sent out to subscribers (where relevant). The recall is also posted on the social media profile of DVFA. The FBO is obliged to publish a press release, and to inform the media.

98. The Alert Unit for Food and Feed is also responsible for the investigation and co-ordination of food-borne outbreaks within the DVFA and holds the contact to the public health authorities within the National Central Outbreak Management Group.

99. The handling of cases of food-borne outbreaks is outlined in a guide: “Handbook on food-borne outbreak management”, which is available to all DVFA personnel. Food-borne outbreak investigation is performed in an integrated collaboration between specialists in the FIU, in relevant DVFA Divisions, the Alert Unit for Food and Feed and the National Central Outbreak Management Group.

100. The audit team reviewed two RASFF notification files and two product recalls (one of them was linked to an outbreak) related to RTE food (due to *Listeria monocytogenes*) and noted that in general, the above mentioned procedure was followed: an adequate investigation was carried out at establishment level and corrective actions were taken by the FBOs.

101. However, in two RTE meat products establishments visited which were involved in product recalls (one of them was linked to an outbreak) the CA inspector at the time of the audit team visit noted several non-compliances related to maintenance, cleaning and disinfection (some of them posing risk for product contamination) which question the effectiveness of controls in these establishments regarding prevention of reintroduction...
Conclusions on official controls on the production of RTE food

102. The CA has put in place a system of risk based official controls over production of RTE food, supported by several IT applications and documented procedures. Most establishments producing RTE products are placed in the very high and high risk category reflected in a higher frequency of controls, and which is implemented by the CA.

103. However, there are weaknesses in relation to organisation of controls, in particular in establishments with multiple activities, as routine inspections are not sufficiently targeting the risks in these types of establishments.

104. The CCA's action to address the recommendation of the 2014 audit report regarding FBOs' measures to prevent cross-contamination has not been fully effective.

105. The official control system in place also includes taking official samples for microbiological analyses in order to verify how the FBOs can guarantee the safety of RTE products.

106. The official controls over the compliance with the requirements of traceability, labelling and identification marks were satisfactory.

107. CA uses its enforcement powers to take actions or impose sanctions when non-compliances are identified. However, when some of the non-compliances detected are classified as minor ones the CA does not routinely take into account the specific risks linked to RTE food products. Concerning recording and reporting non-compliances, the CA procedure is not fully implemented in this respect as minor non-compliances are not consistently recorded and reported.

108. The system for follow-up of RASFF notifications and product recalls/withdrawals implemented in Denmark provides guarantees that adequate actions are taken by the CA in case of these notifications linked to RTE food, particularly concerning their follow-up and measures adopted regarding the products involved.

5.4.3 Challenges encountered by the CA in the organisation and performance of controls over the production of RTE food

109. Challenges related to the understanding and implementation of the legal requirements have also been highlighted by the CA. For example:

- Correct application of the requirements of Regulation (EC) No 2073/2005 in relation to categorisation of RTE products whether they are able to support the growth of *Listeria monocytogenes* or not is a challenge for the FBOs.
- Low temperature heat treatment of meat (e.g. roast beef) might pose a risk to consumers especially related to *Clostridium* and *Bacillus* species.
• Challenge for CA inspectors how to report minor non-compliances as the report is published, especially in the case of "Elite" status establishments where there is a pressure from the FBOs not to lose their "Elite" status.

5.4.4 Suggestions and measures put in place to address the identified challenges and for reducing food-borne outbreaks related to RTE food

110. After a serious food-borne outbreak in 2014 where 19 people died due to consumption of food which was contaminated with \textit{Listeria monocytogenes} several measures were put in place by the CA:

• The CCA established a special website to provide information both to FBOs and to control staff: "All about \textit{Listeria}" website (for more information, see paragraph…);

• There have been several control campaigns related to \textit{Listeria} (including intensified official sampling);

• Training for CA officials (including how to use predictive mathematical modelling for shelf life studies of RTE products able to support \textit{Listeria} growth in order to investigate criteria throughout the shelf life);

• Expert groups on \textit{Listeria} were established;

• There are several guidance documents available: new guidance on shelf life studies; Danish guidelines on microbiological criteria was updated to bring in line the requirements with EURL guidelines on sampling the food processing area and equipment for detection on \textit{Listeria monocytogenes} (sampling of environment should be taken place also during processing);

• CA updated their procedures to follow up product recalls.

111. The audit team noted that following detection of \textit{Listeria} in official samples the isolate is subject to whole genome sequencing and the result is introduced into a database which is common for human and food isolates. The CA is thus able to identify if an isolate from and establishment would correspond to a human case.

112. Technical assistance is provided both to FBOs and to CA by Danish Technical University (e.g. Danish tools are available to support FBOs performance on shelf life studies using predictive mathematical modelling;

113. Technical support to the FBOs by different organisations: e.g. in a dairy establishment visited, the audit team saw an example when the Danish Agricultural and Food Council assisted the FBO by providing technical support (developing own-check programmes and analysing microbiological risk factors for raw milk cheese);

114. The CA put in place accredited official sampling to address the challenges related to questioning of reliability of official sampling by the FBOs.
6 **OVERALL CONCLUSIONS**

The official controls over production of RTE food are organised and implemented on a risk basis using comprehensive documented procedures and guidance, covering relevant aspects of the legislation and supported by IT systems.

Certain shortcomings and weaknesses are mainly related to approval of establishments, to auditing GHPs and procedures based on the HACCP principles, in particular FBO procedures to prevent cross-contamination and to reporting audit findings.

Several measures to facilitate compliance and reduce food-borne outbreaks are in place addressing CAs and FBOs.

7 **CLOSING MEETING**

A closing meeting was held on 22 June 2018 with representatives of CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit.

8 **RECOMMENDATIONS**

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table to correct the deficiencies found should be presented to the Commission within twenty-five working days of the translated draft report.

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>1.</td>
<td>The CCA should ensure that RTE food establishments are approved for the activities they actually carry out, that approval is adequately kept under review and that the list of approved establishments is kept up to date in order to comply with the requirements of Article 31 (2)(e), (e) and (f) of Regulation (EC) No 882/2004. Recommendation based on conclusion No 36. Associated findings Nos 29, 30, 31, 35.</td>
</tr>
</tbody>
</table>
| 2.  | The CCA should ensure that:  
  - official controls over FBOs' prevention measures for cross-contamination hazards are adequate and appropriate documents and records are kept by the FBOs in line with Article 5(2)(a) of Regulation (EC) No 852/2004 to demonstrate the effective application of the HACCP principles,  
  - official controls verify the FBO's relevant records in line with Article 4(8)(b) of Regulation (EC) No 854/2004. Recommendation based on conclusion No 104. Associated findings Nos 61, 62, 63, 64. |
<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
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</table>
| 3.  | The CCA should ensure that official controls organised in such a way as to adequately cover FBOs compliance with all the relevant EU legislation and that non-compliances detected are adequately classified taking into account risks related to RTE products.  
Recommendation based on conclusions Nos 103, 107.  
Associated findings Nos 55, 59. |
| 4.  | In order to allow monitoring of corrective actions and, where appropriate initiation of enforcement, the CCA should ensure that non-compliances detected are systematically recorded and in particular that the relevant CCA procedures are consistently followed by the CA staff.  
Recommendation based on conclusion No 107.  
Associated findings Nos 54, 55. |

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

### ANNEX 1 – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
</tr>
</thead>
</table>