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 Poland from 8 to 19 October 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, are supported by comprehensive documented procedures and guidance and cover the relevant aspects of the legislation.

Nonetheless, the audit team noted an inconsistent interpretation and implementation by the competent authority staff at regional and district levels of the procedures provided by the central competent authorities. This concerned in particular the risk assessments carried out to determine inspection frequencies of establishments.

Shortcomings were detected regarding implementation of official controls to verify FBOs’ compliance with the provisions of Regulation (EC) No 2073/2005.

Certain measures to facilitate compliance and reduce food-borne outbreaks are in place.

The report contains a recommendation to the competent authorities to address the identified shortcomings.
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<td>DG Health and Food Safety</td>
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1 INTRODUCTION

This audit took place in Poland from 8 to 19 October 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 authorities (CCA) which for this audit were the General Veterinary Inspectorate (GVI) of the Veterinary Inspection (VI) and General Sanitary Inspectorate (GSI) of the State Sanitary Inspection (SSI).

An opening meeting was held in Warsaw on 8 October 2018 with the representatives from the central and other competent authorities (CAs). 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 OBJECTIVE AND SCOPE

The objective of the audit was to assess the arrangements put in place by the 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 CAs 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 foodborne 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 foods 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

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<th>COMPETENT AUTHORITIES</th>
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FOOD PRODUCTION ACTIVITIES

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<td>Dairy establishments</td>
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<td>Salads and sandwiches producers</td>
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<tr>
<td>Airline catering establishment</td>
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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 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 foods 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 Food Safety audit, the official controls over the production of different food, 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 CCAs highlighted the types of RTE foods that are commonly consumed in Poland and which may pose a particularly high microbiological risk. For example:

- steak *"tatar"* – a traditional raw (beef) meat preparation which is eaten without prior heat treatment;
- raw *"Metka"* sausage – a traditional raw sausage consumed in some regions of Poland, without prior heat treatment, made from minced pork or beef meat and fat, with added water, spices (including onions);
- beef carpaccio – a dish which has gained popularity in Poland in recent years, made from raw beef, cut into very thin slices;
- regional cheeses made from unpasteurised milk;
- cold-smoked fish – products that undergo heat treatment which does not ensure inactivation/destruction of micro-organisms;
- traditionally made ice cream;
- pastry and cakes.

The CCAs highlighted some food business operator’s (FBO) practices related to the production of RTE food which may pose particular risks. For example:

- inadequate heat treatment;
- recontamination/cross-contamination of heat-treated food by staff;
• determining the shelf-life of products without taking into account consumer behaviour (reasonably foreseeable conditions of storage and use);

• incorrect defrosting of frozen products (e.g. excessively long thawing time).

According to the reports on the findings of official food safety controls (including official sampling) by the SSI, the most common source of microbiological contamination of RTE food in 2016-2018 (until July 2018) was food from the following groups: traditional ice cream, fine bakery products, ready-made foods and meals, meat products and certain other products such as raw vegetables and vegetable/fruit products.

Between 1 January 2016 and 30 September 2018 127 Rapid Alert System for Feed and Food (RASFF) alerts concerning food originating from Poland were launched, most of them due to pathogenic microorganisms in non-RTE food (Salmonella in fresh poultry meat and in eggs). Three of these alerts were related to food-borne outbreaks (all of them occurred in countries other than Poland) linked to RTE food (two to frozen vegetables/fruits and one to meat products) and were caused by Salmonella Enteritidis, Listeria monocytogenes and Hepatitis A virus respectively.

During the above mentioned period, there were 24 RASFF notifications related to products originating from Poland due to Listeria monocytogenes contamination (most of them related to smoked fishery products). Seven of these notifications were generated on the basis of presence of Listeria in 25 grams in samples taken at retail shops. During the same period there were 34 food incidents related to RTE products at national level which did not reach RASFF (11 of them due to Listeria contamination).

In 2016 and 2017 in total, there were 42 food-borne outbreaks caused by Salmonella (mainly Salmonella Enteritidis) in RTE foods, out of which 13 cases were linked to the consumption of pastries and cakes, six to meals with meat and eggs and four to meat and meat products. In the same period there were eight outbreaks caused by Norovirus in RTE foods and most of these cases were linked to the consumption of vegetables and vegetable dishes.

The CAs informed the audit team that there was no food-borne outbreak in 2016-2017 in Poland caused by Listeria spp and that the identified Listeria cases were not connected to RTE food.

5 FINDINGS AND CONCLUSIONS

5.1 NATIONAL MEASURES

Legal requirements


Findings

1. The national legislation supporting official controls in establishments producing or
handling RTE foods is described in the country profile for Poland available at:

http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=PL

VI

2. Although no specific national legislation or further guidelines 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 GVI’s official guidelines contain instructions/measures which are relevant to the RTE food sector.

3. Based on the Commission guidance document on *Listeria monocytogenes* shelf-life studies for RTE foods (developed in accordance with Regulation (EC) No 2073/2005) the GVI has issued the "Guidelines for official veterinarians on official control procedures to verify own-check sampling and testing programmes for microbiological analyses of food of animal origin and composite products of FBOs’ subject to supervision by the VI". The audit team noted that the guidelines cover several topics, among which the assessment of *Listeria monocytogenes* risk in RTE food by verifying:

- the studies carried out by FBOs in accordance with Article 3 of Regulation (EC) No 2073/2005;
- FBOs’ procedures on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*;
- the analytical methods used for FBOs’ own-check analyses;
- FBOs’ corrective actions in case of non-compliant results detected;
- whether a specific food of animal origin has been correctly selected as RTE food for official analysis for *Listeria monocytogenes*.

4. The audit team also noted that the above mentioned guidelines provide detailed information on the most important pathogens (including *Listeria monocytogenes, Salmonella spp., E. coli*, etc.) that FBOs should take into account in their Hazard Analysis and Critical Control Points (HACCP) plans when performing analyses on microbiological hazards.

SSI

5. The SSI informed the audit team that at the time of the audit there were no guidelines available specifically related to RTE food within the remit of the SSI. Nevertheless, "Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*" is available and the CCA informed the audit team that they have plans to develop further guidelines to cover RTE foods in 2019.

National guides to Good Practices

6. Two guides have been developed at national level (produced by the Polish Milk
Chamber), which pertain to the dairy sector:

- "Guide to good hygiene and production practices in the dairy industry", which discusses potential risks linked to milk production and processing, preventive actions and measures to be taken in order to prevent those risks from occurring at every stage of production and distribution.

- "Guide to dairy product labelling", which provides an overview and interpretation of the most relevant provisions and rules currently applicable in Poland and in the EU.

7. In a dairy products establishment visited the FBO informed the audit team that when they developed their HACCP-based procedures these guidelines were taken into account.

Information for consumers

8. Information on infectious diseases, including food-borne diseases, is available on the website of the SSI. Individual descriptions of infectious diseases contain information on infection channels, infection symptoms in humans and prevention methods including the need to maintain an appropriate hygiene level.

9. The list of infectious diseases available at www.gis.gov.pl contains those diseases which can be transmitted via contaminated food or water, e.g. *listeriosis*, *yersiniosis*, *campylobacteriosis*, *hepatitis A*, *norovirus* infections or *salmonellosis*.

10. A leaflet "Five steps to safe food" is also available online – and contains information on the basic principles of hygiene and safe meal preparation.

11. Awareness-raising campaigns take place at a regional and district level. Examples of information materials are available on the websites of the VSEs and PSEs.

<table>
<thead>
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<th>Conclusions on national measures</th>
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<td>12. There are some measures in place supporting FBOs and consumers in addressing the microbiological hazards of RTE food and reducing the risk of food-borne outbreaks, as well as supporting CAs in performing the related official controls.</td>
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5.2 COMPETENT AUTHORITY

Legal requirements


Findings

13. Detailed information on the structure and organisation of the Polish CAs can be found in the country profile for Poland (see paragraph 1).
14. The VI under the Ministry of Agriculture and Rural Development is the designated CA responsible for official controls of RTE foods in establishments which fall under the scope of Regulation (EC) No 853/2004 (including retail establishments with marginal, localised and restricted activity and retail establishments at farm level selling food directly to the final consumer). The VI has a pyramidal structure with a direct line of command between central, regional and district levels. The VI, at central level, has the GVI, acting as the CCA, at regional level it has 16 VVIs and at district level 305 PVIs. These are headed by the Chief Veterinary Officer (CVO), Regional Veterinary Officers (RVOs) and District Veterinary Officers respectively.

SSI

15. The SSI under the Ministry of Health is the designated CA responsible for official controls of RTE food in establishments which fall exclusively under the scope of Regulation (EC) No 852/2004. These include retail, wholesale establishments and establishments producing RTE foods containing both products of plant origin and processed products of animal origin (composite products). The SSI, at central level, has a GSI, acting as the CCA, at regional level it has 16 VSES and at district level 318 PSES.

16. However, the audit team noted in one of the establishments visited that despite the fact that this establishment used unprocessed food of animal origin (chilled fish) for producing composite products, which activities fall within the scope of Regulation (EC) No 853/2004, it was under the supervision of SSI. The CCAs attributed this discrepancy to a translation error in the Polish version of the relevant section of Regulation (EC) No 853/2004 which had already been corrected (published on 24 September 2018 in the Official Journal). Nevertheless, the CCAs stated that similar cases will be avoided by the issuance of the new Framework Agreement (see paragraph 19).

17. The PVIs and PSESs adapt national control programmes to local needs (including planning of inspections and in the case of SSI, planning of official sampling at establishment level). Their responsibilities inter alia, include registration/approval of establishments, auditing of establishments, follow up of non-compliances, imposing sanctions and official sampling for laboratory analyses.

18. VVIs and VSESs have mainly supervisory tasks over the work of PVIs and PSESs. VVIs and VSIIs are responsible for providing training to PVIs and PSESs.

19. Co-operation and co-ordination between the VI and the SSI is governed by a Framework Agreement of 21 September 2007, laying down detailed conditions and rules for co-operation and collaboration regarding supervision of foodstuffs. This agreement is replicated at regional and local levels. The audit team was informed that a new Framework Agreement is prepared and was signed by the two parties during the course of this audit (16 October 2018). The new agreement clarifies in more detail the competencies of the two CAs, especially in the area of retail.

20. The audit team reviewed cases of co-operation during RASFF notifications and product recalls e.g. during incidents of RTE product which tested positive for Salmonella
*Enteritidis* at retail level (recall activities and investigations organised by the VI at production establishment level after sampling performed by the SSI at retail level).

**Training**

21. Both CAs have a training system in place. CCAs provide training to the Regional CA officials and a cascade system is applied where the Regional CAs are obliged to disseminate the knowledge to colleagues at district level.

22. The audit team saw evidence of staff (from both CAs) participation in training sessions relevant to official controls of RTE food at each level. Several CA staff have also participated in the relevant "Better Training for Safer Food" courses. Evidence was provided that the acquired knowledge was disseminated to other official control staff.

**VI**

23. The centrally provided training is usually organised by the National Veterinary Institute and other institutions (e.g. Warsaw University of Life Sciences). Between 2016-2018 as part of the multiannual training programme four main topics were provided which are relevant to official controls of RTE food:

- Veterinary requirements in the production of food of animal origin;
- Essentials of food processing and food technology;
- Microbiological hazards in the production of food of animal origin;
- Parasitic diseases and parasites in food of animal origin.

24. In addition, every year an American company is invited by the CA and provides training on the US requirements on RTE foods which includes issues related to *Listeria monocytogenes*.

25. The audit team also noted that most of the VI inspectors have post-graduate degree in food hygiene.

26. When observing the official controls carried out by the VI inspectors in the establishments visited, the audit team noted that in general, the inspectors are knowledgeable, competent, had training certificates (including on topics relevant to official controls on RTE food) and identified issues which were also found by the audit team.

**SSI**

27. Between 2016 and 2018 SSI held 159 training sessions which included microbiological contamination of food.

28. Although in each establishment visited, PSES inspectors provided the audit team with evidence (i.e. training certificates) on their participation in training sessions relevant to official controls of RTE food, these were not effective as the audit team noted some
weaknesses in their knowledge regarding the relevant requirements. For example:

- in one establishment visited, the audit team noted that when carrying out verification on the FBO’s own-check sampling programme for microbiological analyses, the PSES inspector was not familiar with the existing CCA Order on this subject (see paragraph 64). The inspector attributed the lack of knowledge of the CCA Order to the absence of adequate training;

- in other establishments visited PSES inspectors had lack of knowledge on certain provisions of Regulation (EC) No 2073/2005 (number of sample units to be taken and how to evaluate FBOs' shelf-life studies) and on the CCA guidelines on environmental sampling and testing for *Listeria monocytogenes* (see paragraphs 74, 77 and 78).

29. The audit team was informed that the SSI recognised the needs of district officials for further training and as a new initiative (since the beginning of 2018) SSI provides training, where the CCA identified this need, from central level directly to district level officials in addition to the cascade system.

**Audits and Verification activities**

30. For both CAs the systems for verification and audits are described in the country profile of Poland and for VI in the audit reports DG(SANTE)2014-7160\(^5\) (Poultry meat) and DG(SANTE)2016-8687\(^6\) (Fishery products).

31. The GVI's internal audit unit provided the audit team with information on the internal audit carried out in 2014 on fishery products which is relevant for RTE food. During the internal audit 50 PVIs were visited and the main recommendations (which, according to the CA, had already been addressed) were as follows:

- System for obligatory training should be established for newly recruited inspectors;

- Training is needed for Regional and District officials on how to prepare inspection plans;

- Training is needed on the requirements of Regulation (EC) No 2073/2005 with special regard to *Listeria monocytogenes* and histamine in fishery products;

- Report template is needed for official sampling;

- Technological and sanitary guidelines are needed for official controls of fishery products.

32. The audit team saw evidence in establishments visited under the supervision of VI that the RVO evaluated the performance of the district veterinary inspector during a joint


Conclusions on competent authority

33. The CAs responsible for the official control system over the production of RTE foods are clearly designated. The CAs' structure and organisation are adequate for the performance of their tasks.

34. There is a system in place for co-operation and co-ordination between the CAs which includes rules regarding supervision of establishments and actions to be taken in the case of food incidents.

35. A training system, also covering issues related to the RTE food sector, aimed at ensuring that official staff can execute their tasks effectively is in place. However, the system could not ensure in some cases that official controls are carried out in a consistent manner; in particular, weaknesses were noted in the knowledge of SSI staff on the procedures and guidance for official controls to verify the FBOs’ compliance with Regulation (EC) No 2073/2005.

36. Internal audit systems are in place for both CAs in line with the requirements of Article 4(6) of Regulation (EC) No 882/2004. In the case of VI, the system covers aspects relevant to the official controls carried out over the production of RTE food.

5.3 REGISTRATION/APPROVAL OF FBOs

Legal requirements


Findings

VI

37. Registration and approval of establishments under VI supervision are performed in accordance with Polish legislation, Act of 16 December 2005 on products of animal origin. CVO instructions of November 2017 provide detailed guidance to VI staff on the procedures to be followed for registration, conditional approval and approval of establishments as well as for suspension and withdrawal of approval and for removing food businesses from the register. The registration/approval procedure is described in the audit report DG(SANCO)2010-84527 (poultry meat) and the procedures have not changed since then.

38. The audit team noted that all establishments visited were approved for all the activities carried out and the approval procedure was followed. The audit team also noted that the approval certificates specify the maximum capacities of production for each activity. The indicated capacities are based on the information provided by the FBO in the

7 http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2625
The technological design of the establishment when submitting his application for approval.

39. The list of approved establishments is publicly available on the GVI website.

**SSI**

40. SSI informed the audit team that food businesses under their supervision also require approval in accordance with the relevant national legislation (Food and Nutrition Safety Act of 25 August 2006), since Poland exercised its right under Article 6 of Regulation (EC) No 852/2004. The audit team noted that this applies to most producers of RTE food and requires an on-site visit before the approval is granted. The list of approved establishments under the supervision of SSI is available at regional and district level.

41. The audit team was informed by both CAs that FBOs are obliged to notify the CAs if they want to extend the scope of activities of the establishments.

42. As no specific data in relation to RTE food is kept in the registers, none of the CCAs could provide the audit team with the number of establishments involved in RTE (including high risk RTE) production or sales at national level. The audit team noted both CAs are aware of this information at regional level.

43. One of the VVIs (Kujawsko-Pomorskie Region) visited provided the audit team with some regional data as an example. In this region under VI supervision, there are in total 86 establishments producing RTE food, out of which 59 meat, 22 dairy and 5 fishery products establishments. In 2017, 220 inspections were planned and 455 were carried out in these establishments.

44. In another region visited (Wielkopolskie Region) VSES informed the audit team that in total, there are 1,203 RTE food production establishments under SSI supervision in this region (94 ice cream production facilities, 379 ice cream machines, 353 confectionery, 174 fruits and vegetable processing, 58 producing ready-made meals, 145 catering services). The audit team noted there are another 5,815 food production establishments in this region under the supervision of this CA but only some of them deal with RTE food.

### Conclusions on registration/approval of FBOs

45. Procedures are in place for registration and approval of establishments handling or producing RTE food and they are correctly implemented. The national approval system which goes beyond EU requirements supports the CAs in identifying risks related to RTE food and in the organisation of related official controls.
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

46. Both CAs have procedures in place for risk based official controls.

VI

47. In accordance with Instruction No GIWbż-500-2/11 of 1 September 2011 on determining, based on risk assessment, the frequency of controls of FBOs subject to supervision by the VI, an establishment is assigned to one of the three risk categories, which determines the minimum frequency of comprehensive controls (see paragraph 59):

- low-risk establishments – minimum control frequency: once every 12 months;
- medium-risk establishments – minimum control frequency: once every 6 months;
- high-risk establishments – minimum control frequency: once every 3 months.

48. The instruction comprises specific criteria (risk groups) in line with the requirements of Article 3 of Regulation (EC) No 882/2004: e.g. structure and organisation of the establishment, competence of establishment management, reliability of own-check systems, compliance history, sanitary conditions, products and production technology. Risk points are allocated to each risk group.

49. The audit team noted that there is no specific risk group or category for establishments handling or processing RTE food. Specific risks related to RTE foods are taken into account in the risk group for “products and production technology”. In this risk group, in line with the instruction, RTE products should count with the highest risk points. Based on the total number of risk points given, the establishment is placed in one of the three categories mentioned above. The audit team noted however, that the points given to the risk associated with the RTE element have no significant impact on the calculated frequency of controls. In addition, the risk assessment does not give any additional risk points for production of RTE foods considered by the CA as high risk (see Chapter 4.1).

50. According to the instruction, newly approved establishments are automatically placed in the “high-risk” category. No later than three month after the approval, the establishment should be audited and the above mentioned risk-categorisation should be carried out by the district veterinary inspectors. Each approved establishment should be subject to risk assessment at least annually during a comprehensive control.

51. The audit team noted in all establishments visited under the supervision of VI that the
procedure was followed and that following RASFF alerts or food incidents the establishments concerned were automatically placed in the highest risk category increasing the inspection frequency to once every three months in line with the instruction. When followed up, the audit team noted that if the outcome of the next comprehensive control was satisfactory, the categorisation was reviewed and the inspection frequency was reduced accordingly.

52. All RTE establishments under VI supervision visited by the audit team were categorised as “low risk” establishments by the CA as a result of the above mentioned risk assessment procedure. The VI informed the audit team that the inspection frequency determined by risk assessment applies to the “comprehensive controls” and “ad-hoc controls” can be carried out at any time (see paragraph 59).

SSI

53. Annex No 7 to the Order No 104/17 of the Chief Sanitary Inspector contains the instructions regarding risk categorisation of establishments under SSI control. Similarly to the system established by VI, an establishment may be assigned to one of the three risk categories, which determines the minimum frequency of controls:

- High risk establishments:
  a) once every 12 months for production establishments;
  b) once every 18 months for retail establishments;

- Medium risk establishments:
  a) once every 18 months for production establishments;
  b) once every 24 months for retail establishments;

- Low risk establishments:
  a) once every 24 months for production establishments;
  b) once every 36 months for retail establishments;

54. For establishing the frequency of controls, risks taken into account (in line with EU requirements) are: sanitary and technical condition (e.g. layout, maintenance, etc.) of the premises, hygiene of production, distribution and sales, reliability of the food safety management system and activity profile of the establishments. Specific risks related to RTE foods are taken into account in the risk group for the "activity profile of the establishment".

55. The instruction lists those activities which should be given the highest risk points within the category. The audit team noted that most of these activities are related to production/handling of RTE foods and some of them to commodities which are the most involved in food-borne outbreaks (see Chapter 4.1). For example: production of ice cream, non-heat treated pastries and cakes, production of sprouts, mass catering, preparing meals for vulnerable groups of consumers, etc. The audit team also noted however, that the weight of the risk points in relation to the "activity profile of the establishment" is low and has no significant impact on the calculated frequency of controls.
56. The audit team noted in each establishment visited under SSI supervision that the risk assessment was carried out using the assessment sheet contained in the instruction. Based on the total number of risk points given, all these establishments would normally be categorised in the “low risk establishment” category. The audit team noted however, that PSES inspectors ignored this result and categorised those establishment in the "high risk establishment" category with the inspection frequency of at least once per year.

57. The audit team noted disagreement between GSI and VSES/PSES officials regarding the interpretation of the CCA procedure to be followed. GSI informed the audit team that frequency of inspections should be determined based on the result of the risk assessment (as described above). However, the VSES visited informed the audit team that when calculating the frequency of visits PSES inspectors should take into account further risk elements (e.g. volume of production, if the establishment is one of the major producers in the district, etc.).

58. The cases reviewed by the audit team showed an adjustment of inspection frequency by the PSES inspectors, resulting in a higher frequency of planned visits than based solely on risk assessment. However, in the absence of clear CCA procedures on determining the frequency of inspection, this result is not guaranteed in the future. Nevertheless, GSI informed the audit team of their commitment to review the risk assessment procedure in the light of the findings and conclusions of this audit (see Chapter 7).

5.4.1.2 Procedures for official controls

VI

59. Official controls are carried out by the VI on the basis of the Instruction of the CVO No GIWhig-500-4/08 of 1 April 2008 on the methods of conducting official controls. This instruction distinguishes between two main types of inspections:

- **Comprehensive control** (including both inspection and audit): the frequency is based on risk assessment conducted by the district CA (PVI) and aimed at verifying the compliance with all the aspects of relevant legislation including those in the scope of this audit.

- **Ad-hoc control**: any inspection outside the planned controls (including inspections in relation to complaints, RASFF notifications, upon request of the CVO or RVO, etc.).

60. VI informed the audit team that comprehensive controls are announced whilst ad-hoc controls are unannounced.

61. Based on the aforementioned instruction, inspectors document the results of official controls by using the uniform "SPIWET" checklist templates. In addition, the GVI has developed additional supporting documents:

- procedure for official veterinarians when checking FBOs’ compliance with traceability and identification marking rules – CVO Instruction No GIWhig-500-1/10 of 23 March 2010 on conducting official controls on traceability of products of
animal origin and on identification marking;

- guidelines for official veterinarians on official control procedures to verify own-check sampling and testing programmes for microbiological analyses of food of animal origin and composite products of FBOs’ subject to supervision by the VI (see paragraph 3).

62. The audit team noted in all establishments visited that the frequency of inspections was in line with the planned arrangements. All the approved establishments had undergone at least one comprehensive control annually. After each inspection, an official control report is prepared (on the spot after ad-hoc inspection and at the office after comprehensive control) and a copy is given to the FBO.

63. The VI informed the audit team that a comprehensive control could take – depending on the size of the establishment and the types of activities – from one to three days and usually the control is carried out by two inspectors.

SSI

64. Official controls are carried out by the SSI on the basis of Order No 104/17 of the Chief Sanitary Inspector of 8 May 2017 on the procedure for conducting of official controls on food, materials and articles intended to come into contact with food. This Order contains 18 annexes with instructions and checklists (11 checklists in total) covering different areas official of controls. Among others, specific checklists are available for verifying FBOs' compliance with microbiological criteria and for food additives.

65. The audit team noted however, that there is no specific checklist for controls on FBOs' Good Hygiene Practices (GHP) and HACCP-based procedures. In this respect, PSES informed the audit team that they follow the points of the risk assessment sheet which cover also GHP and HACCP issues.

66. The audit team noted in all establishments visited that the frequency of inspections was in line with the planned number of visits (see paragraph 58).

5.4.1.3 Scope/coverage of official controls

67. Both CAs are required by their procedures to carry out controls to verify the FBO's compliance with the relevant requirements, amongst other those of Regulations (EC) Nos 852/2004 and 853/2004 including FBOs HACCP-based procedures and GHPs.

68. The audit team noted that the checklists used by VI inspectors follow the requirements of the above mentioned regulations and cover inter alia GHP, HACCP, own-check sampling and analyses, identification marking, labelling, traceability and all general and specific requirements related to the activities of the establishments.

69. The audit team also noted that during inspection the CA focuses on cross-contamination issues. For example: in one fishery products establishment visited (producing cold-smoked fish) the audit team observed when the inspector detected possible cross-contamination of exposed final products (rusty ventilation grids with some dripping of
water above one of the packaging lines) and ordered the FBO to take immediate action to stop the line and requested testing of the products concerned.

70. The audit team noted that when carrying out inspection PSES inspectors followed the points of the risk assessment sheet and the inspection covered all issues required by the relevant EU legislation.

71. The audit team noted that CAs check the FBOs’ traceability systems at least annually. Official controls over FBOs compliance with traceability, labelling and identification marking were satisfactory.

Own-check sampling and testing

72. The audit team noted in all establishments visited that verification of FBOs’ compliance with microbiological sampling and testing requirements of Regulation (EC) No 2073/2005 is part of the official controls of both CAs. Both CAs have comprehensive documented procedures for these controls (see paragraphs 3, 61 and 64).

73. FBOs own-check sampling plans were available and followed the legislative requirements. *Listeria* testing included both final products and environmental samples. The audit team saw evidence that the analytical method (reference or validated alternative method) used was verified by the inspectors. The audit team also noted that inspectors check FBOs compliance with Article 3(2) of Regulation (EC) No 2073/2005 (studies to verify compliance with microbiological criteria throughout the shelf-life).

74. In one of the establishments visited (under the control of SSI) that produced certain RTE products able to support the growth of *Listeria monocytogenes*, the food safety criterion of point 1.2, Chapter 1, Annex I to Regulation (EC) No 2073/2005 was applied, with the limit to be 100 cfu/g during the shelf-life of products. The audit team noted however, that the CA inspector accepted the use of this limit without the FBO's adequate demonstration that the product will not exceed the limit 100 cfu/g throughout the shelf-life, which is in breach of footnote 5 of point 1.2, Chapter 1, Annex I to Regulation (EC) No 2073/2005 (see paragraph 96).

75. Both CCAs informed the audit team that FBOs are strongly recommended to use an accredited laboratory for the analyses of their own-check samples taken in accordance with Regulation (EC) No 2073/2005. The audit team saw several examples that own-check samples required by the mentioned EU legislation were analysed in external accredited laboratories, whilst other samples taken by the FBO were tested in a non-accredited in-house laboratory.

76. Official controls carried out by VI as regards number of sample units taken, parameters tested and analytical methods used within FBOs own-check sampling and testing programmes were largely satisfactory. However, the audit team identified some shortcomings in these controls carried out by SSI.

77. The audit team noted in one establishment visited under SSI supervision that the FBO took one sample from RTE products instead of the required five for microbiological
analysis without being able to demonstrate to the CA by historical documentation that it has effective HACCP-based procedures (which is in breach of Article 5(3) of Regulation (EC) No 2073/2005).

78. Moreover, in two establishments visited under SSI supervision, the FBOs regularly took swab samples from processing areas and equipment and analysed them for *Listeria monocytogenes*. However, all these samples were taken after cleaning and disinfection. This is neither in line with SSI guidelines on this issue nor with the guidelines of the EU Reference Laboratory (EURL) (Guidance on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*) which recommends (in order to increase the probability of detecting a persistent strain) that the sampling should be carried out during processing. Sampling only after cleaning and disinfection makes the detection of the pathogen difficult and can lead to a false sense of security. These practices had not been noted during official controls as the CA inspectors were not familiar with the provisions of the above mentioned SSI guidelines.

5.4.1.4 **Official sampling and laboratory analysis**

79. Both CAs have official sampling programmes implemented by PVIs and PSESs.

80. Official sampling programmes are applied by the PVIs in order to verify the implementation of FBOs' own-check sampling programmes and are based on specific GVI guidelines (see paragraph 3). According to the relevant guidelines, to decide when to take official samples the PVIs should take into account the conditions laid down in the guidelines: e.g. reliability of own-check testing results, sanitary conditions of the establishments, RASFF notifications, consumer complaints, etc.

81. The audit team was informed that if, in relation to food safety criteria, any non-compliant testing result was obtained (either in own-check or official testing) the PVI is recommended to take samples from at least two different batches of products for official microbiological analyses, after the corrective measures taken by the FBO. The audit team saw evidence for such sampling and testing.

82. The audit team noted that in order to verify that FBOs own-check procedures in RTE establishments are effective in relation to the risk of *Listeria monocytogenes*, PVIs shall collect samples (five sample units) for *Listeria* testing. Sampling should include at least one type of product from each product group (product groups are listed in the CA’s instruction), excluding those RTE products which are not able to support the growth of *Listeria monocytogenes*. There is an assessment sheet available which helps the PVIs to verify whether a specific food of animal origin has been correctly selected as RTE food for official analysis for *Listeria monocytogenes*. This procedure for sampling has been in place since February 2018 and has been implemented in all establishments visited under VI supervision.

83. VI provided the audit team with the data on official sampling carried out in 2017 in different food groups which included (but not limited to) RTE products. The audit team
noted that the CA tests target the most relevant RTE foods for *Listeria monocytogenes*. According to the data, 2,251 food batches were analysed for *Salmonella spp.*, of which 44 were non-compliant and 4,730 batches for *Listeria* of which 212 tested positive for *Listeria monocytogenes*. The highest number of non-compliances was found in samples taken in the fishery products (2.5% for *Salmonella* and 5.2% for *Listeria*) and in the meat/meat products (2.2% for *Salmonella* and 5.2% for *Listeria*) sectors. In addition, during the same period, 1,126 environmental (food processing area and equipment) samples were analysed for *Salmonella* (one positive) and 4,560 for *Listeria* (133 positive).

SSI

84. The official sampling programme prepared at central level is broken down to district level by the VSESs. The number of samples to be taken by the PSESs takes into account the population of the given district (population coefficient). SSI provided the audit team with the sampling programme for 2018. The audit team noted that the programme takes into account RASFF notifications from previous years related to certain microbiological risks (e.g. *Salmonella*, *Listeria*, etc.) and the product groups where they occurred (e.g. poultry meat or egg products, fishery products, etc.).

85. SSI provided the audit team with the data on official sampling carried out in 2017 in different food groups which included (but not limited to) RTE products. The audit team noted that the CA test target both food of animal origin, non-animal origin and composite products. Samples are taken both at retail and production level. According to the data, in total, 51,426 samples were taken (12,624 from confectionery and pastry products) and analysed for different microbiological parameters. *Enterobacteriaceae*, *Bacillus cereus*, *Salmonella spp.* and *Listeria monocytogenes* were the most frequently detected pathogens. The highest number of non-compliances was found in confectionery and pastry group (mainly ice cream and cakes with non-heat treated cream) for *Salmonella* (0.5%) and for *Listeria monocytogenes* (0.08%).

86. Both CAs have a network of official laboratories where official samples are analysed. The audit team was informed that all these laboratories are accredited to ISO 17025.

5.4.2 Measures in case of non-compliance

Legal requirements


Findings

87. The legal basis for enforcement is described in the country profile for Poland (see paragraph 1). When non-compliances are detected, PVIs and PSESs are responsible for taking the necessary measures to ensure that the FBO remedies the situation. The deadlines for follow-up actions are determined according to the seriousness of the non-compliance detected.
88. The audit team noted that for correction of minor non-compliances and if the FBO is co-operating with the CA to eliminate the shortcomings, the inspector can set a deadline in the inspection report. If the FBO is not co-operating with the CA or for correction of major non-compliances an administrative decision is issued by the CAs with deadlines. Administrative decisions also include: limiting/suspending production, suspending of operation and withdrawal of approval. Nevertheless, in the case of risks for direct product contamination or risks for public health, inspectors can request immediate corrective actions (see paragraph 69).

89. Examples of enforcement measures (administrative decisions) were seen by the audit team in some of the establishments visited.

90. Both CAs have the legal powers to impose fines in case of non-compliances. PVIs can impose financial penalties up to 66,000 PLN. The amount can be multiplied if there are several deficiencies linked to the same establishment. PSES can directly impose 50-500 PLN fines. Nevertheless, upon request of the PSES, the VSES can impose financial penalties up to 120,000 PLN. The audit team saw evidence in one of the establishments visited under SSI supervision that the inspector imposed 200 PLN (approximately 50 EUR) fine to the FBO due to deficiencies related to sanitary conditions.

91. GSI has put in place procedures that have to be applied by the CAs in case of RASFF notifications. The audit team reviewed several cases of RASFF notifications and food incidents related to RTE food which did not reach RASFF (in most cases due to *Listeria monocytogenes*) and noted that the CA procedures were followed: an adequate investigation was carried out at establishment level and corrective actions were taken by the FBOs. CA actions were prompt and comprehensive and in general effective concerning the contaminated product.

### Conclusions on official controls on the production of RTE food

92. The CAs put in place a system of risk based official controls over production of RTE foods, supported by comprehensive documented procedures and guidance. Although these procedures do not fully take into account the specific risks related to RTE food (in particular those identified by the CAs as high risk RTE), the impact is mitigated by the frequent and efficient controls in place. Some inconsistencies in the implementation of GSI procedures for risk assessments to determine inspection frequencies were noted.

93. Official controls and enforcement actions over RTE foods were satisfactory. However, shortcomings in the official controls to verify FBOs’ compliance with Regulation (EC) No 2073/2005 were noted in particular for GSI.

94. 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.

95. The system for follow-up of RASFF notifications and for food incidents which did not reach RASFF implemented in Poland provides guarantees that adequate actions are taken
by the CAs in case these notifications/incidents are 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

96. Challenges were highlighted by the CAs in relation to:

- enforcing provisions of EU guidelines (e.g. EURL guidance);
- the lack of clear criteria for the CAs when to accept FBOs limits (i.e. food safety criteria of 100 cfu/g in food category 1.2, of Chapter I, of Annex I to Regulation (EC) No 2073/2005) in RTE foods able to support the growth of *Listeria monocytogenes*.
- some industry practices as regards establishing responsibility (if non-compliances were detected e.g. *Listeria monocytogenes* above the limit). For example: defrosting frozen retail packs of cold-smoked fish produced in Poland (with the identification mark of the production company) at cold store level (before being sold to retail) in another Member State where they put the “use-by dates” on it. The shelf-life of the product after defrosting is established by the production company.
- classification of non-heat treated frozen vegetables: i.e. whether they should be classified as RTE foods, although preparation instructions provided on the packaging of these products clearly stated that the products needed to be cooked, micro-waved or fried.

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

97. By noting increasing trends in the number of RASFF notifications related to *Listeria monocytogenes* (mainly in cold-smoked fish), VI put in place new official control procedures and guidelines applicable from the beginning of 2018. In addition, in order to verify that FBOs own-check procedures in RTE establishments are effective in relation to the risk of *Listeria monocytogenes*, a mandatory official sampling programme for the detection of this pathogen has been agreed with the relevant industry and implemented since February 2018.

98. To address the challenges related to the reliability of own-check microbiological test results, the CAs recommend the use of accredited laboratories to the FBOs.

99. VI indicates the maximum capacities in the establishments' approval certificates for food of animal origin in order to prevent non-compliances (e.g. cross-contamination, lack of adequate cleaning and disinfection, etc.) that may arise when FBOs increase their production above a limit which does not facilitate hygienic performance of operations.

100. The National Institute of Public Health – National Institute of Hygiene (NIPH – NIH) is
currently in the process of implementing the "EpiBaza" project, which aims to consolidate and make available epidemiological data and data collected during official food safety controls. This will allow for forecasting trends, performing risk assessments and reducing the existing consumer health risks.

6 OVERALL CONCLUSIONS

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

Nonetheless, the audit team noted an inconsistent interpretation and implementation by the CA staff at regional and district levels of the procedures provided by the CCAs. This concerned in particular the risk assessments carried out to determine inspection frequencies of establishments.

Shortcomings were detected regarding implementation of official controls to verify FBOs’ compliance with the provisions of Regulation (EC) No 2073/2005.

Certain measures to facilitate compliance and reduce food-borne outbreaks are in place.

7 CLOSING MEETING

A closing meeting was held on 19 October 2018 with representatives of the CCAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. GSI informed the audit team of their commitment to review the risk assessment procedure in the light of the findings and conclusions of this audit.
### 8 RECOMMENDATIONS

<table>
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| 1.  | The CCAs should ensure that staff performing official controls at all levels undertake their duties competently and in a consistent manner in compliance with the provisions of Article 6 of Regulation (EC) No 882/2004. In particular, GSI should:  
  - provide the control staff involved in official controls of RTE foods establishments with training on the documented control procedures to verify the FBO’s compliance with Regulation (EC) No 2073/2005 especially with the provisions on RTE food;  
  - revise their documented control procedures in relation to risk assessments to determine inspection frequencies of establishments.  
Recommendation based on conclusion Nos 35, 92 and 93.  
Associated findings Nos 28, 57, 58, 74, 77 and 78. |

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

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<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
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<td>Regulation</td>
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## ANNEX 2

### RELEVANT GUIDANCE DOCUMENTS

<table>
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<tr>
<th>Title</th>
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<tr>
<td>Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses</td>
<td>OJ No C278, 30.07.206, p.1</td>
</tr>
<tr>
<td>Guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes</td>
<td><a href="https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidelines_on_sampling.pdf">https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidelines_on_sampling.pdf</a></td>
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