EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2020-6919

FINAL REPORT OF AN AUDIT
CARRIED OUT OF
POLAND
FROM 15 SEPTEMBER 2020 TO 04 NOVEMBER 2020
IN ORDER TO
ASSESS THE OFFICIAL CONTROLS ON THE PRODUCTION CHAIN OF SMOKED FISHERY PRODUCTS

In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Directorate-General for Health and Food Safety audit of Poland carried out from 15 September to 4 November 2020, as part of its work programme of controls in Member States.

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 - in particular those aimed to ensure smoked fish meets the microbiological food safety criteria – as well as the measures taken by the competent authorities in case of non-compliance with these requirements.

In the context of this audit, the audit team also assessed the measures taken by the competent authorities in relation to the outbreaks and Rapid Alert System for Food and Feed notifications issued due to Listeria monocytogenes in smoked fishery products produced in Poland.

Since the COVID-19 pandemic precluded an on-site verification and assessment of the operation of official controls, the audit outcome is based on a review of documentation and control records pertinent to the audit scope, and interviews of and discussions with representatives of the competent authority at various levels, via videoconference.

The report concludes that the official control system in place for smoked fishery products cover the production chain, it is implemented as planned and in accordance with the applicable procedures. It provides a largely satisfactory basis for the competent authority to verify compliance of several European Union food hygiene requirements.

Nonetheless, the audit also identified gaps/shortcomings in relation to the ability of the controls to detect relevant deficiencies, most notably the storage of frozen products (prolongation of the stiffening) and the assessment of the shelf life studies (for which existing guidance was not taken into account). These factors impact the overall effectiveness of controls in this area in terms of its ability to verify compliance and to ensure the implementation of appropriate corrective measures which, in turn, would also contribute to prevention of future incidents.

The competent authority investigated the Rapid Alert System for Food and Feed notifications on Listeria monocytogenes in smoked fishery products, including the ones linked with the multi-country outbreaks. This work contributed to certain improvements of the control system, in particular, staff training, official sampling and testing for the microbiological criteria. Further improvements can be achieved with whole genome sequencing expected to start at the end of this year. However, in the case of the non-compliances detected in the concerned establishments, the corrective action was limited to those food business operators involved and there is no evidence that the acquired knowledge was used to improve the overall control system.

The report contains recommendations to the competent authority aimed at rectifying the identified shortcomings and enhancing the control system in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CVO	Chief Veterinary Officer
DG Health and Food Safety	Directorate-General for Health and Food Safety of the European Commission
DVI	District (*Poviat*) Veterinary Inspectorates
DVO	District Veterinary Officers
EC	European Commission
ECDC	European Centre for Disease Control
EFSA	European Food Safety Authority
EU	European Union
EURL	EU Reference Laboratory
FBO	Food Business Operator
GVI	General Veterinary Inspectorate
HACCP	Hazard Analysis Critical Control Points
RASFF	Rapid Alert System for Food and Feed
ROA	Rapid outbreak assessment
RVI	Regional (*Voivodship*) Veterinary Inspectorates
RVO	Regional Veterinary Officers
SSI	State Sanitary Inspectorate
VI	Veterinary Inspection

1 INTRODUCTION

The audit took place in Poland from 15 September to 4 November 2020 and was undertaken as part of the Directorate-General for Health and Food Safety of the European Commission (DG Health and Food Safety) work programme. The audit team comprised two auditors from DG Health and Food Safety.

The audit team held an opening meeting on 15 September 2020 with the competent authorities relevant for the audit – the Veterinary Inspection (central, regional and district levels) of the Ministry of Agriculture and Rural Development, the Department of Fisheries of the Ministry of Maritime Economy and Inland Navigation and the State Sanitary Inspectorate of the Ministry of Health. At this meeting, the audit team confirmed the objectives of the audit and the scheduling of the different videoconferences.

NOTE: The COVID-19 pandemic precluded on-site verifications and assessment of the performance of official controls. The audit findings and outcome are therefore based on and limited to a review of documentation and records pertinent to the audit scope, and discussions with representatives of the competent authorities at various levels, via video-conference.

2 OBJECTIVE AND SCOPE

The objective of the audit was to assess the arrangements put in place by the competent authorities to verify compliance with European Union (EU) food hygiene requirements - in particular those aimed to ensure smoked fish meets the microbiological food safety criteria – as well as the measures taken by the competent authorities in case of non-compliance with these requirements.

In the context of this audit, the audit team also assessed the measures taken by the competent authorities in relation to the outbreaks and Rapid Alert System for Food and Feed (RASFF) notifications issued due to *Listeria monocytogenes* in smoked fishery products produced in Poland.

In terms of scope, the audit focused on:

- the organisation and performance of the competent authorities;
- the control system in place covering production of certain types of smoked fishery products that have given rise to iRASFF notifications and food-borne outbreaks due to *L. monocytogenes*.

Particular attention was given to:

- the competent authorities' assessment of the food business operators' (FBO) Hazard Analysis Critical Control Points (HACCP) based procedures and related own-check programmes in relation to managing microbiological hazards and addressing risks related to *L. monocytogenes*;

- the official sampling and testing of fishery products and the measures taken when non-compliances are detected; and,
- the actions taken by the competent authorities in relation to iRASFF notifications and food-borne outbreaks due to *L. monocytogenes*, related to smoked fishery products manufactured in Poland.

Accordingly, relevant aspects of the EU legislation referred to in Annex 1 [1] were used as technical basis for the audit.

In pursuit of this objective, the audit team held six videoconference meetings, including opening and closing meetings, with the competent authorities from the different organisational levels.

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular, Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

4 BACKGROUND

4.1 GENERAL BACKGROUND

"*The European Union One Health 2018 Zoonoses Report"* [2] issued by the European Food Safety Authority (EFSA) and the European Centre for Disease Control (ECDC) highlights listeriosis as one of the most serious food-borne diseases under EU surveillance, being the agent with the highest case fatality rate among outbreak related illnesses.

The EFSA/ECDC scientific opinion on *L. monocytogenes* contamination of ready-to-eat foods [3] – reveals that the highest level of non-compliance in ready-to-eat food was observed in the food category 'fish and fishery products'.

The ECDC and EFSA issued a joint rapid outbreak assessment (ROA) on 25 October 2018 – Multi-country outbreak of *L. monocytogenes* sequence type 8 infections linked to consumption of salmon products [4] – concluding that the contamination of the salmon products could have occurred at a processing company in Poland. This ROA is linked to the iRASFF notifications 2017.1319 and 2017.1546, involved two Member States and porducts produced by the same establishment in Poland. This supported the hypothesis that the

[1] Full legal references to EU legal acts quoted in this report refer, where applicable, to the last amended version.

[2] *The European Union One Health 2018 Zoonoses Report*, EFSA Journal 2019;17(12):5926.

[3] *Listeria monocytogenes contamination of ready-to-eat foods and the risk for human health in the EU*, EFSA Journal 2018;16(1):5134.

[4] Multi-country outbreak of *Listeria monocytogenes* sequence type 8 infections linked to consumption of salmon products- 25 October 2018, available in Internet at: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2018.EN-1496 and https://www.ecdc.europa.eu/en/publications-data/multi-country-outbreak-listeria-monocytogenes-sequence-type-8-infections-linked.

contamination of the products may have occurred at the processing company in Poland. However, due to the lack of whole genome sequencing data on the isolates from environmental and food samples taken at the Polish processing plant, it was not possible to confirm this hypothesis at the time. The Polish company implemented corrective measures but, despite that, the same strain was later identified in two Member States and in new cases, suggesting that the source of contamination was still active.

The Commission services requested the Polish competent authorities to investigate thoroughly the potential source of contamination by using the appropriate analytical techniques and to ensure that the establishment concerned improved the relevant hygiene conditions. In that context, the Commission services offered the support of the EU Reference Laboratory (EURL). In response, the Polish competent authorities described the actions already taken following the outbreaks and committed to additional long-term actions.

Previously, Poland was audited for fishery products in 2016 (DG(SANTE) 2016-8687) [5] (hereinafter: "the 2016 audit") and for ready-to-eat food in 2018 (DG(SANTE) 2018-6451) [6] (hereinafter: "the 2018 audit").

4.2 PRODUCTION AND TRADE INFORMATION

According to the lists available in the General Veterinary Inspectorate (GVI) website [7] there were at the time of the audit 284 establishments approved for fishery products in general, distributed as follows: 275 processing establishments, 5 wholesale markets, 1 auction hall, 2 factory vessels and 1 freezer vessel. Also according to those lists, there were 94 approved cold stores to deal with fishery products. The Polish fishery authorities provided to the audit team a list of 793 registered primary production fishing vessels and GVI made available the list for aquaculture farms.

In terms of relevance for the scope of the audit, and in addition to the generic figures above, GVI indicated that 88 processing establishments were manufacturing smoked fishery products and 11 additional establishments have been approved for local, marginal and limited activities. Also according to GVI, other 37 approved establishments may be involved in the production chain of salmon/trout smoked products (e.g. pre-processing establishments and cold stores).

In relation to the production of smoked fishery products, the Polish fisheries authorities informed that audit team that:

- The vast majority of the salmon raw materials used it the manufacture of smoked fishery products is imported from Norway, directly or indirectly via other EU Member States (the latter related only to a commercial transaction).

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5 Audit report available at: https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3683.
6 Audit report available at: https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4113.
7 Available at: https://www.wetgiw.gov.pl/handel-eksport-import/listy-zakladow.

- In 2019 Poland imported approximately 195 000 tonnes of salmon (86% under the CN code 0302 – chilled whole fish), which represents approximately 99% of the raw materials used the industry of smoked fishery products.
- Poland has two salmon farms that currently do not provide raw materials for the production of smoked fishery products.
- The Polish fleet of primary production fishing vessels can supply pelagic species for the production of smoked fishery products. The main species are sprat, herring and mackerel. Catches of salmon represent less than 30 tonnes per year. It is not possible to know exactly how much of the captured fish is used for the production of smoked fishery products.

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

Since 2015 the members of the RASFF network [8] have issued 61 notification for Polish fishery products. From those, 14 of them were alert notifications relation to *L. monocytogenes* mainly for smoked salmon products and 34 were information notifications on the same issue. As regards to the criteria that triggered those notifications, 23 were linked with the detection of *L. monocytogenes* in 25g and 25 were related to the quantification of *L. monocytogenes* above the regulatory limit of 100 cfu/g).

As indicated above, two of 2017 iRASFF notifications involving a Polish processing establishment have been linked with the joint ROA issued by ECDC and EFSA on 25 October 2018. After that ROA a new one was issued in 13 December 2018 describing a multi-country cluster of ten invasive listeriosis involving three Member States and linked to a different Polish processing plant. This latter establishment has been involved in several iRASFF notifications.

5 FINDINGS AND CONCLUSIONS

5.1 NATIONAL MEASURES

Legal requirements

Article 291(1) of the Treaty on the Functioning of the EU and Article 7 of Regulation (EC) No 852/2004.

Findings

1. Currently Poland does not have national laws establishing requirements additional to those of the EU food law applicable to smoked fishery products.

2. With respect to national guides to good practice for hygiene in smoked fishery products, the competent authority indicated that the Polish Association of Fish Processors would

[8] European Commission, European Food Safety Authority (EFSA), European Free Trade Association (EFTA) Surveillance Authority, EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

make a “Code of good production practices in fish processing” available to the food business operators, in the last quarter of 2020.

3. According to the competent authority, this association commissioned the Maritime Fisheries Institute of the State Research Institute in Gdynia to develop that guide, which will have a chapter dedicated to *L. monocytogenes*, with particular emphasis in the manufacturing process of smoked fishery products.

5.2 COMPETENT AUTHORITY

Legal requirements

Articles 4, 5, 6, 8, 11, 12, 15, 18(10), 28, 29, 30, 31, 32, 33 and 139 of Regulation (EU) 2017/625.

Findings

4. The competent authorities designated for the official control of fishery products and their production chain are clearly indicated in the country profile for Poland [9], last published in July 2019 (hereinafter referred to as: "the country profile for Poland"), describing the organisation of official controls in Poland. The report of the 2016 audit presents additional information specific to the fishery products sector, which remains valid.

5. In summary:
   a. The overseeing competent authorities are the Veterinary Inspection (VI), of the Ministry of Agriculture and Rural Development, and State Sanitary Inspectorate (SSI), of the Ministry of Health.
   b. The VI is headed by the Chief Veterinary Officer (CVO), and it is responsible for the controls of food of animal origin. In terms of its operation, the VI is divided in into the GVI (central level), Border Veterinary Inspectorates, Regional (*Voivodship*) Veterinary Inspectorates (RVI) and District (*Poviat*) Veterinary Inspectorates (DVI).
   c. The RVIs and the DVIs are headed by, respectively, Regional Veterinary Officers (RVO), and District Veterinary Officers (DVO). The DVI staff carry out most of the official control tasks. Additionally, the DVO may authorise (contract) private veterinarians to carry out specific official tasks.
   d. The GVI has a co-ordinating role over the RVIs and DVIs in relation to veterinary matters. GVI provides RVO and DVO with interpretation of provisions, instructions and guidelines on implementation of EU and national legislation, official procedures for food control as well as training.

[9] Available in the Internet at https://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=PL, Ref. Ares(2019)7055550 - 14/11/2019.

e. The SSI is headed by the Chief Sanitary Inspector, and, within the remit of this audit, is responsible for the controls at retail level [10]. Those controls include the sampling and testing of fishery products at retail.

6. As indicated in the 2018 audit report (paragraph 19 of that report), VI and SSI adopted a new Framework Agreement, of 16 October 2018. This agreement, lays down amongst others, detailed conditions and rules of co-operation and collaboration regarding control of foodstuffs, including controls on retail trade in food of animal origin. It replaces the one of 21 September 2017 and better clarifies the previous control overlaps between the two authorities in respect of establishments manufacturing/handling both food of animal origin and non-animal origin.

7. The GVI stated that the information of the country profile for Poland in relation to the following matters is updated and valid:

a. powers to carry out controls, including the access to food business premises and documentation);

b. arrangements in place to ensure the impartiality, transparency and confidentiality of the controls, and;

c. arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest.

8. In addition to paragraph 7.c. above, GVI indicated that the "*CVO instruction on the methodology of official controls and verification of the performance of official activities*" (of 31/12/2019) provides to official staff guidance on avoiding potential conflict of interest. In relation to the private veterinarians contracted by the DVOs, GVI stated that the private veterinarians must submit a declaration of absence of conflict of interest for the tasks covered by the contract.

9. The VI did not delegate or transfer control tasks to other official or private entities.

10. In their response to the pre-audit questionnaire, the GVI indicated the number of staff dedicated to official control tasks relevant for the scope of the audit. GVI staff did not flag any particular issues related to staff.

11. In that response the GVI also provided information on the training provided to control staff and relevant for the scope of the audit. According to the GVI, a multiannual training plan organised by the National Veterinary Research Institute has relevant training which take place annually and have been attended by staff of the different authority levels (central, regional and district). The trainings covered "Veterinary requirements in the production of the food of animal origin", "Essentials of food processing and food technology", "Microbiological hazards in the production of food of animal origin", and "Parasitic diseases of animals and parasites in food of animal origin". In addition, in 2019, staff of the central level had training on "Quality and safety

[10] Due to the restricted role of SSI in relation to the scope of the audit, section 5.2 of the report will focus mainly on the VI matters.

of frozen raw materials and fishery products" organised by the National Marine Fisheries Research Institute.

12. The VI also informed that, following the different iRASFF notifications related to the presence of *L. monocytogenes* in Polish smoked fishery products, the CVO organised in 2019 a specific training on "Food sampling in the food production chain - theoretical and practical issues" which was attended by the relevant official control staff.

13. Also in relation to training, the GVI stated that official control staff participates regularly in the training provided by the European Commission under the *Better Training for Safer Food* programme, which is then passed internally in Poland by a cascade training system.

14. GVI developed largely adequate documented procedures for the performance of official controls. Those procedures will be further detailed in the respective sections of this report and include CVO instructions and guidelines covering the following aspects:

a. approval and registration of food business operators;
b. risk analysis to establish the frequency of controls;
c. methodologies for the official controls;
d. controls on traceability;
e. sampling and testing of foodstuffs for microbiological criteria, and;
f. scope and operation of national RASFF system.

15. According to GVI and SSI, both services have access to an adequate laboratory network to test official control samples.

16. In terms of procedures to verify the implementation of control tasks, the GVI indicated that its audit office carries out supervision over the regional and district levels (thematic controls), throughout a documentary assessment, which may include an on-the-spot assessment. These controls can be planned or non-planned, the former based on a risk analysis and the latter carried out to address specific emergent issues. GVI stated that no thematic controls have been recently carried out to the regions and districts involved in the current audit. In addition, the GVI also stated that it has in place other mechanisms with a view of co-ordination and supervision, which include regular meetings between the different Officers and exchange of correspondence by conventional and electronic mail.

17. The audit office of GVI carries out internal audits to the services performing official control tasks. These audits are carried out annually and cover particular topics and services. The audit office intends to cover all relevant topics within a five-year period. The last internal audit that covered fishery products matters, including smoked fishery products, was carried-out in 2015.

18. The country profile for Poland indicates the main legal acts that cover the enforcement measures that can be taken by the competent authority following the detection of non-

compliances. Within the VI those measures include administrative decisions and/or fines taken by DVO and legal decisions taken at court level. In the case of administrative decisions, they can include the seizure of products, suspension of activities and withdrawal of the approval.

Conclusions on the competent authority

19. Poland has designated competent authorities for the official controls of smoked fishery products. The main authority covered by this audit continues to have the necessary powers and resources for the performance of the control tasks.

20. The control tasks are supported by largely adequate documented procedures and are carried out in a transparent and confidential manner, by official staff that received relevant training. This staff is subject to requirements concerning the conflict of interest.

21. The authority has in place certain supervision mechanisms as well as internal audits. However, in relation to the controls of smoked fishery products, the implementation of these mechanisms had not been used in recent years and as such, potential deficiencies of the control system were not identified.

22. The competent authority can apply adequate enforcement measures, if needed.

23. The elements above constitute an adequate basis for the authority to implement the official control system covering smoked fishery products.

5.3 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATOR ESTABLISHMENTS

Legal requirements

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

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

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

Article 45 of Regulation (EU) 2019/1715.

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

Findings

24. According to the GVI there are no changes in respect of the registration and approval of the establishments, fishing vessels and farms, relevant for the current audit. The information in paragraphs Nos 24 and 25 of the 2016 audit report and No 37 of the 2018 audit report is still valid. The procedure for the approval and registration of FBOs is still the CVO Instruction No GIWpr-02010-9/2017 of November 2017.

25. In relation to primary production, as indicated in the background section above, the relevant competent authorities have updated lists of fishing vessels and aquaculture farms, which have been made available.

26. As indicated in the background section above, the list of approved establishments is publically available in the GVI website and it is updated. The audit team noted that that list has several establishments with the remark "suspended approval". The table below summarises the situation at the time of the audit:

Year of the decision to suspend the approval	No of establishments concerned
2005	1
2010	1
2011	1
2013	1
2014	2
2016	3
2017	1
2018	1
2020 (April)	1

27. The GVI stated that this practice is in accordance with their procedures. According to those procedures, an FBO that suspends its activity for reasons not related with the food safety requirements of the approval must notify the authority and an approval withdrawal is not necessary. If that suspension lasts more than three months, then an on-the-spot visit must be carried out before the revocation of the suspension. Furthermore, GVI informed the audit team that for legal reasons they cannot remove those suspended establishments from the list of approved establishments until the FBO requests the approval withdrawal.

28. The audit team noted that the procedure for approval and registration cover completely the production chain for fishery products and it is largely in line with the EU rules. However, the audit team noted that the procedure was unclear in the case of a conditional approval. The procedure does not indicate that the competent authority must carry out a new on-the-spot visit within 3 months of the first visit (the one that allowed granting the conditional approval), to verify if the final approval could be granted, or, clear progress had been made, which would allow the extension of the conditional approval for a total period of not more than 6 months.

29. GVI acknowledge the point indicated immediately above and committed to address it in the revision currently being prepared for updating their procedures with the references of the recent "Official Control Regulation" (Regulation (EU) 2017/625).

Conclusions on registration/approval

30. The procedures in place for approving and/or registering facilities/FBOs dealing with smoked fishery products is largely in line with the EU rules. Lists of those facilities/operators are available in the webpages of the relevant competent authorities and are updated. However, the deadlines set for a first visit within the conditional approval process do not follow the requirements of Article 148(4) of Regulation (EU) 2017/625.

31. Moreover, the list of approved establishments for fishery products has eight establishments with the approval suspended for more than four years.

5.4 OFFICIAL CONTROLS

5.4.1 Official controls on the production chain of smoked fishery products

Legal requirements

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

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

Commission Regulation (EC) No 2073/2005.

Annex II to Regulation (EC) No 2074/2005.

Regulation (EC) No1333/2008

Regulation (EC) No1321/2013

Articles 9(1) and (4) to (6), 10 (1), 12(1), 13, 14, 15, 18 (1) and (8)(f), and 138 of Regulation (EU) 2017/625.

Articles 3, 4, 5 and 67 of Regulation (EU) 2019/627.

Findings

General description of the control system in place

32. The generic descriptions made in the 2016 and 2018 audit reports in relation to the organisation of the official control system in place remain valid (respectively, sections 5.3.1 and sections 5.4.1 of those audit reports).

33. Since the 2018 audit the CVO issued two new instructions:
    a. CVO Instruction No GIWpr02010-14/2019, of 31/12/2019, "*on methodologies of official controls and verifications of performance of official activities*", repealing the CVO Instruction No GIWhig-500-4/08.

b. CVO Instruction No GIWpr0200.1.16/2020, of 23/06/2020, "*on the determination, on the basis of a risk analysis, of the frequency of controls*", repealing the Instruction No GIWbż-500-2/11.

34. These new instructions incorporate revisions of the previous instructions and updates to the legal references to the new "official control regulations".

35. The remaining instructions related to the performance of official controls on the production chain indicated in paragraphs Nos 3 and 61 of the 2018 audit report are still valid and applied. In this regard, the audit team noted that, after that audit, the annexes of the "*CVO 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*" have been updated, and, are largely in line with the EU rules.

36. Based on the procedures above, and supporting legislation, GVI developed a control system, covering the complete production chain, which the RVIs and DVIs implement.

37. Each approved establishment is assessed on a risk basis using the instruction indicated in paragraph 33.b. At the time of approval, every establishment is categorised as high-risk (mainly due to the lack of historical data). The newly approved establishments must be controlled within three months of the approval, which will include a risk assessment of the establishment. The risk categorisation of every approved established is then reassessed every 12 months. The instruction encompasses the relevant risk criteria in line with the rules set in Art. 9(1) of Regulation (EU) 2017/625. A frequency for the routine controls is set based on the outcome of the risk-based assessment (no changes since the 2018 audit – see paragraph 47 of that audit report.).

38. The instruction also covers primary production fishing vessels. For these vessels, a generic frequency of one routine control every 24 months after the first control for the registration has been established.

39. The controls are carried out by the relevant level of VI in accordance with the instruction indicated in paragraph 33.a and using relevant checklists (SPIWET checklists available at the VI website). The controls can be periodic (routine), *ad hoc* or for verification (follow-up). The routine and *ad hoc* controls are un-announced, except if prior notice is necessary to carry them out. The instruction indicates the different methods and techniques to be used in the performance of the controls, which are in line with Art. 14 of Regulation (EU) 2017/625. In terms of scope, and according to the instruction and respective checklists, the controls cover all relevant requirements of Regulations (EC) Nos 852/2204, 853/2004 and 2073/2005.

40. This instruction indicates also the obligations of the FBO in relation to assisting official staff in the performance of the controls and granting access to relevant documents and production facilities.

41. The instruction also covers the actions to be taken following the detection of non-

compliances. They include the follow-up controls mentioned above and the sampling for testing, seizure of products and subsequent enforcement measures if required (referred to in paragraph 18).

42. In relation to aquaculture farms GVI informed he audit team that the CVO Instruction No GIWz400/R-01/2011 of 18 March 2011, and associated SPIWET checklist was used for their control. This instruction covers both food safety and animal health aspects and sets the frequency of the controls on risk basis, considering the animal health requirements.

Primary production fishing vessels and aquaculture farms

43. According to the information provided by the competent authorities the vast majority of the raw materials used in the production of smoked fishery products from salmon are imported and not derived from the aquaculture facilities of Poland. In relation to smoked fishery products from trout, they account to small quantities in the overall production of smoked fishery products and they derive mainly from aquaculture farms.

44. The audit team noted that the checklists developed by GVI adequately cover the requirements of Regulations (EC) Nos 852/2004 and 853/2004 for fishing vessels and aquaculture farms.

45. GVI indicated that DVI performed controls to fishing vessels likely to be involved in the production of smoked fishery products in 2018 (59 controls) and 2019 (95 controls).

Official control of approved facilities – establishments on land

46. According to the information provided by GVI, RVI and DVI the audit team noted that the controls of the establishments have been carried out in accordance with the defined frequencies.

47. From the assessment made on the control records provided by GVI for five establishments (three of them associated with iRASFF notifications), the audit team noted they have been controlled by the relevant competent authority, in accordance with the planned arrangements. The establishments had been assessed and categorised in accordance with the risk and the frequencies set for the periodic controls was respected. The audit team also noted that, as an enforcement action, the risk category of the establishment involved in iRASFF notification was modified to high, which led to an increased frequency for the periodic controls.

48. The records show that during the periodic controls the establishment/FBO is assessed to verify its compliance with the relevant EU requirements and the conditions that allowed for the approval. This includes amongst others the assessment of the level of compliance of premises, of good-hygiene practices (including their implementation), of the drafting and implementation of permanent procedures based on the HACCP principles, of the drafting and adherence to own-check sampling plans, of the correct use of authorised additives and of labelling (including the use of the identification mark).

49. In addition to the periodic controls, the competent authorities also made visits for the collection of samples, follow-up of controls where deficiencies have been detected and *ad hoc* inspection to investigate iRASFF notifications (or other justified reasons – e.g. foreign market access/assessment).

50. The audit team noted in several instances that the competent authority detected non-compliances during the periodic visits. Consequently, the competent authority notified the FBO to implement corrective actions to address the deficiencies and established deadlines for the implementation of those actions. The audit team noted that at the end of those deadlines, the competent authority carried-out verification visits (follow-up).

51. The audit team noted that in certain cases where follow-up visits had established that the deficiencies were not addressed, the competent authority took enforcement measures, such as administrative decisions, fines, and/or the imposition of increased sampling of products.

52. In one particular case, linked to the ROA and iRASFF notifications, the audit team noted that the FBO was assessed in May 2019 by a private third party, who identified several issues that could contribute to the presence of *L. monocytogenes* in the products (which was the cause of the iRASFF notifications). These issues were mainly related to the pooling, splashing, drainage and flow of water of containers, equipment (including ventilation equipment) and conveyers, cross-contamination of working clothes of different staff (working clothes of clean area staff and dirty area staff), which can be considered non-compliances with the general hygiene rules of Annex II to Regulation (EC) No 852/2004. That private assessment also recommended changes on the collection of swabs from fishery products to enhance the capability to detect the presence of *L. monocytogenes*. The competent authority have not identified those deficiencies in previous controls, however they were acknowledged and endorsed in a control carried out June 2019. The 2018 control does not indicate any non-compliance, but a previous control carried out by the competent authority in 2017 made recommendations on the hygiene of staff, environmental sampling and the correct use of cleaning agents (surface disinfectants).

53. One important element raised by the private third party control was the reduced number of samples tested for absence in 25g and the lack of statistical correlation between the positive samples and the number of cfu/g of those products.

54. The competent authority informed that the FBO indicated that positive raw materials are processed at the end of the production day to minimize cross-contamination.

55. On the last point above, the FBO indicated that those positive raw materials would be used for the production of hot smoked fishery products, in which the time/temperature of the smoking process would minimise the *Listeria* risk (according to the FBO at least 4 minutes at 68 °C). The FBO provided to the audit team records of the hot smoking process which showed a cooking times between two to three hours and a final temperature of 68 °C.

56. The audit team noted that after the control of June 2019, the competent authority carried out several *ad hoc* controls to verify the implementation of corrective actions to address the deficiencies noted by them and by the external party. A periodic control was carried out in December 2019 with satisfactory results.

57. With regard to the requirements set in Regulation (EC) No 2073/2005 the audit team noted that the SPIWET checklist instructs official staff to verify if the establishment/FBO has a sampling plan (own-checks) respecting the following points:

    a. it covers all products, or group of products, for which Regulation (EC) No 2073/2005 establishes criteria (including *L. monocytogenes*);
    b. it covers all food safety criteria (parameters) established by the same regulation;
    c. it is implemented in terms of the planned frequency to ensure that products are checked at the end of their production and during their shelf life;
    d. uses the sampling plans and the testing methods indicated in Annex I Chapter 1 of Regulation (EC) No 2073/2005;
    e. uses reference analytical methods or alternative methods validated against the reference ones;
    f. justifies correctly the use of the limit 100 cfu/g for ready-to-eat foods that support the growth of *L. monocytogenes*;
    g. the sampling plan is implemented as planned;
    h. unsatisfactory results trigger adequate corrective measures including for the product produced, and;
    i. the reprocessing of products need to be approved by the competent authority.

58. The audit team did not note non-conformities in respect of the points above in the official control records checked. Moreover, official staff stated that the checklist currently in use, together with the CVO guidelines on official control procedures to verify compliance of FBOs won-checks, is sufficient and demonstrate that the requirements of Regulation (EC) No 2073/2005 have been assessed. The audit team also noted that FBOs include in their own-check sampling plan to take environmental samples to be tested for *L. monocytogenes*.

59. From the files reviewed the audit team noted that the competent authority allows FBOs to keep frozen products for a period of up to three months at temperatures above minus 18 °C. The competent authority indicated that this practice is included in the so-called *stiffening*, which is a necessary technological step in the production of some smoked salmon products. The *stiffening* is well described in the "Guidance document on good practice for *smoked and/or salted and/or marinated fish*" [11]. However, as also mentioned in that guidance, this practice should be strictly limited to the minimum time necessary to carry out the manufacture operations, which is clearly not the case observed (extending the *stiffening* step to up to three months, with a storage between minus 12 °C

[11] Available in DG SANTE website at: https://ec.europa.eu/food/safety/biosafety/food_hygiene/guidance_en.

and minus 8 °C). Therefore, the procedure adopted and implemented by the FBOs and the interpretation of official staff, are not in line with the requirements of set in point 2 of Chapter VII of Section VIII of Annex III Regulation (EC) No 853/2004 for the temperature of storage of frozen fishery products.

60. Additionally, the audit team requested access to the studies carried out by the FBOs to investigate compliance with the *L. monocytogenes* criteria throughout the shelf life of ready-to-eat smoked fish of three establishment involved in the iRASFF notifications and noted some shortcomings.

61. In one case, the competent authority held the view that the company established the shelf life of the products based on historical data and extensive product testing. At a later stage, the competent provided a shelf life study that was carried out not respecting the temperature regime set in the EURL guidance document [12] and the alternative time/temperature profile applied was not justified to reflect the reasonable, foreseeable storage and distribution conditions, as requested by Art. 3 and Annex II of Regulation (EC) No 2073/2005.

62. In a second case, the competent authority considered that the company had carried out the challenge tests in accordance with the EURL guidance document. According to the competent authority this is demonstrated by the last paragraph of the introduction chapter of the test report - *The present challenge test has been designed following the methodology indicated in the guide: "EURL Lm TECHNICAL GUIDANCE DOCUMENT for conducting shelf life studies on L. monocytogenes in ready-to-eat foods Version 3 - 6 June 2014"*. The competent authority did not make any assessment or evaluation of those challenge test reports. On this case, the audit team noted several elements suggesting the challenge tests had not been carried out in line with the EURL guidance document:

a. The challenge-tests were conducted only on one batch, without consideration of the inherent variability of the physico-chemical characteristics of the products which can impact the growth of *L. monocytogenes*.

b. Moreover, the FBO has requested the laboratory to conduct the challenge test without data characterizing the product. In such case, the challenge test carried out is only valid for the product under study. The obtained result cannot be extrapolated to other productions. The comment made by the laboratory at the end of the report, *"the product contained in the packaging studied is truly representative of the product in question*", was made without providing the adequate justification.

c. The report classified a product in the category ready-to-eat food unable to support the growth of *L. monocytogenes*, on the basis of only one challenge test conducted on only one batch without information on the variability of the food characteristics.

63. From the paragraphs above the audit team finds that, in two of the three assessed cases,

[12] EURL Lm TECHNICAL GUIDANCE DOCUMENT for conducting shelf life studies on *Listeria monocytogenes* in ready-to-eat foods Version 3 – 6 June 2014 (Amended 1 made on 21 February 2019)

the competent authority was not able to assess adequately the information provided by the FBOs in relation to the setup of the shelf life period for their products, and, the information provided does not support the decision of the FBO.

Conclusions on official controls on the production chain of smoked fishery products

64. The official control system in place covers the production chain of fishery products. This system seems to cover adequately all the applicable requirements, except for the temperatures allowed for the storage of frozen products and the controls on FBOs shelf life studies.

65. The competent authority's limited assessment of FBOs shelf life studies on *L. monocytogenes* on ready-to-eat smoked fish/salmon impacts the ability of the control system to detect when the conclusions of these studies are incorrect or inadequately justified. This calls into question the suitability and/or the validity of the shelf life period of products concerned which, in turn, may impact on the safety of those products. Moreover, during the official control visits, official staff did not identify non-compliances that may have an impact on the control of *L. monocytogenes*.

66. The competent authority implements the controls as planned and in accordance with applicable procedures. Approved establishments are categorised following a risk evaluation and the control frequencies are based on that categorisation. Records of the controls are kept and were made available to the audit team.

5.4.2 Official controls of fishery products, including sampling and testing

Legal requirements

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

Articles 18 (8)(f), 34, 35 and 39 of Regulation (EU) 2017/625.

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

Findings

67. In terms of official control of the products, and according to the information provided by the competent authority, the audit team noted that those controls include the relevant parameters for fishery products, and in particular, for smoked ready-to-eat foods.

68. The competent authority indicated that the district levels implement a yearly control plan. In accordance with the information provided for 2018 and 2019 smoked fishery products (or their raw materials) were sampled and tested for organoleptic examinations, freshness indicators, histamine and microbiological checks (mainly *L. monocytogenes*). The results showed to the audit team do not show any non-compliant result for the first three criteria mentioned before.

69. In relation to the testing for *L. monocytogenes* the audit team noted that the competent authority planned to take 195 samples in 2018 and took 208 with 4 of them having non-compliant results. For 2019, the competent authority planned to take 294 samples and took 324, with 26 of them having non-compliant results. Based on these figures, one can estimate that in 2018 circa 1.9% of the samples were non-compliant, whereas in 2019 that figure rose to 8%. The competent authority presented as possible explanations for this increase the targeting of products involved in iRASFF notifications and also the training provided to official staff on sampling of products for microbiological testing (see paragraph 12). The vast majority of the samples were tested for the detection in 25g and all the positive results, except for one case in 2019, were on those samples tested for the detection in 25 g.

70. The competent authority took measures for all positive results – fines, administrative decisions, disposal of the products, additional sampling of the same batch. Some of the measures taken in 2019 included the identification of the root causes to prevent the reoccurrence of the non-conformity.

71. The same trend as indicated in paragraph 69, was observed, in a lesser extent for the percentage of non-compliant results, for the environmental samples. In 2018 the competent authority planned to take 296 samples and took 434, with 3% non-compliant results, while in 2019, it planned to take 450 samples and took 511 with 4% non-compliant results.

72. In relation to sampling at retail level, under the responsibility of the SSI, that authority informed the audit team that sampling of fishery products for microbiological criteria (*L. monocytogenes* and *Salmonella spp.*) is included in their yearly control plan.

73. SSI also informed that after the 2017 iRASFF notification made a specific monitoring plan targeting Polish products placed in the country's retail. According to SSI, it sampled 181 batches in 2018 with one non-compliant result – two units of the sample with 1 800 cfu/g and 3 400 cfu/g, and remaining three units with less than 10 cfu/g (this triggered an iRASFF notification). In 2019, SSI sampled 195 batches of products with one non-compliant result – four units of the sample with more than 1 500 cfu/g and one unit with 160 cfu/g (this also triggered an iRASFF notification).

74. In relation to the compliant samples, SSI further clarified that in 2018 it was detected four positive samples with sampling units presenting a counting of *L. monocytogenes* above 10 cfu/g but less than 100 cfu/g (results ranging between 40 to 59 cfu/g). In 2019, it was detected one positive sample with a sampling unit with 30 cfu/g. These tests results were obtained in products manufactured in two establishments.

75. SSI informed the team that in these cases it contacts the respective VI service (the RVI or the DVI) to seek information on the FBO and product implicated, to ascertain if those products had been placed on the market using the criteria of less that 100 cfu/g for products placed on the market during the shelf life. This procedure was followed in the cases mentioned above.

76. Both competent authorities confirmed to use only laboratories that are part of the network of official laboratories accredited to ISO/IEC 17025:2017 and these laboratories use the EU reference methods.

Conclusions on official controls of fishery products

77. The official control of fishery products is carried out in accordance with the competent authority planned arrangements and in principle in line with the EU requirements.

78. However, the increased detection of non-compliant test results, did not impact on the overall organisation and implementation of the controls.

5.5 ACTION FOLLOWING THE iRASFFS NOTIFICATIONS

Legal requirements

Articles 50(5) and 52 of Section 1 Chapter IV to Regulation (EC) No 178/2002.

Regulation (EU) 2019/1715.

Findings

79. The national contact point in Poland for the RASFF network is the Chief Sanitary Inspector (from SSI). The national contact point forwards to the CVO, the *subsection of the national contact point*, all information related to the matters subordinated to the Ministry of Agriculture and Rural Development. The operation of the Polish system to handle iRASFF notifications is described in the CVO instruction No GIWbż-500-1/12 of 19 January 2012 (Scope and operation of the National Rapid Alert System for Food and Feed). That instruction follows largely the principles set in Regulation (EC) No 178/2002 and Commission Implementing Regulation (EU) 2019/1715.

80. With regard to the specific iRASSF notifications linked with the scope of the audit, namely the ones related to the multi country outbreaks of *L. monocytogenes* in Polish smoked fishery products, audit team noted that the different levels of the VI took the necessary actions to investigate the source of those notifications. Those actions encompassed several *ad hoc* visits which were extended over a long period of time due to multiple additional requests made by the other involved EU member states and also the series of different iRASFF notifications linked with the establishment and sometimes with the same product. These follow-ups can also present additional complexity when some of the products are frozen after being produced (sliced vacuum-packed products in final consumer packaging), have a shelf life while frozen of up to 18 months, and an additional shelf life of up to 45 days after being defrosted to be put on sale in the retail sector of another EU Member State.

81. The audit team noted that for each individual establishment involved in the iRASFF notifications, the competent authority increased its awareness of the deficiencies that could justify the contamination of the products with *L. monocytogenes* but it took time

for the competent authority to progress in terms of identification and correction of deficiencies. The initial iRASFF notifications dated from 2017 and the training to official staff was provided in 2019 (see paragraph 12) which is coincident with increased detection of non-compliant results during the official sampling (see paragraph 69). Also at the beginning of 2019 the guidance document indicated in paragraph 35 was updated (in particular its annex 5). However, as indicated in paragraphs 61 to 63 official staff is not always able to correctly assess shelf life studies.

82. The inability of Poland to carry out whole genome sequencing also hindered the ability of the competent authority to identify the source of the contamination of the products. In this regard, the competent authority stated that from December 2020 would be able to carry out whole genome sequencing in official samples and the same would be available to FBOs for their own-check testing.

83. Despite of all the progress done in the control of the concerned establishments, the audit team did not find evidence that this progress was adequately captured and disseminated within the relevant levels of the VI. This would enhance the ability of official control staff to identify similar issues in establishments, other than the ones implicated in the iRASSF notifications, in advance, and if possible prevent the occurrence of the same type of outbreaks.

Conclusions on measures in case of non-compliance and follow up of iRASFF notifications

84. The competent authority has in place adequate arrangements to deal with iRASFF notifications.

85. The investigations carried out during 2018/2019 with regard to the establishments involved in iRASFF notifications and multi country outbreaks, contributed to the overall improvement of the official controls of specific establishments.

86. At national level, the authority provided training on official sampling and improved the guidance documents, but the audit team did not find evidence that the improvements observed in the official controls carried out in particular establishments would be disseminated throughout the relevant levels of VI across Poland.

6 OVERALL CONCLUSIONS

The official control system in place for smoked fishery products cover the production chain, it is implemented as planned and in accordance with the applicable procedures. It provides a largely satisfactory basis for the competent authority to verify compliance of several European Union food hygiene requirements.

Nonetheless, the audit also identified gaps/shortcomings in relation to the ability of the controls to detect relevant deficiencies, most notably the storage of frozen products

(prolongation of the stiffening) and the assessment of the shelf life studies (for which existing guidance was not taken into account). These factors impact on the overall effectiveness of controls in this area in terms of its ability to verify compliance and to ensure the implementation of appropriate corrective measures which, in turn, would also contribute to prevention of future incidents.

The competent authority investigated the iRASFF notifications on Listeria monocytogenes in smoked fishery products, including the ones linked with the multi-country outbreaks. This work contributed to certain improvements of the control system, in particular, staff training, official sampling and testing for the microbiological criteria. Further improvements can be achieved with whole genome sequencing expected to start at the end of this year. However, in the case of the non-compliances detected in the concerned establishments, the corrective action was limited to those FBOs involved and there is no evidence that the acquired knowledge was used to improve the overall control system.

7 CLOSING MEETING

A closing meeting was held on 6 November 2020 with representatives of the competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. During this meeting, the competent authority acknowledged the findings and preliminary conclusions presented by the audit team and provided a commitment to look into the issues identified.

8 RECOMMENDATIONS

No.	Recommendation
1.	The competent authority should strengthen the implementation of the arrangements in place to ensure the effectiveness of official controls covering the production chain of fishery products. Recommendation based on conclusions No 21 and 86. Associated findings No 16, 17, 81 and 83.
2.	The competent authority should ensure that procedures for approval of establishments, in particular in relation to the intermediate deadlines in the case of conditional approval, comply with the requirements of Article 148(4) of Regulation (EU) 2017/625. Recommendation based on conclusion No 30. Associated finding No 28.
3.	The competent authority should ensure that, while performing controls to ascertain compliance with the EU rules, as required by Article 10(1)(c) and 138 of Regulation (EU) 2017/625, official control staff verify adequately the requirements of point 2 of Chapter VII of Section VIII of Annex III Regulation (EC) No 853/2004. Recommendation based on conclusion No 64. Associated finding No 59.
4.	The competent authority should ensure that, while performing controls to ascertain compliance with the EU rules, as required by Article 10(1)(c) and 138 of Regulation (EU) 2017/625, official control staff verify adequately the requirements of Article 3(2) and Annex II to Regulation (EC) No 2073/2005. Recommendation based on conclusions No 64 and 65. Associated findings Nos 60 to 63.
5.	The competent authority should ensure that, while performing controls to ascertain compliance with the EU rules, as required by Article 10(1)(c) and 138 of Regulation (EU) 2017/625, official control staff verify adequately the hygiene and structural requirements of Annex II to Regulation (EC) No 852/2004. Recommendation based on conclusions No 65. Associated finding No 52.

No.	Recommendation
6.	As required in Article 9(e) of Regulation (EU) 2017/625, the competent authority should ensure that it performs official controls on all operators taking into account information that might indicate non-compliance with the applicable and relevant EU rules. Recommendation based on conclusions Nos 65, 78 and 86. Associated findings Nos 60 to 63, 69, 81 and 83.

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2020-6919

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 2065/2003	OJ L 309, 26/11/2003, p. 1-8	Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 1334/2008	OJ L 354, 31.12.2008, p. 34-50	Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC
Reg. 231/2012	OJ L 83, 22.3.2012, p. 1-295	Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance.
Reg. 2019/627	OJ L 131, 17.5.2019, p. 51–100	Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls
Reg. 2019/1715	OJ L 261, 14.10.2019, p. 37–96	Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components

ANNEX II

RELEVANT GUIDANCE DOCUMENTS

Title	Publication
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	OJ No C278, 30.07.206, p.1
Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin	https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_legis_guidance_reg-2004-853_en.pdf
Guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf
Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs	https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_legis_guidance_reg-2004-852_en.pdf
Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*	https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidelines_on_sampling.pdf