



HEAD OF LEGAL AND ASSURANCE SERVICES

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Subject: Your complaint submitted on 18 November 2019

Dear Mr Noormägi,

We thank you for having contacted the European Food Safety Authority (EFSA).

In the letter enclosed to your e-mail of 18 November 2019, you raised concerns about the European Centre for Disease Prevention and Control (ECDC) and EFSA's Joint Technical Report concerning "Multi-country outbreak of *Listeria monocytogenes* clonal complex 8 infections linked to consumption of cold-smoked fish products"¹ approved on 3 June 2019 (hereinafter referred to as 'Joint ROA Technical Report') and Commission Regulation (EC) No 2073/2005 of on microbiological criteria for foodstuffs². You highlight in your letter that you represent a legal person who is directly affected by EFSA's omission and the Union legislation relevant to EFSA, namely the Estonian Association on Fisheries.

In order to reply to the questions you listed in your letter to EFSA, we would like, first to clarify the mission of EFSA, second the purpose and the content of the ECDC and EFSA Joint Technical Report at stake and third to reply to your questions.

1. EFSA's remit and mission

Please note that EFSA has a special status that was conferred upon it by Regulation (EC) No 178/2002³ (hereinafter referred to as 'EFSA's Founding Regulation') as risk assessor in charge of preparing and delivering scientific assistance and advice at European Union (EU) level.

Indeed, the tasks of risk assessment and risk management concerning food safety in the EU are separated between different institutions. Pursuant to Article 22 of EFSA's Founding Regulation, EFSA, as a risk assessor, is responsible for delivering independent, objective and transparent scientific advice

¹ ECDC (European Centre for Disease Prevention and Control) and EFSA (European Food Safety Authority), 2019. Multi-country outbreak of *Listeria monocytogenes* clonal complex 8 infections linked to consumption of cold-smoked fish products. EFSA supporting publication 2019:EN-1665. 20 pp. doi:10.2903/sp.efsa.2019.EN-1665, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1665>.

² Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, OJ L 338, 22.12.2005, p. 1–26, as last amended.

³ 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, OJ L 031, 1.2.2002, p.1, as last amended.

to the risk managers, which are the European Commission, Member State authorities and the European Parliament. Based on EFSA's scientific opinions, risk managers are the one managing the risks related to food and feed safety, animal health and welfare and plant health, by developing policies, authorising products and making Union laws. Besides some scientific work carried out on its own initiative in the area of emerging issues and new hazards, EFSA's work is therefore undertaken in response to requests for scientific advice from the risk managers in the areas falling within its mission.

In addition, EFSA has been mandate by the European Commission in accordance with Directive 2003/99/EC⁴ to directly collect and publish information on the monitoring of zoonoses, zoonotic agents and food-borne outbreaks.

The European Commission has also mandated EFSA, back in July 2013, in accordance with Article 31 of EFSA's Founding Regulation (EC) No 178/2002, to provide scientific assistance on the investigation of multinational foodborne outbreaks and contribute to the production of Rapid Outbreak Assessments (ROA) Technical Reports in collaboration with the ECDC (Mandate number M-2013-0119⁵).

In multinational foodborne outbreaks investigations, the European Commission and Member States are responsible for risk management activities (investigations, sampling, analyses) aimed at the confirmation of suspected food sources and their tracing back and forward, the management and use of the Rapid Alert System for Food and Feed (RASFF) and the adoption of possible trade restrictions.

ECDC and EFSA collaborate in the area of foodborne outbreak investigations but have different tasks and responsibilities es defined in their respective founding legislations.

The mission of ECDC, according to Article 3 of its Founding Regulation (EC), is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. ECDC therefore reports on human cases.

2. The ECDC and EFSA Joint Rapid Outbreak Assessment Technical Report concerning multi-country outbreak of *Listeria monocytogenes* clonal complex 8 infections linked to consumption of cold-smoked fish products

In the production of the Joint ROA Technical Report at stake, ECDC is responsible for the collection and analysis of all the information related to human cases, including information on food consumption obtained during epidemiological investigations, *ad hoc* surveys or case-control studies. ECDC is responsible for the case definition of the outbreak under investigation and for summarising the epidemiological investigations performed by Member States and shared through the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD).

EFSA is requested to contribute to the Joint ROA Technical Report by providing information from the monitoring of zoonoses, zoonotic agents and foodborne outbreaks, and by providing in-depth analysis of the food data including the robustness of the link to the suspected food source based on epidemiological and analytical data. Upon specific request from European Commission, EFSA is regularly asked to conduct tracing-back and forward analyses of the incriminated foods, animals or feed, based on the official information shared by Member States in the Rapid Alert System for Food and Feed (iRASFF). The specific tasks of EFSA for contributing to the ROA are specified in the EC Mandate of July 2013 which is publicly available on EFSA's website (Mandate number M-2013-0119).

The threat assessment included in the document is prepared jointly by both ECDC and EFSA and it should be considered the official conclusion of both agencies based on the results of the investigations performed at Member States level and available at the time of publication of the document.

⁴ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC, OJ L 325, 12.12.2003, p. 31-40, as last amended.

⁵ Available at : <file:///C:/Users/pintaci/Downloads/Chrono%20in%2078330%20-%20MRC%2009%20July%202013.pdf>.

3. Reply to your questions

Considering the remits of both ECDC and EFSA which are limited to risk assessment, and as a result from the above, you may understand that EFSA is not the competent authority to address all your concerns.

With regard to your **questions "(a)" to "(d)"**, they concern issues relating to the interpretation of Union legislation, namely Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. As a decentralised agency of the European Union, EFSA is not in charge of explaining and interpreting Union legislation.

Please also be informed that the EU institution in charge of ensuring that Union legislation is complied with is the European Commission. Therefore, should you wish to contact also the European Commission, you may do so by filling in the form available at this link or by calling the number +32 2 299 11 1.

Regarding **question "(e)"** who reads as follows "has EFSA stated or determined with a binding effect that the products of the Estonian company mentioned in the EFSA report have caused several deaths?": we would like to clarify the work carried out by EFSA and its legal effects.

We would like to highlight the sections of Joint ROA Technical Report a stake where you can find the specific information on which EFSA was able to conclude with the information available. Please note that on page 14, first paragraph of the chapter "ECDC and EFSA threat assessment for the EU/EEA" ECDC and EFSA stated that: "Most cases were over 65 years of age, and at least **five died due to, or with, the disease.**" On the same page, in the third paragraph of the Technical Report, it is stated that "in Denmark, where half of the outbreak cases (and the most recent ones) were reported and a thorough investigation was performed, most (7/9) patients were found to have consumed cold-smoked fish products during the incubation period. However, **there was no specific information on the brands and batches of these products at the time of publication of this report to verify direct epidemiological link to exposure.**"

Collection of detailed information of exposures and human cases are on the remit of ECDC. EFSA does not have access to this type of information. Therefore, for further clarification the information collected on the lethal cases, you should contact ECDC. You can submit your enquiries to by e-mail to info@ecdc.europa.eu. Or by phone, calling the following number: +46 (0)8 586 010 00 .

ECDC and EFSA concluded that (see page 15, second paragraph of the ROA Technical Report): "**Traceability information of the contaminated batches pointed to an Estonian processing plant run by Company A as the single common manufacturer of all fish products** that were produced with raw materials originating from suppliers in Norway and Finland. **Environmental investigations and food testing** at the Estonian processing plant run by Company A **showed the presence of *L. monocytogenes* that matched the outbreak strain in two samples found at the processing line and in four batches of the final product** (two batches of cold-smoked trout, one batch of cold-smoked salmon, one batch of salted salmon products)."

It follows from the wording of the Joint ROA Technical Report at stake that although, EFSA and ECDC have not concluded that the Estonian processing Company A was responsible for the deaths and further investigations still need to be performed⁶, a link was found with the Estonian processing Company A since the traceability information of the contaminated batches pointed to the latter company

Finally, with regard to your question whether the Joint ROA Technical Report at stake has a binding effect, please allow me to clarify that as a decentralised agency of the EU with the special status described under point 1 above, EFSA's outputs⁷ are not vested with a hierarchical authority within the

⁶ See abstract at the beginning of the Joint ROA Technical Report.

⁷ Please see the definition of EFSA's outputs available on EFSA's website: <https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>.

EU law⁸ and do not possess the characteristics of legislative acts with binding legal effects and capable of affecting the interests of the Estonian Union of Fisheries. Therefore, they cannot produce, *per se*, direct effects on third parties⁹. In addition, the Joint ROA Technical Report has not the legal characteristic of an individual act adversely affecting a natural or legal person or of legal acts intended to produce legal effects *vis-à-vis* third parties which can be subject to an action for annulment before the General Court of the European Union, in accordance with Article 263 of the Treaty on the Functioning of the European Union (TFEU).

4. Remedies

Please allow me to highlight that if you believe that EFSA committed maladministration in dealing with the matter addressed by this communication, you have the right to make a complaint about it to the European Ombudsman pursuant to Article 228 of the TFUE and within two years of receiving this position. The Ombudsman's online complaint form and further indications on how to file a complaint are available at www.ombudsman.europa.eu.

I trust this addresses your e-mail.

Yours sincerely,


Dirk Detken

CC: V. Rizzi, E. Liebana Criado (EFSA)

⁸ Article 288(5) of the Treaty on the Functioning of the European Union (TFEU).

⁹ T-123/03, Order of the Court of First Instance of 2 June 2004, *Pfizer Ltd v Commission of the European Communities*, ECLI:EU:T:2004:167, paragraphs 21-23, 26. T-311/06, Order of the Court of First Instance of 17 June 2008, *FMC Chemical SPRL and Arysta Lifesciences SAS v European Food Safety Authority (EFSA)*. ECLI:EU:T:2008:205, paragraphs 43-50. T-397/06, Order of the Court of First Instance of 17 June 2008, *Dow AgroSciences Ltd v European Food Safety Authority (EFSA)*. ECLI:EU:T:2008:208, paragraph 50-51.