



JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Prolonged multi-country outbreak of *Listeria* monocytogenes ST173 linked to consumption of fish products

19 June 2024

Abstract

Between 2012 and 2024, a prolonged outbreak of 73 cases of *L. monocytogenes* ST173 infections ('My2' - cluster) has been ongoing in Belgium (5), Czechia (1), Germany (39), Finland (2), Italy (1), the Netherlands (20), and the United Kingdom (UK) (5). Fourteen deaths have been recorded as associated with this outbreak. Males aged over 60 years represent the most affected population group. Most patients with available information from case interviews report consuming various fish products before illness. Among 73 cases, an ongoing 'My2' sub-cluster 1 was identified with 38 cases reported in six EU countries and the UK.

The 'My2' sub-cluster 1 includes 83 non-human isolates, of which 48 are food isolates and six are environmental isolates with traceability data corresponding to 37 fish products (different typologies) and 12 fish manufacturers (located in six EU countries and one third country). The epidemiological and traceability information did not allow identification of a single common point or food business operator in the traceability of all products. Five countries reported the implementation of control measures.

The whole genome analysis (WGS) analysis, the tracing evidence, and the detection in fish products between 2017 and 2024 suggest that the strain has been geographically spread in Europe for several years, most likely originated from a past single source high up in the production chain, and has been established in different fish processing plants. Overall, the evidence supports the hypothesis of fish products as the vehicle of infections.

Given the detection of the outbreak strain in multiple types of fish products and its wide circulation in the EU/EEA fish production chain, new cases are likely to be reported. Corrective measures should be implemented in the plants where the contamination is detected, and further investigations should be carried out to identify the point of entry and prevent possible re-contamination.

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Event background

On 9 March 2020, **Germany** reported 15 different listeriosis clusters taking place from 2010 to 2020 and delineated by whole genome sequencing (WGS) in the Epidemic Intelligence Information System (EPIS, UI-632), now called the European surveillance portal for infectious diseases (EpiPulse, 2020-FWD-00012) and hosted by the European Centre for Disease Prevention and Control (ECDC). Based on investigation in Germany, the clusters were epidemiologically and/or microbiologically linked (by WGS) to salmon products [1].

On 26 January 2022, **the Netherlands** reported in EpiPulse (2022-FWD-00010) a cluster of five cases identified since December 2021. The cases were part of a cluster of eight cases reported since October 2017. The isolates of human cases were microbiologically linked (by WGS) to salmon products and the five most recent cases reported consumption of fish products prior to illness. The Dutch cluster belonged to a larger, salmon-linked cluster reported earlier by Germany in 2020, called 'My2' according to the nomenclature used by the Robert Koch Institute.

Since 2020, and as of 20 March 2024, several countries have continued reporting listeriosis cases in the 'My2'-cluster, suggesting possible continuous and active source(s) of contaminated fish products. As the 'My2' cluster involves several countries, is associated with a large number of severe and fatal cases, and has been active for several years indicating a prolonged risk for *L. monocytogenes* infections in the EU, ECDC and EFSA decided to produce a Joint Rapid Outbreak Assessment.

Outbreak strain characterisation

The 'My2' outbreak strain has the following characteristics:

- serogroup IIa;
- clonal complex (CC) 19, sequence type (ST) 173, cluster type (CT) 3242 (Ridom, SeqSphere) [2];
- L2-SL378-ST2894-CT3909 (Institut Pasteur scheme) [3];
- negative for pathogenicity islands LIPI3 and LIPI4.

Representative German *L. monocytogenes* strains of the 'My2' cluster are available at the European Nucleotide Archive (ENA) [4] with codes ERR3971807 and ERR7057716.

European outbreak case definition

The European outbreak case definition is the following:

A confirmed outbreak case in the genetic 'My2' cluster:

 A laboratory-confirmed Listeria monocytogenes case with disease onset on or after 1 January 2017 (date of sampling or date of receipt by the laboratory if date of onset is not available)

AND

- Fulfilling at least one of the following laboratory criteria:
 - clustering with the German reference strains within seven allelic differences (ADs) by cgMLST in a centralised single-linkage WGS analysis; OR
 - clustering with the German reference strains within seven ADs by cgMLST in a national sequencing pipeline; OR
 - clustering with the German reference strains within 10 SNPs (single nucleotide polymorphism) in a pipeline in the United Kingdom Health Security Agency (UKHSA) [5].

A historical confirmed outbreak case in the genetic 'My2' cluster:

A laboratory-confirmed Listeria monocytogenes case with disease onset before 1 January 2017 (date of sampling
or date of receipt by the laboratory if date of onset is not available)

AND

- Fulfilling at least one of the following laboratory criteria:
 - clustering with the German reference strains within seven ADs (cgMLST) in a centralised single-linkage WGS analysis; OR
 - clustering with the German reference strains within seven ADs (cgMLST) in a national pipeline; OR
 - clustering with the German reference strains within 10 SNPs in a pipeline in the UKHSA.

An <u>ongoing</u> multi-country genetic <u>sub-cluster 1</u> within 'My2' cluster was defined using the following criteria:

• Listeria monocytogenes ST173 isolates within four ADs to the German reference strain ERR3971807 in a centralised single-linkage clustering WGS analysis

AND

Cases also reported from 2022 onwards

AND

• Cases reported in more than one country.

The stricter laboratory criterion of four ADs was based on a centralised WGS analysis using seven ADs as a cut-off and a review of available metadata for these isolates [6].

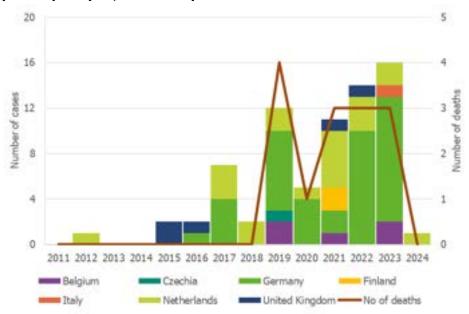
Epidemiological and microbiological investigations of human cases

As of 29 May 2024, 73 cases of *L. monocytogenes* ST173 infections have been reported since 2012 in Belgium (5), Czechia (1), Germany (39), Finland (2), Italy (1), the Netherlands (20), and the United Kingdom (UK) (5) (Table 1). Among 73 cases, 14 deaths have been reported either due to or with *Listeria* infection, giving a case fatality of 19.2%. The first sporadic case was reported in the Netherlands in 2012, followed by two cases reported in the UK in 2015 (Figure 1). Between 2019 and 2023, the annual number of cases has been \geq 5, involving six EU countries and the UK (Figure 1). The sex distribution is significantly dissimilar, with more males than females reported (p<0.05, chi-square-test) and a male-to-female ratio of 1.8:1. The age ranges between 24 and 91 years, with most infections in patients aged 60 years or more (Table 1). The most recent case was reported in the Netherlands in January 2024.

Table 1. Demographic overview of confirmed cases of *L. monocytogenes* ST173 in 'My2' cluster (n=73) by country, as of 29 May 2024

Country	No of cases	No of deaths	Male	Female	Age range (median)/years	Comments
Belgium	5	0	3	2	53-80 (68)	Two cases in Flanders, two in Brussels, one in Wallonia.
Czechia	1	0	1	0	> 60	
Germany	39	10	26	13	24-91 (78)	One pregnancy-associated case.
Finland	2	2	0	2	> 80	
Italy	1	0	1	0	> 75	Strain isolated from pleural fluid.
Netherlands	20	2	16	4	54-87 (72)	Five years between the first and the second case (2012-2017).
United Kingdom	5	0	0	5	21 - 70 (35)	
Total	73	14	47	26		

Figure 1. Confirmed cases of *L. monocytogenes* ST173 and number of deaths in 'My2' cluster (n=73) by country and year, as of 29 May 2024



The Netherlands opens an event in EpiPulse on 26 January 2022

Germany opens an event in EpiPulse on 9 March 2020

2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024

My2 - other than sub-cluster 1 cases* (n-35)

My2-sub-cluster 1 - centralised WGS analysis (n=38)

Figure 2. Confirmed cases of human L. monocytogenes ST173 in 'My2' cluster by year, as of 29 May 2024

Information from patient interviews

Belgium: One case interview was available from 2021. The case reported no consumption of fish products prior to illness.

Germany: A total of nine patients were interviewed regarding their eating habits.

- Seven of nine reported that they ate fish;
- Five of seven reported that they are smoked fish. Of these, the following types of fish were reported (multiple answers were possible):
 - 2x smoked salmon,
 - 2x halibut
 - 2x mackerel
 - 1x trout
 - 1x eel
- In addition, six of seven patients reported that they had eaten soused herring (matjes).

Italy: The case suffered from liver cirrhosis and was hospitalised with gastroenteritis. The case reported consuming smoked and fresh salmon; furthermore, he also consumed tartare, *würstel*, cured meat (raw ham, cooked ham, salami, bresaola), strawberries, homemade rice salad, packaged mozzarella cheese and pesto.

The Netherlands: Food consumption data are available for 15 of 20 cases. Of those, 13/15 reported fish consumption. All 13 cases reported at least one type of fish that most likely was eaten without heating before consumption. The consumed fish types varied and could not always be well specified due to the long period of 4 weeks covered. Seven cases reported consumption of smoked salmon.

The United Kingdom: Food exposure data were available for four of the five cases. Three cases reported consumption of fish products, with 2/3 of these cases indicating consumption of smoked mackerel, one of which also noted consumption of smoked salmon.

^{*} According to the European outbreak case definition.

Microbiological and environmental investigations of food and control measures

In the frame of this assessment, EFSA has contacted the country officers of the EFSA One Health WGS System that had shared the genomic information from the non-human isolates matching the *L. monocytogenes* ST173 ('My2' sub-cluster 1). EFSA has asked the country officers to liaise with the RASFF contact points of their own country to retrieve the traceability data related to those matching isolates. Subsequently, the RASFF contact points of the involved countries have shared the traceability data, if available, under the RASFF Notifications 2024.2352 (16 follow-up, *fup*, as of 28 May 2024), 2024.3104 (6 *fup* as of 3 June 2024), and 2023.7767 (2 *fup*, as of 16 November 2023).

Below is the list of isolates per fish product and per country for which some traceability data were retrieved. A detailed description of their traceability is provided in Annex 1.

Italy

- Two RTE cold-smoked salmon products sampled in 2023 (Product A and Product B) and manufactured by the Polish Manufacturer A with fish farmed in Iceland and Norway, respectively, one isolate each, for a total of two isolates. RASFF 2024.2352.
- One cream cod sampled in 2022 (Product C) and manufactured by the Italian Manufacturer B (five isolates) and one environmental sample in 2022 from the same manufacturer (one isolate). RASFF 2024.2352, 2024.3104.

Belgium

• Two salmon products sampled in 2023 (Product G and Product H) and manufactured by the Belgian Manufacturer C with fish farmed in Norway. Five isolates. RASFF 2024.2352, RASFF 2023.7767.

The Netherlands

- Fourteen salmon products sampled between 2017 and 2021 (Product P to Product AC) and manufactured by the Dutch Manufacturer G; 14 isolates, RASFF 2024.2352. There were five isolates from environmental samples (non-food contact surface and food contact surface swabs) sampled in 2019 and in 2022 from the same manufacturer.
- Two smoked salmon products (Product AD and Product AE) sampled in 2021 and manufactured by the Dutch Manufacturer H; one isolate each, for a total of two isolates.
- One mackerel product (Product AF) sampled in 2020 and manufactured by the Dutch Manufacturer I; one isolate.
- Three fish products (smoked salmon, herrings, and mackerel) (Product AG, Product AH, Product AI) sampled between 2021 and 2022 and with information on the manufacturers not available. One isolate each, for a total of three isolates.

Estonia

• Two fish products (herrings and salmon) (Product I and Product J) sampled in 2020 and manufactured by the Estonian Manufacturer E and the Dutch Manufacturer F, respectively. Six isolates.

Luxembourg

• Five smoked salmon products (Product K, Product L, Product M, Product N, Product O) sampled between 2022 and 2024 and with information on the manufacturers not available. One isolate each, for a total of five isolates, RASFF 2024.2352.

Austria

 One fish meat product (Product AJ, not specified) sampled in 2022 and with information on the manufacturers not available. One isolate.

Germany

- One fish salad (Product AK) sampled in 2021 and manufactured by the German Producer C. One isolate; RASFF 2024.2352.
- Two cod products (Product AL and Product AM) sampled in 2023 and manufactured by the German Producer E and by the Russian Producer K, respectively. One isolate each, for a total of two isolates; RASFF2024.2352.
- One smoked salmon (Product AN) sampled in 2017 and manufactured by the Dutch Producer F, one isolate.

The details of the overall isolates collected from each fish product and fish product-related environments are available in Table 2 in Annex 1.

European whole genome sequencing analysis of human and non-human isolates

WGS data collection and cross-sectoral analysis

In a cluster analysis of *L. monocytogenes* ST173 isolates' sequences related to this event, ECDC has identified a total of 53 human isolates matching the European outbreak case definition for the genetic 'My2' cluster (Figure 3). The 53 isolates were submitted by Belgium (5 isolates), Czechia (1), Germany (39), Finland (2), Italy (1), the Netherlands (4), and the UK (1). The cluster code in_EpiPulse is '2017-10.LIST.54..AscI.0031.ApaI.0612'. All human isolates in the 'My2' cluster are within five AD in a single-linkage clustering analysis.

Of the 53 human isolates within the 'My2' cluster, 38 belonged to the genetic sub-cluster 1 (within four ADs in a single-linkage clustering analysis) and were identified in Belgium (5), Czechia (1), Germany (25), Finland (1), Italy (1), the Netherlands (4) and the UK (1) from 2012 to 2023 (Figures 2 and 4).

Regarding food isolates of *L. monocytogenes* ST173 ('My2' cluster), in March 2024 EFSA launched a call for data inviting all EU and EEA countries to submit to the EFSA One Health WGS System the genomic and related epidemiological information of fish products isolates collected between 2022 and 2024. By 7 May 2024, 13 countries replied, of which eight countries (Austria, Belgium, Estonia, Germany, Italy, Luxembourg, the Netherlands, and Poland) successfully shared genomic information. Five countries (Denmark, Finland, France, Portugal, and Romania (supported by EURL-*Listeria*)) replied to not have *L. monocytogenes* ST173 sequences from food isolates.

Countries with genomic data matching the outbreak strain, and included in the centralised analysis, were consulted in May 2024 for data verification and validation.

For cross-sectoral analysis, the cgMLST single-linkage analysis was performed by ECDC and by EFSA as previously described [7]. Briefly, genome profiles were calculated from assembled genomes using chewBBACA version 2.8.5 (https://github.com/B-UMMI/chewBBACA) using the schema as described by Moura et al 2016 for *L. monocytogenes* [3] made available by chewie Nomenclature Server at https://chewbbaca.online/species/6. All food isolates included in the analysis have < 1% missing loci (< 17 missing loci over a total of 1748 loci).

ECDC queried the EFSA One Health WGS System on 27 May 2024 using 53 *L. monocytogenes* ST173 as reference genomes isolated from human cases and seven ADs as threshold.

Results of cross-sectoral WGS analysis

As a result of the query by ECDC with 53 human sequences, 102 submitted profiles of non-human isolates (63 fish meat and products thereof, one unspecified non-human isolate, and 38 fish-related processing environment) clustered within seven ADs ('My2' cluster) in a single-linkage cluster analysis with the human isolates, giving a total of 155 (53 human and 102 non-human) *L. monocytogenes* ST173 isolates in the joint isolate dataset (Figure 3).

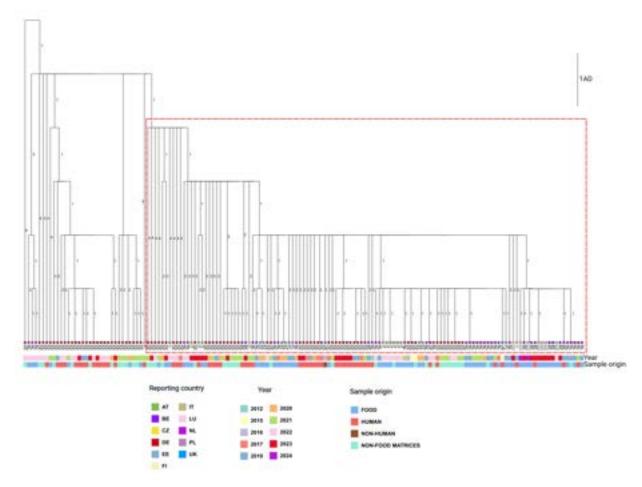
The 102 non-human matching isolates were collected between 2015 and 2024 from Austria (1 isolate), Belgium (5), Estonia (6), Germany (43), Italy (8), Luxembourg (7), the Netherlands (28), and Poland (3). One sequence from the UK was imported from ENA.

The cross-sectoral WGS analysis revealed one ongoing 'My2' multi-country sub-cluster 1 at maximum four ADs with human cases reported in at least 2022-2023 and non-human isolates collected between 2017 and 2024. Thus, the focus of the trace back analysis and the risk assessment is on the ongoing 'My2' sub-cluster 1.

The cross-sectoral centralised WGS analysis with available sequences for 'My2' sub-cluster 1 consisted of 121 *L. monocytogenes* ST173 isolates, of which 38 were human isolates and 83 non-human isolates (57 food isolates and 26 environmental isolates). Details of the non-human isolates belonging to 'My2' sub-cluster 1 are available in the Table 2 in Annex 1.

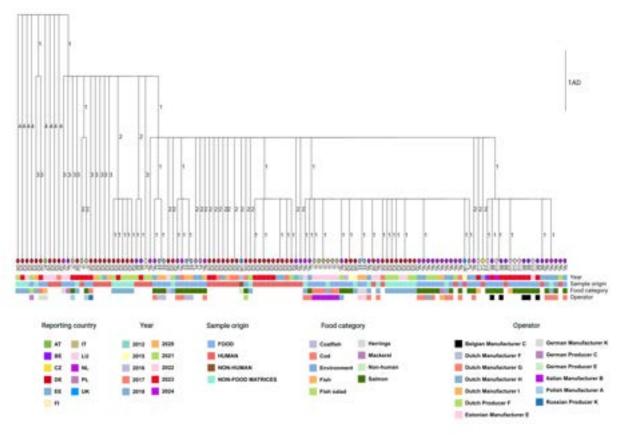
Both the single-linkage cluster tree and the minimum spanning trees (MSTs) of the 'My2' sub-cluster 1 show the genetic closeness between human and non-human isolates as well as across countries (Figures 4 and 5).

Figure 3. Single-linkage tree of *L. monocytogenes* ST173 isolates in the 'My2' cluster (n=155), including 53 human, 63 food, 38 processing environment, and one unspecified non-human isolate from 10 EU countries and the UK, as of 27 May 2024 ('My2' sub-cluster 1 highlighted)



Source: https://microreact.org/project/rrUGkChqZxJMCBXrcXM2oX-prolonged-multi-country-outbreak-of-listeria-monocytogenes-st173-linked-to-consumption-of-fish-products-my2-cluster

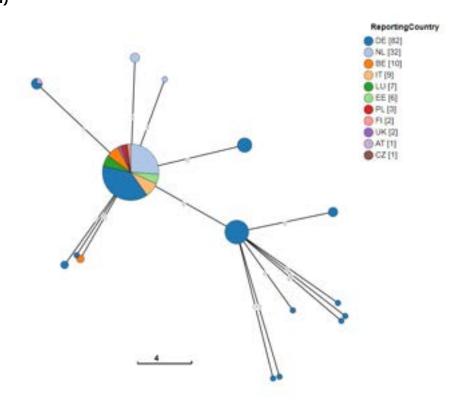
Figure 4. Single-linkage tree of *L. monocytogenes* ST173 isolates in the 'My2' sub-cluster 1 (n=121), including 38 human, 56 food, 26 processing environment, and one unspecified non-human isolate from 10 EU countries and the UK, as of 27 May 2024



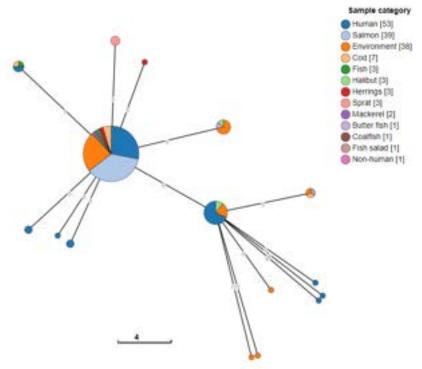
Source: https://microreact.org/project/p817jhwJXF9azVzdZhQhXL-prolonged-multi-country-outbreak-of-listeria-monocytogenes-st173-linked-to-consumption-of-fish-products-my2-sub-cluster-1

Figure 5. Minimum spanning tree of human and non-human *L. monocytogenes* ST173 isolates in the 'My2' sub-cluster 1 by a) reporting country and b) sample category, (n=121), isolates collapsed at 4 AD, as of 27 May 2024

a)







ECDC and EFSA risk assessment for the EU/EEA

A prolonged cross-border outbreak of *L. monocytogenes* ST173 has been revealed by WGS under the name 'My2' cluster according to the nomenclature used by the Robert Koch Institute. As of 29 May 2024, and since 2012, 73 cases have been reported in Belgium (5 cases), Czechia (1), Germany (39), Finland (2), Italy (1), the Netherlands (20), and the UK (5), showing a continuous threat of severe human infections ongoing for many years. Among 73 cases, 14 deaths (19.2%) have been recorded due to or with *L. monocytogenes* infection, highlighting the severity of the disease. In 2023, 16 cases were reported, the highest annual number of cases so far. These were reported by Belgium (2), Germany (11), Italy (1), and the Netherlands (2).

There is a significant difference by sex, with more males than females reported (p<0.05), resulting in a male-to-female ratio of 1.8:1. The age ranges between 24 and 91 years, with most infections in cases aged 60 years or older, suggesting that males over 60 years represent the most affected population group in this event.

Based on available information from case interviews in Belgium, Germany, Italy, and the Netherlands, 25 of 30 (83.3%) cases confirmed consumption of various types of fish products prior to illness. It is known that due to the relatively long incubation period of severe listeriosis, which is usually around two weeks but could be up to 67 days for pregnancy-associated infection [8], recall biases may influence the patient's consumption history.

Among 73 cases, a 'My2' sub-cluster 1 was identified as ongoing with 38 cases reported in six EU countries and the UK between 2012 and 2023. The focus on the traceback analysis and the risk assessment was on the 'My2' sub-cluster 1.

The call for genomic data allowed the identification of overall 102 non-human isolates within the 'My2' cluster of which 83 are part of the ongoing multi-country 'My2' sub-cluster 1. Therefore, out of 83 non-human isolates (57 from fish products isolates and 26 from fish-related environment isolates) for which the national food traceability investigations were conducted retrospectively, 48 fish products' isolates and six environmental isolates were complemented with minimum traceability data. For the remaining isolates tracing information was not available (i.e. nine fish product isolates and 20 environmental isolates).

The 48 fish products' isolates and the six environmental isolates with minimum traceability data corresponded to 37 fish products of different typologies and 12 fish manufacturers, located in six EU countries (Belgium, Estonia, Germany, Italy, the Netherlands, and Poland) and one third country (Russia), whose role as source of infections could not be verified. The 37 products tested positive for the outbreak strain in the period between 2017 and 2024. In 2023, contaminated fish products were collected in Belgium (producer located in Belgium), Germany (producer located in Germany), and Italy (producer located in Poland), countries where also human cases were reported in 2023.

Overall, the implementation of control and corrective measures was reported by five countries (Belgium, Estonia, Germany, Italy, and the Netherlands) that had identified the contaminated fish products and the involved manufacturers.

The microbiological evidence from the centralised WGS cluster analysis, the tracing evidence, and the detection of the outbreak strain from fish products between 2017 and 2024 suggest that the strain is geographically spread in Europe, most likely originated from a past single source high up in the fish production chain, has been established in different fish processing plants, and circulating since at least 2017 (the year of oldest food detection according to this genomic dataset). The first historical human case was reported already in 2012 (in the Netherlands), indicating an earlier circulation of the outbreak strain in the food chain. However, a single common point or food business operator in the traceability of all products could not be identified based on the information available.

Overall, the evidence supports the hypothesis of fish products as the vehicle of infections in this multi-country outbreak.

Given the detection of the outbreak strain in multiple types of fish products and its wide circulation in the EU/EEA fish production chain, new cases are likely to be reported.

Recommendations

- Countries are encouraged to share sequences of human L. monocytogenes isolates with ECDC as part of the EU/EEA-wide WGS-enhanced listeriosis surveillance in the ECDC One Health WGS system. ECDC can provide sequencing support for recently isolated human L. monocytogenes strains.
- Countries are invited to update the information about 'My2' cluster in the event 2020-FWD-00012 in EpiPulse should new cases continue to be reported.
- Countries are encouraged to investigate food exposure information, when feasible, if new cases are reported, and to collaborate with food safety authorities to identify contaminated food products.
- Countries are invited to share the sequence of the *L. monocytogenes* ST173 food isolates linked to the
 present cluster either microbiologically (serotype or ST) or epidemiologically (e.g. suspected food items
 reported by human cases), to share in RASFF the traceability information related to those sequences, and to
 submit genomic data of *L. monocytogenes* ST173 isolates from any kind of food, feed, animal and related
 environment to the EFSA One Health WGS System.

- Countries are invited to conduct their investigations to identify the point(s) of contamination and the origin of the contamination upstream into the fish production chain and to share the related outcome in RASFF.
- Corrective measures should be implemented in the plants where the contamination has been detected and
 further investigations should be carried out to identify and prevent the possible point of entry of the
 outbreak strain.

Source and date of request

ECDC sent a request to EFSA on 20 March 2024 to produce a Joint Rapid Outbreak Assessment. EFSA accepted the request on 21 March 2024.

Consulted experts and national contact points

ECDC experts (in alphabetical order): Saara Kotila, Cecilia Jernberg, Priyanka Nannapaneni, Johanna Takkinen

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Finland: Saara Salmenlinna (Finnish Institute for Health and Welfare);

Italy: Antonietta Gattuso, Alfonsina Fiore and Gaia Scavia (Istituto Superiore di Sanità); Sobha Pilati (Italian

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EFSA staff (in alphabetical order): Sofia Fusco, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, Frank Verdonck.

RASFF contact points: Austria, Belgium, Estonia, France, Germany, Italy, Latvia, Luxembourg, the Netherlands, Norway, Poland.

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Italy: Raffaello Lena, Valentina Cambiotti, Fabrizio Lazzara (Italian Ministry of Health); Francesco Pomilio, Marina Torresi, Alexandra Chiaverini, Gabriella Centorotola, Fabrizia Guidi (National Reference Laboratory for *Listeria monocytogenes*); Luca Bolzoni, Stefano Pongolini, Erika Scaltriti (Istituto Zooprofilattico Sperimentale della Lombardia ed Emilia Romagna B. Ubertini (IZSLER));

Luxembourg: Sylvie Neis and Jérémy Neves (Veterinary and Food Administration (ALVA);

Netherlands: Coen van der Weijden (Netherlands Food and Consumer Product Safety Authority (NVWA)), Joost Stassen (Wageningen Food Safety Research);

Norway: Asne Sangolt (Norwegian Food Safety Authority).

Country Officers of the EFSA One Health WGS system consulted: Austria, Belgium, Estonia, Germany, Italy, Luxembourg, the Netherlands, Poland.

National experts consulted by the Country Officer of:

Estonia: Jelena Sõgel (Food Department, Agriculture and Food Board);

Luxembourg: Catherine Ragimbeau (Laboratoire National de Santé (LNS)) and Manon Bourg (Veterinary and food administration (ALVA));

Netherlands: Ife Slegers-Fitz-James (Netherlands Food and Consumer Product Safety Authority (NVWA).

Disclaimer

This rapid outbreak assessment was written jointly by the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA).

ECDC issued this outbreak assessment document in accordance with Article 20 of Regulation (EU) 2022/2371 on serious cross-border threats to health, Articles 7(1) and 8a of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control. EFSA's contribution is based on a mandate from the European Commission requesting EFSA to provide scientific assistance from EFSA in the investigation of multinational food-borne outbreaks (Ares (2013) 2576387, Mandate M-2013-0119, 4 July 2013) in accordance with

Article 31 of 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.

The specific purpose of an ECDC-EFSA rapid outbreak assessment is to present an analysis of a cross-border food-borne threat to health and to provide science-based recommendations and options for response. The responsibility for the choice of which options to pursue and which actions to take at national level, following ECDC and EFSA's recommendations, lies with EU/EEA countries.

All data published in this rapid outbreak assessment are collected from EU and/or EEA countries concerned by the outbreak until the date this assessment was produced. Maps and figures published do not represent statements from ECDC or EFSA on the legal or border status of the countries and territories shown but constitute the information on which this rapid outbreak assessment is based.

Annex 1. Description of the traceability, food investigations, and control measures by country

Subsequent to the identification of the genomic cluster (per centralised WGS analysis) of *Listeria monocytogenes* ST173 (My2) and the call for genomic food data launched by EFSA in March 2024, the countries listed below collected and shared the traceability data related to the food isolates part of the genomic cluster (My2 sub-cluster 1).

This section summarises the results of the traceability investigations, the analytical results, and the implemented control measures on fish products as shared by the EU countries under the RASFF Notifications 2024.2352 (16 follow-up, *fup*, as of 28 May 2024), 2024.3104 (6 *fup* as of 3 June 2024), and 2023.7767 (2 *fup*, as of 16 November 2023).

Italy

The food safety authority in Italy informed in RASFF (2024.2352 and 2024.3104) that the sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from the following food products:

- cold-smoked salmon Product A Batch A
- cold-smoked salmon Product B Batch B
- cream cod Product C Batch C.

The chilled RTE cold-smoked Icelandic salmon Product A Batch A was sampled in official control on 23 October 2023 at wholesaler level (Italian Wholesaler A) and tested positive for the outbreak strain (one isolate). The product was marked with an expiry date of December 2023 and had been manufactured by the Polish Manufacturer A (*fup10*, 2024.2352) with salmon farmed in Iceland (Farm B) (*fup12*, 2024.2352). The salmon was then distributed as gutted (fresh) by the Norwegian Supplier C to the Polish Manufacturer A (*fup12*, *fup14*, 2024.2352). No other information on traceability was available from RASFF (*fup1*, 2024.2352).

The chilled sliced RTE Norwegian smoked salmon Product B Batch B was sampled in official control on 19 June 2023 and tested positive for the outbreak strain (one isolate). The sample was collected at retail level (Italian Retailer A). The product was marked with an expiry date of July 2023 and had been manufactured by the Polish Manufacturer A for the Italian Producer A. The salmon was farmed in Norway (Farm A) and then distributed as frozen by the Polish Producer H to the Polish Manufacturer A via the Norwegian Producer I (*fup12*, 2024.2352). Product B Batch B was withdrawn and disposed of as animal by product category 3 (*fup1*, 2024.2352).

The cream cod Product C Batch C was sampled in official control on 26 September 2022 and tested positive (>15,000 UFC/g) for the outbreak strain (five isolates) (*fup4*, 2024.3104). The sample was collected at retail level (Italian Retailer B). The product was marked with an expiry date in October 2022 and had been manufactured by the Italian Manufacturer B with rehydrated stockfish Product D Batch D produced and supplied by the Italian Wholesaler B.

The rehydrated stockfish Product D Batch D consisted of one batch (Batch N produced on 2 December 2021) of stockfish supplied by the Norwegian Supplier A and of two batches (Batch O and Batch P, both produced in 2021) of stockfish supplied by the Norwegian Supplier B (*fup1*, *fup5*, 2024.3104). The Italian Wholesaler B had imported the three stockfish batches from Norway.

In addition, *Listeria monocytogenes* had been isolated (400 CFU/g) from an own-check sample of a RTE sandwich with cream cod (Product E Batch E) collected by the Italian Retailer B on 22 September 2022. The product was marked with an expiry date in September 2022 and the Italian Retailer B had distributed it only in Italy, withdrawn it from the market and recalled from the consumers (2024.3104).

On 25 September 2022, the Italian Retailer B informed the Italian Manufacturer B about the detection of *Listeria monocytogenes* (4,320 CFU/g) in an own-check sample of cream cod from Product C Batch C marked with an expiry date in October 2022. The Italian Manufacturer B investigated and identified the issue in the pasteurisation step of the specific batch (Batch C) (no other batches concerned) on 13 September 2022, which was delivered only to the Italian Retailer B (*fup3*, 2024.3104).

On 7 October 2022, the food safety authority carried out an inspection at the Italian Manufacturer B and verified the pasteurisation procedures (time/temperature combinations, namely 75°C per 5 min) of the products manufactured between 13/08/2022 to 07/10/2022. In September 2022, the Italian Manufacturer B collected 12 swab samples and one of the samples tested positive (one isolate) for *L. monocytogenes* matching the outbreak strain (*fup1*, 2024.2352; *fup2*, 2024.3104). The plant performed the cleaning and the disinfection, and the official sampling performed on 10 October 2022 resulted in negative results.

Belgium

The food safety authority in Belgium informed in RASFF (2024.2352, 2023.7767) that the sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from the following food products:

- marinated salmon (gravad lax) Product G Batch G
- smoked salmon Product H Batch H.

The chilled marinated salmon (gravad lax) Product G Batch G was sampled in official control on 29 August and 8 September 2023 at manufacturer level (Belgian Manufacturer C) and tested positive for the outbreak strain (four isolates). The product was marked with an expiry date in September 2023 and had been manufactured by the Belgian Manufacturer C with salmon farmed in Norway supplied by the Norwegian Supplier C. The salmon had been filleted by the Dutch Manufacturer D before the delivery (salmon fillets Batch Q). The food safety authority informed that the marinated salmon (gravad lax) Product G Batch G was not placed into the market (*fup2*, 2024.2352).

The chilled smoked salmon Product H Batch H was sampled in official control on 2 August 2023 at retail level (Belgian Retailer C) and tested positive (<40 CFU/g) for the outbreak strain (one isolate). The product was marked with an expiry date in August 2023 and had been manufactured by the Belgian Manufacturer C with salmon from Norway supplied by the Norwegian Supplier C (filleted before the delivery by the Dutch Manufacturer D, salmon fillets Batch R) and with salmon (Batch S) supplied by the Dutch Manufacturer G (2023.7767).

The Netherlands

The food safety authority in the Netherlands informed that the 26 sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from 20 food products and five environmental swab samples. Fourteen salmon products were manufactured by the Dutch Manufacturer G, two smoked salmon products manufactured by the Dutch Manufacturer H, and one mackerel product manufactured by the Dutch Manufacturer I. The manufacturers were not available for three remaining products. The five environmental swab samples were collected at the Dutch Manufacturer G.

With regards to the 14 salmon products manufactured by the Dutch Manufacturer G there were two smoked Norwegian salmon chips Product P Batch V and Product Q Batch W sampled in official control on 25 September 2017 and 30 October 2017 (Dutch Retailer D) (two isolates). No other information on traceability was available.

There were 10 smoked salmon products (i.e. smoked salmon and smoked salmon cuts (e.g. cubes, scraps)) (Product R to Product AA) (details in table 2, Annex 1) sampled between March 2019 and December 2019 (ten isolates). In particular, Products S, T, U, V, W, X, Y, and Z were sampled in own check at the Dutch Manufacturer G and Products R and AA were sampled in official control at retail level. The fish used in these eight products (Products S, T, U, V, W, X, Y, and Z) was processed at different packing/slaughter stations and supplied to the Manufacturer G via different suppliers without further treatment (*fup15*, *fup16*, 2024.2352). There were two smoked salmon cuts (cubes and scraps) Product AB Batch AG and Product AC (batch not available) sampled on 18 May 2020 and on 12 March 2021 (two isolates). The smoked salmon scraps Product AB Batch AG was collected in own check in May 2020 at the Dutch Manufacturer G. The fish was processed at the packing/slaughter station and supplied to Manufacturer G via the Supplier A, without further treatment (*fup15*, *fup16*, 2024.2352). No other information on traceability was available. The diced salmon Product AC was sampled in official control at the Dutch Retailer F in March 2021.

With regards to the two smoked salmon products manufactured by the Dutch Manufacturer H there were one smoked wild salmon Product AD Batch AH and one Norwegian smoked salmon Product AE Batch AI collected in official control on 1 July 2021 and on 30 November 2021 at the Dutch Retailer E (two isolates). No other information on traceability was available.

With regards to the mackerel product manufactured by the Dutch Manufacturer I there was a smoked mackerel fillet (Product AF Batch AJ) sampled in official control on 20 February 2020 (one isolate) at the Dutch Retailer E. Product AF was frozen and packed at the Manufacturer I but purchased already as product smoked by the Dutch Manufacturer J.

With regards to the three fish products with no information available on the manufacturers, there were a smoked salmon product (Product AG), herrings (Product AH), mackerel (Product AI) (batches not available) sampled between 2021 and 2022 and without further available tracing information. Product AG was sampled in official control at wholesale level (Dutch Wholesaler H). The unpacked salted herrings Product AH was sampled in official control in April 2022 at retail level (fishing stall/market). The mackerel fillet Product AI was sampled in own check in August 2021 at the Dutch Manufacturer J (three isolates).

With regards to the five environmental samples collected at the Dutch Manufacturer G there were three non-food contact surface swabs collected in January 2019 (three isolates) and there were two environmental swab samples (non-food contact and food contact surfaces (cutting machine)) collected in February 2022 (two isolates).

Finally, the food safety authority informed in RASFF that Batch S produced by the Dutch Manufacturer G and sold to the Belgian Manufacturer C was sampled in own check on 26 June 2023 and tested *Listeria* negative (*fup1*, 2023.7767).

Norway

The food safety authority in Norway informed in RASFF that the salmon (Product G Batch G) from the Norwegian Supplier C (supplied to the Belgian Manufacturer C) was slaughtered on 15 August 2023 at the Norwegian Slaughterhouse B (on behalf of the Norwegian Producer G). The food safety authority informed that the official control performed at the slaughterhouse revealed the detection of *Listeria monocytogenes* from an environmental sample collected on 15 August 2023 out of the 581 samples collected in August 2023 (*fup9*, 2024.2352).

In addition, the salmon (Product H Batch H) from the Norwegian Supplier C supplied to the Belgian Manufacturer C was slaughtered on 21 June 2023 at the Norwegian Slaughterhouse A where *Listeria* was not detected from both environment and fish. However, further information on this testing was not available from RASFF (*fup2*, 2023.7767).

Furthermore, the food safety authority reported in RASFF that an official control was carried out at the Norwegian Supplier A and the Norwegian Supplier B that had both supplied the stockfish (produced in 2021) used in Product D by the Italian Manufacturer B. The authority reported that any issue was detected at the two plants in 2021 and that *Listeria* was not detected from the environment of the Norwegian Supplier B. Sampling information for the Norwegian Supplier A was not available from RASFF (*Fup6*, 2024.3104).

Estonia

The food safety authority in Estonia informed that the sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from the following food products:

- marinated herring fillets Product I Batch I
- salted salmon fillets Product J Batch J.

The chilled RTE marinated herring fillets Product I Batch I was sampled in official control on 1 July 2020 at manufacturer level (Estonian Manufacturer E) and two out of the five aliquots tested positive for the outbreak strain (two isolates). The product was marked with an expiry date in July 2020 and had been manufactured by the Estonian Manufacturer E with frozen herrings sourced from the Latvian Wholesaler C. Product I Batch I was sold only in Estonia and was immediately withdrawn and recalled. The food authority informed that the Estonian Manufacturer E performed the sampling of the raw materials used at the plant and that *Listeria* was not detected. In addition, corrective measures consisting in a thorough disinfection were implemented and further testing revealed no *Listeria* detection.

The frozen salted salmon fillets Product J Batch J was sampled in own check on 8 June 2020 at the Estonian Producer B that used it for the preparation of RTE sandwiches. Two out of the five sampled aliquots tested positive for the outbreak strain (four isolates). The product, originating from the Dutch Producer D, was marked with an expiry date in April 2021, Product J Batch J was manufactured by the Dutch Manufacturer F part of the Dutch Manufacturer G with fish farmed in Norway and wholesaled by the Estonian Wholesaler G.

Luxembourg

The food safety authority in Luxembourg informed in RASFF (2024.2352) that five out of the seven sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from the following food products:

- Cold-smoked salmon Product K Batch K
- Cold-smoked salmon Product L Batch K
- Cold-smoked salmon Product M Batch K
- Cold-smoked salmon Product N Batch L
- Cold-smoked salmon Product O Batch M.

The food safety authority could not verify the authenticity of the above-mentioned batch numbers.

Cold-smoked salmon Product K Batch K, cold-smoked salmon Product L Batch K, and the cold-smoked salmon Product M Batch K were distributed in Luxembourg by the Belgian Wholesaler D.

Cold-smoked salmon Product N Batch L and cold-smoked salmon Product O Batch M were distributed in Luxembourg by the French Wholesaler E and by the French Wholesaler F, respectively. The five products were sampled in own-check between 2022 and 2024 in Luxembourg (five isolates).

Despite the food investigation performed by the food safety authority in Luxembourg, further traceability and sampling information, including information on the manufacturers and batch numbers, and information on control measures could not be made available in RASFF.

The remaining two out of the seven sequences belonged to isolates from fish meat samples sampled in own check in 2023. However, further information including tracing was not available from RASFF.

Austria

The food safety authority in Austria informed that the sequence shared in the EFSA WGS System and matching the representative outbreak strain originated from an own-check sample of fish meat Product AJ (not specified) Batch T (not available) collected in October 2022 (one isolate) at manufacturer level. There was no traceability information available besides its origin: the German Manufacturer K.

Germany

The food safety authority in Germany informed in RASFF (2024.2352, *fup?*) that the sequences shared in the EFSA WGS System and matching the representative outbreak strain originated from the following products.

- Fish salad Product AK (batch not available)
- Cod product Product AL (batch not available)
- Cod product Product AM Batch U
- Smoked salmon Product AN (batch not available).

There was an official sample of a fish salad preparation Product AK (batch not available) collected on 7 April 2021 and taken at a local street market (one isolate). The fish salad had been prepared by the German Producer C.

There was an official sample of cod fillet Product AL (batch not available) collected on 23 March 2023 at a local street market (one isolate) and originated from the German Producer E. The sampled cod fillet was a loose product and therefore, the food safety authority considered that a cross-contamination event could not be ruled out (2024.2352, *fup8*).

Following the *Listeria* finding, the food safety authority increased the frequency of inspections and sampling at the production site, which remained under monitoring (2024.2352, *fup11*).

There was an official sample of cod fillet Product AM Batch U (pre-packed) collected on 14 February 2023 (one isolate) in the storage room of the German Producer J and purchased (frozen products) from a trader operator in Dubai (via the Dutch Transporter A). The product's label indicated that the fish originated from the Russian Producer K. The product was thawed at the German Producer J and further distributed (trace forward details not available) as pre-packed chilled product (2024.2352, *fup13*).

There was a smoked salmon Product AN (batch not available) sampled in 2017 at retailer level (one isolate) and produced by the Dutch Producer F.

Table 2. Overview of the non-human isolates (n=83) within the 'My2' sub-cluster 1 per each fish product and fish product-related environment

Sampling country	Sampling Year	Sample matrix description	Sampling point	Manufacturer	Product/Batch	N. isolates
With available	traceability info	ormation	·			
Austria	2022	Fish meat	Not available	Not available	Product AJ (not specified) Batch T (not available)	1
Belgium	2023	Marinated salmon	Manufacturer	Belgian Manufacturer C	Product G Batch G	4
Belgium	2023	Smoked salmon	Retailer	Belgian Manufacturer C	Product H Batch H	1
Estonia	2020	RTE marinated herring fillets	Manufacturer	Estonian Manufacturer E	Product I Batch I	2
Estonia	2020	Salmon fillets	Producer	Dutch Manufacturer F	Product J Batch	4
Germany	2017	Smoked salmon	Retailer	Dutch Producer F	Product AN (batch not available)	1
Germany	2021	Fish salad	Retailer (street market)	German Producer C	Product AK (batch not available)	1
Germany	2023	Cod fillet	Retailer (street market)	German Producer E	Product AL (batch not available)	1

Sampling country	Sampling Year	Sample matrix description	Sampling point	Manufacturer	Product/Batch	N. isolates
Germany	2023	Cod fillet	Producer	Russian Producer K	Product AM Batch U	1
Italy	2023	RTE cold-smoked Icelandic smoked salmon	Wholesaler	Polish Manufacturer A	Product A Batch A	1
Italy	2023	RTE Norwegian smoked salmon	Retailer	Polish Manufacturer A	Product B Batch B	1
Italy	2022	Cream cod	Retailer	Italian Manufacturer B	Product C Batch C	5
Italy	2022	Environment	Manufacturer	Italian Manufacturer B	Not available	1
Luxembourg	2022– 2024	Cold-smoked salmon	Not available	Not available	Product K Batch K; Product L Batch K; Product M Batch K; Product N Batch L; Product O Batch M	5
The Netherlands	2017	Smoked Norwegian salmon chips	Retailer	Dutch Manufacturer G	Product P Batch V	1
The Netherlands	2017	Smoked Norwegian salmon chips	Retailer	Dutch Manufacturer G	Product Q Batch W	1
The Netherlands	2019	Diced wood-smoked salmon	Retailer	Dutch Manufacturer G	Product R Batch X	1
The Netherlands	2019	Diced wood-smoked salmon	Manufacturer	Dutch Manufacturer G	Product S Batch Y	1
The Netherlands	2019	Diced salmon	Manufacturer	Dutch Manufacturer G	Product T Batch Z	1
The Netherlands	2019	Diced salmon	Manufacturer	Dutch Manufacturer G	Product U Batch AA	1
The Netherlands	2019	Smoked salmon scraps	Manufacturer	Dutch Manufacturer G	Product V Batch AB	1
The Netherlands	2019	Diced smoked salmon	Manufacturer	Dutch Manufacturer G	Product W Batch AC	1
The Netherlands	2019	Smoked salmon scraps	Manufacturer	Dutch Manufacturer G	Product X Batch AD	1
The Netherlands	2019	Salmon scraps	Manufacturer	Dutch Manufacturer G	Product Y Batch AE	1
The Netherlands	2019	Vacuum-packed Norwegian salmon	Manufacturer	Dutch Manufacturer G	Product Z Batch AF	1
The Netherlands	2019	Smoked Norwegian salmon	Retailer	Dutch Manufacturer G	Product AA Batch AK	1
The Netherlands	2020	Smoked salmon scraps	Manufacturer	Dutch Manufacturer G	Product AB Batch AG	1
The Netherlands	2021	Diced salmon	Retailer	Dutch Manufacturer G	Product AC (batch not available)	1
The Netherlands	2021	Smoked wild salmon	Retailer	Dutch Manufacturer H	Product AD Batch AH	1
The Netherlands	2021	Norwegian smoked salmon	Retailer	Dutch Manufacturer H	Product AE Batch AI	1
The Netherlands	2020	Smoked mackerel fillet	Retailer	Dutch Manufacturer I	Product AF Batch AJ	1
The Netherlands	2021	Smoked salmon	Wholesaler	Not available	Product AG (batch not available)	1
The Netherlands	2022	Herrings	Retail	Not available	Product AH (batch not available)	1

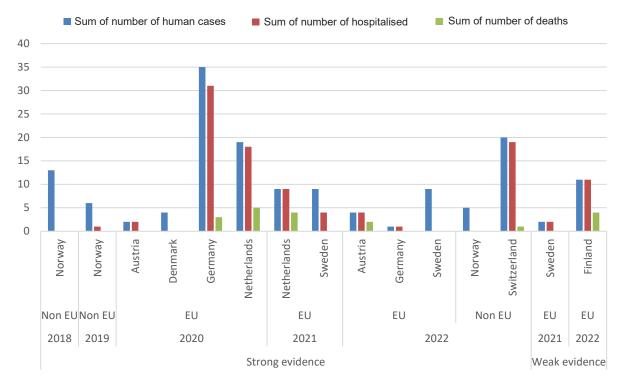
Sampling country	Sampling Year	Sample matrix description	Sampling point	Manufacturer	Product/Batch	N. isolates
The Netherlands	2022	Mackerel fillets	Manufacturer	Not available	Product AI (batch not available)	1
The Netherlands	2019	Environment	Manufacturer	Dutch Manufacturer G	Not available	3
The Netherlands	2021	Environment	Manufacturer	Dutch Manufacturer G	Not available	2
With no available	traceability	information				
Germany	2015-2023	Environment	Processing plant -Trader	Not available	Not available	20
Germany	2015-2016	Smoked salmon	Not available	Not available	Not available	2
Germany	2022	Coalfish	Not available	Not available	Not available	1
Poland	2019	Sliced salmon	Fish processing	Not available	Not available	3
Luxembourg	2023	Fish meat	Not available	Not available	Not available	2
UK	2016	Non-human	Not available	Not available	Not available	1 (ENA)

Annex 2. Food-borne outbreaks caused by L. monocytogenes

This section summarises country-specific data on food-borne outbreaks associated with *L. monocytogenes* for the category fish and fish products, as reported between 2018 and 2022 to EFSA by EU Member States and non-EU countries in accordance with the Zoonoses Directive 2003/99/EC.

Over these five years, 20 food-borne outbreaks were caused by *L. monocytogenes*, with 149 human cases, 102 hospitalisations, and 19 deaths overall. Five EU Member States, Norway, and Switzerland reported 18 strong-evidence food-borne outbreaks: Austria (n=2), Denmark (n=2), Germany (n=2), the Netherlands (n=4), and Sweden (n=4); Norway (n=3), and Switzerland (n=1). There was a total of 136 human cases, 89 hospitalisations, and 15 deaths reported. Two EU Member States reported two weak-evidence food-borne outbreaks: Finland (n=1) and Sweden (n=1). There was a total of 13 human cases, 13 hospitalisations, and four deaths reported (Figure 6).

Figure 6. Distribution of 20 food-borne outbreaks caused by L. monocytogenes in fish and fish products reported by EU Member States and non-EU countries between 2018 and 2022



Occurrence of L. monocytogenes in fish and fish products

This section summarises country-specific data on the occurrence of *L. monocytogenes* for the category fish and fish products from 2018 to 2022 as reported to EFSA by the EU Member States and non-EU countries in accordance with the Zoonoses Directive 2003/99/EC.

During these five years, 156 727 total units were tested for L. monocytogenes in fish and fish products as reported by 25 EU Member States (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden). There were 101 465 units tested for the detection method, resulting in 3 538 units positive (3.49%). There were 68 087 units tested for the enumeration method, resulting in 430 units positive (0.63%) with L. $monocytogenes \le 100$ UFC/g, and in 166 units positive (0.24%) with L. monocytogenes > 100 CFU/g.

Regarding the non-EU countries (Albania, Iceland, Montenegro, Republic of North Macedonia, and Serbia), an amount of 348 total units were tested for *L. monocytogenes* in fish and fish products. There were 304 units tested for the detection method, resulting in 18 units positive (5.92%). There were 93 units tested with the enumeration method resulting in no units positive for *L. monocytogenes* \leq 100 CFU/g and >100 CFU/g.

It is worth noting that it is highly likely that some samples were tested for both methods (i.e. detection and enumeration methods), which is why the total units tested is not equal to the sum of the units tested for both methods.

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