JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Prolonged multi-country outbreak of *Listeria monocytogenes* ST1607 linked to smoked salmon products

25 April 2024

Abstract

A prolonged genomic cluster of 20 human *Listeria monocytogenes* ST1607 infections has been reported to the European Centre for Disease Prevention and Control, with cases identified in Denmark (17), Germany (1), and Italy (2) since 2019. The number of cases has sharply increased after 2021. The most recent case was reported in March 2024 in Denmark, indicating an ongoing risk of further infections. Of 20 listeriosis cases, five have died (one due to another cause than *L. monocytogenes* infection), indicating high severity of infection particularly among elderly people with underlying chronic conditions.

The national investigations the traceability and genomic data analyses revealed the detection of five matching *L. monocytogenes* ST1607 isolates from four sliced smoked salmon products (four batches) produced by the Danish Processing Plant A between 2021 and 2024. These contaminated products were distributed to the three countries (Denmark, Germany, and Italy) reporting human cases to ECDC. The identification of the outbreak strain from the environment of the Danish Processing Plant A in 2023 and in the products since 2021 indicates the persistence of the *L. monocytogenes* ST1607 within the plant and suggests that the point(s) of the contamination in the plant have not been identified and controlled. Although control measures had been implemented at the plant and withdrawals and recalls of contaminated batches were performed, new batches of contaminated products could still be placed on the market until the site(s) at the plant and the root(s) of the contamination in the fish production chain are identified and properly controlled.

Based on the available information from case interviews, microbiological and traceability analysis, the conclusion is that sliced smoked salmon products are the likely sources of infection. New cases could occur in EU/EEA countries, particularly among vulnerable people, until the root(s) of contaminations are identified and corrective measures are implemented.

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Event background

On 9 January 2023, Denmark reported to the European Centre for Disease Prevention and Control (ECDC) a cluster of eight listeriosis cases, defined by whole genome sequencing (WGS), and geographically spread over Denmark (event ID 2023-FWD-00003). On the same day, Germany identified one listeriosis case from 2022 with a genetically close isolate to the reference sequence from Denmark.

On 22 March 2024, Italy opened an alert in the Early Warning and Response System (EWRS ID 4802) to report two cases of listeriosis with *L. monocytogenes* ST1607 isolates genetically close by WGS to a food isolate reported in the Rapid Alert System for Food and Feed (RASFF) [1]. By 22 April 2024, 17 cases had been reported in Denmark, one in Germany, and two in Italy.

Four RASFF alert notifications have been issued and linked to this event: 2024.2029, 2023.4705, 2022.7482, and 2021.2299.

Considering the severity and evolving nature of this multi-country *L. monocytogenes* cluster with an indication of a persistent nature of *L. monocytogenes* in the food chain [2], ECDC and the European Food Safety Authority (EFSA) agreed to proceed with this Rapid Outbreak Assessment (ROA).

Further information about listeriosis in the European Union/European Economic Area (EU/EEA) countries can be found in ECDC's Annual Epidemiological Report of listeriosis in 2022 [3] and the online 'Surveillance atlas of infectious diseases' [4].

Outbreak strain characterisation

The *L. monocytogenes* outbreak strain belongs to serogroup IIa, clonal complex (CC) 14, and sequence type (ST) 1607 [5]. According to the Institut Pasteur scheme [6], the isolate is assigned to a code 'L2-SL91-ST1607-CT5221'. The strain is negative for pathogenicity islands LIPI3 and LIPI4. The resistance profile to antimicrobials was not available.

A representative human isolate from Denmark is available in a public repository at the National Center for Biotechnology Information (NCBI) with a code SRR28714110 [7].

European outbreak case definition

The European outbreak case definition is the following:

A confirmed outbreak case:

- A laboratory-confirmed *Listeria monocytogenes* ST1607 case with disease onset on or after 1 January 2019 (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 within four allelic differences (ADs) by cgMLST in a centralised single-linkage WGS analysis; OR
  - clustering within four ADs by cgMLST in a national pipeline; OR
  - clustering within eight SNPs (single nucleotide polymorphism) in a national pipeline.

The stricter laboratory criterion of four AD was based on a centralised WGS analysis and a review of available metadata for these isolates [8].

Epidemiological and microbiological investigations of human cases

As of 22 April 2024, 20 cases with *L. monocytogenes* ST1607 infection have been reported in Denmark (17), Germany (1), and Italy (2) since 2019 (Table 1). The majority of cases (85%) have been reported in Denmark, where the most recent case was sampled on 23 March 2024. There has been a sharp increase in reported cases since 2021 (Figure 1).

Of 20 cases, 13 are female and seven male, with ages ranging from 20 to 90 years. Five cases have died, giving a case fatality rate of 25% (Table 2). One of the five cases died due to a cause other than *L. monocytogenes* infection.

Table 1. Confirmed cases of *L. monocytogenes* ST1607 CC14 by country and year in the EU/EEA, as of 22 April 2024

Country	2019	2020	2021	2022	2023	2024	Total
Denmark	2	1	1	4	7	2	**17**
Germany	0	0	0	1	0	0	**1**
Italy	0	0	0	0	2	0	**2**
Total	**2**	**1**	**1**	**5**	**9**	**2**	**20**

Figure 1. Distribution of confirmed cases of *L. monocytogenes* ST1607 CC14 infection by country and year, as of 22 April 2024

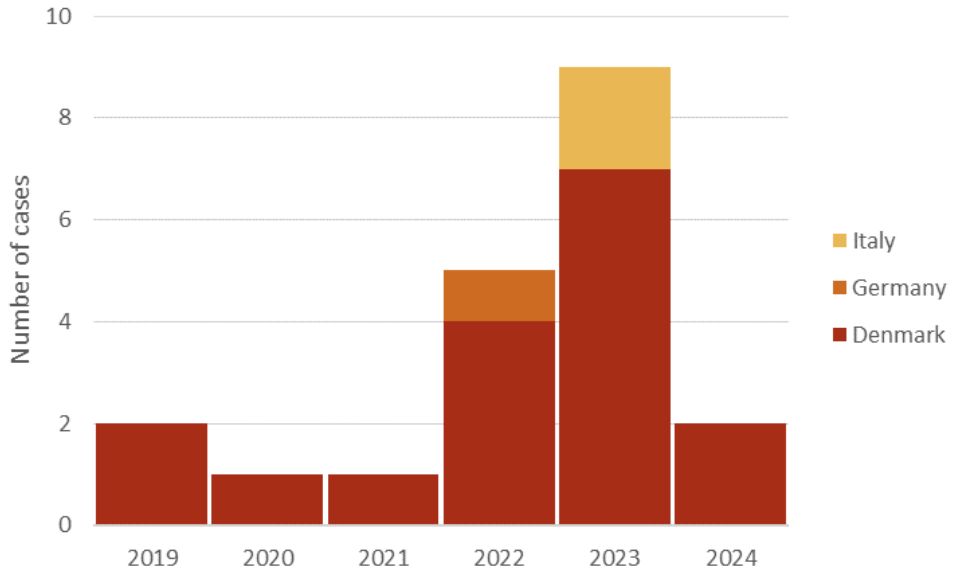


Table 2. Demographic summary of confirmed cases of L. monocytogenes ST1607 CC14 infection in three EU countries, as of 22 April 2024

Country	Total No of cases	Male	Female	Age range (years)	No of deaths	Comments
Denmark	17	4	13	20–90	2	
Germany	1	1		Over 50	1	Due to a cause other than *Listeria* infection
Italy	2	2		Between 50 and 80	2	
Total	**20**	**7**	**13**		**5**	

Information from patient interviews

In Denmark, 13 of 17 cases or their relatives have been interviewed. No common events or epidemiological links were identified between cases. Cases shop in different supermarket chains and eight had eaten out during the 30 days before falling ill. Of 12 cases, 11 report having eaten cold cut meat products (one patient was not asked this question), and eight report having eaten 'rullepølse' (rolled seasoned meat). Eight of 13 report consumption of RTE fish products, including four reporting eating smoked fish products (one reported eating smoked salmon only on the Faroe Islands).

In Germany, an adult male from the federal state of Lower Saxony contracted listeriosis with the same strain as in this cluster in August 2022. The man was hospitalised due to listeriosis and died in August due to another cause than listeriosis. There was no information on eating habits or travel to Denmark. There were no other matching cases of this sequence type in Germany.

In Italy, both patients were affected by underlying chronic conditions. Regarding the food consumption history of the patient between 50 and 60 years of age, who was hospitalised with gastroenteritis and fever, he reported being vegetarian and reported consuming smoked salmon and fresh salmon, smoked swordfish, cod, and sushi. He also consumed vegetables (unspecified), dairy (unspecified). The patient between 70 and 80 years old, hospitalised with sepsis and neurological signs, reported consuming meat, poultry, ham, frozen vegetables and ready-to-eat (RTE) vegetable soups, soft cheese, and dairy products (yogurt); no consumption of fish and fish products was reported.

Microbiological and environmental investigations of food and control measures

This section summarises the results of the traceability investigations, the analytical results, and the implemented control measures on RTE smoked salmon products as shared by the Member States under the RASFF Alert Notifications **2024.2029** (11 follow-up, *fup*, as of 18 April 2024), **2023.4705** (2 *fup* as of 4 August 2023), **2022.7482** (2 *fup* as of 23 December 2022), and **2021.2299** (4 *fup* as of 10 May 2021).

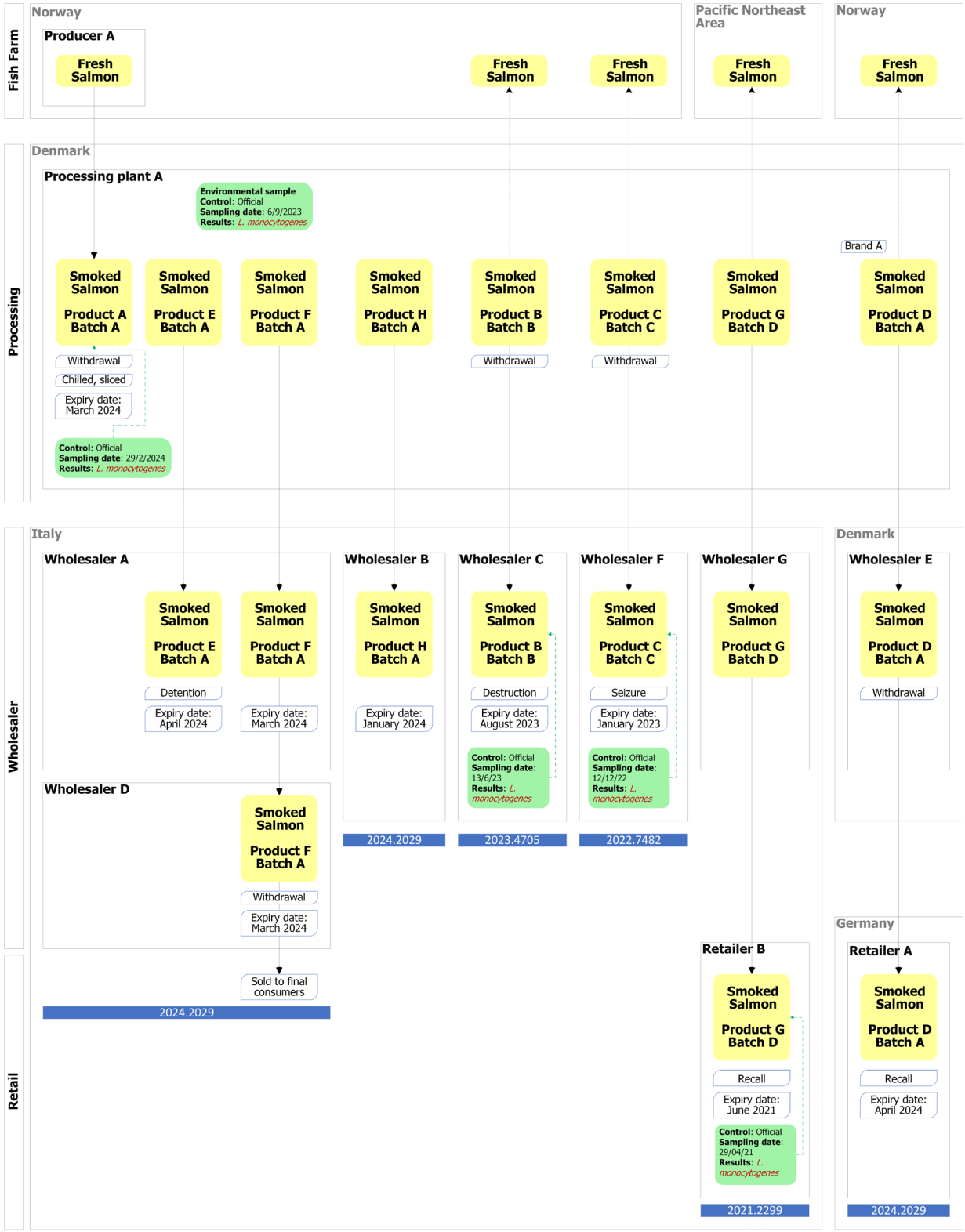
The food investigations identified the following *L. monocytogenes* positive sliced smoked salmon products manufactured by the Danish Processing plant A and matching the outbreak strain in the centralised WGS analysis:

- Cold-smoked Norwegian salmon **Product A Batch A** (chilled, dry salted, sliced) manufactured with fish farmed in Norway; sampled in official control in February 2024 in Denmark (Processing plant A); expiry date in March 2024; testing positive (<10 CFU/g); one isolate, RASFF 2024.2029;
- Environmental sample collected in official control in September 2023 in Denmark (Processing plant A); one isolate, RASFF 2024.2029;
- Smoked Norwegian salmon **Product B Batch B** (chilled, sliced) manufactured with fish farmed in Norway; sampled in official control in June 2023 in Italy (Wholesaler C); expiry date in August 2023; testing positive (<10 CFU/g, pH=5.92, Aw=0.97); two isolates, RASFF 2023.4705;
- Smoked Norwegian salmon **Product C Batch C** (chilled, sliced) manufactured with fish farmed in Norway; sampled in official control in December 2022 in Italy (Wholesaler F); expiry date in January 2023; testing positive (<10 CFU/g, pH=6.03, Aw=0.97); one isolate, RASFF 2022.7482;
- Cold-smoked salmon **Product G Batch D** (chilled, sliced) manufactured with fish fished in in the Pacific Northeast area; sampled in official control in April 2021 in Italy (Retailer B); expiry date in June 2021; testing positive (<10 CFU/g, Aw=0.95); one isolate, RASFF 2021.2299.

Food investigations and control measures, including inspections, trace back and forward, withdrawals and recalls, and detentions and destructions, were reported in RASFF by the food safety authorities of the countries involved: Denmark (2023.4705, *fup1*; 2022.7482, *fup1*), Germany (RASFF 2024.2029), and Italy (2024.2029, *fup4;* 2023.4705, *fup2;* 2022.7482; 2021.2299, *fup3*). The food authority in Denmark informed that the Danish Processing Plant A had implemented preventive and corrective measures such as the change of the cleaning practices and revision of the own-check programme.

A visual representation of their traceability is displayed in Figure 2. A detailed description of their traceability is provided in Annex 1.

Figure 2. Graphical representation of traceability and microbiological analysis of the smoked salmon products manufactured at the Danish Processing plant A as reported by the countries involved under RASFF Alert Notifications 2024.2029, 2023.4705, 2022.7482, and 2021.2299



L. monocytogenes in red = L. monocytogenes ST1607 matching the representative outbreak strain

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

WGS data collection, data validation, and cross-sectoral analysis

In a cluster analysis of *L. monocytogenes* isolates' sequences related to this event, ECDC identified three human isolates matching the European case definition from three countries, one each in Denmark, Germany, and Italy (cluster code in ECDC One Health WGS system in EpiPulse: 2023-08.LIST.60.). Human isolates were within three AD in a single-linkage clustering analysis. By 22 April 2024, additional sequences of 14 human isolates were submitted by Denmark, adding the total number of human *L. monocytogenes* ST1607 isolates in the centralised WGS cluster to 17 (15 in Denmark, one each in Germany and Italy), all within three AD in the single-linkage clustering analysis.

Regarding food isolates of *L. monocytogenes* ST1607, in January 2023 and in April 2024, EFSA launched a call for data inviting Denmark, France, and Italy to share the genomic and related epidemiological information (metadata) in the EFSA One Health WGS System. By 18 April 2024 a total of seven profiles of *L. monocytogenes* ST1607 non-human isolates had been shared by Denmark (n=2), France (n=1), and Italy (n=4). One profile from Norway was imported from the public repository ENA (European Nucleotide Archive). The eight profiles derived from fish meat and products thereof, and related environment (six profiles from smoked salmon, one profile from salmon raw materials, and one from processing environment) and were sampled between 2014 and 2024. Countries with genomic data matching the outbreak strains (Denmark, France, Italy, and Norway), and included in the centralised analysis, were consulted on 12, 16, and 18 April for data validation.

For cross-sectoral analysis, the cgMLST single-linkage analysis was performed by ECDC and by EFSA as previously described [9]. 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* [6] made available by chewie Nomenclature Server at https://chewbbaca.online/species/6. All food isolates included in the analysis has < 1% missing loci (< 17 missing loci over a total of 1748 loci).

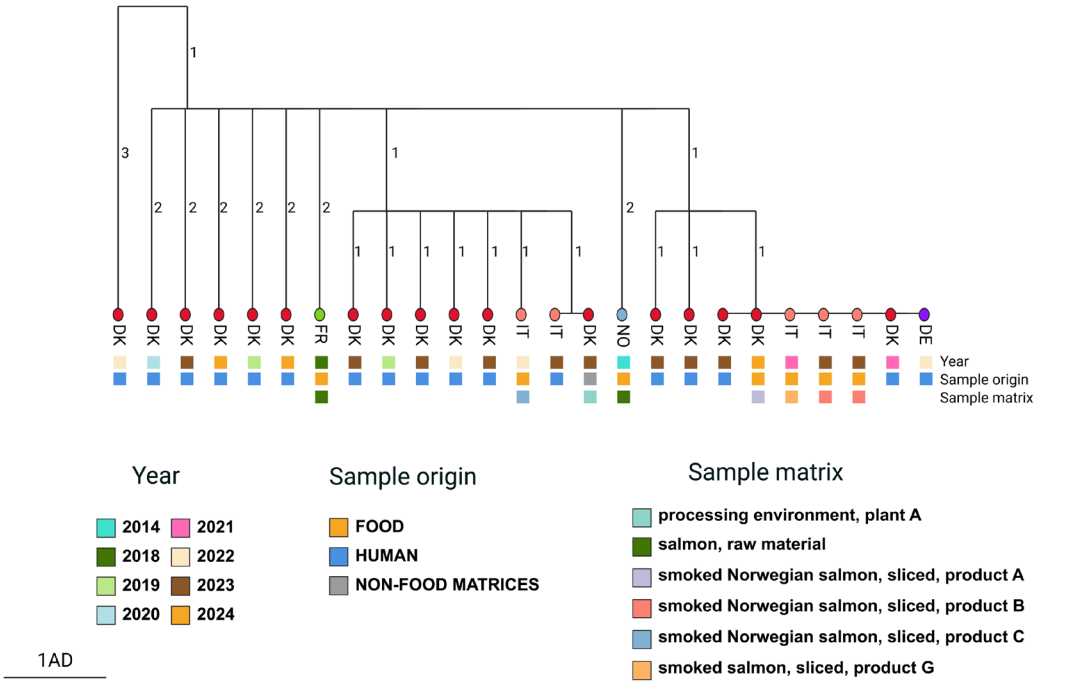
Results of cross-sectoral WGS analysis

ECDC queried EFSA's One Health WGS System on 22 April 2024 using 17 *L. monocytogenes* ST1607 as reference genomes and seven ADs as threshold. As a result of the query, eight shared profiles of *L. monocytogenes* ST1607 non-human isolates clustered within four ADs in a single-linkage cluster analysis with any of the human isolates, giving a total of 25 *L. monocytogenes* ST1607 profiles in the joint isolate dataset. Five out of the eight non-human isolates available originated from cold-smoked Norwegian salmon **Product A Batch A** (one sequence), from smoked Norwegian salmon **Product B Batch B** (two sequences), smoked Norwegian salmon **Product C Batch C** (one sequence), cold-smoked salmon **Product G Batch D** (one sequence) for which tracing information are detailed in Annex 1. One out of the eight non-human isolates available originated from an environmental sample collected at the **Processing plant A** (one sequence). Epidemiological information submitted to the EFSA One Health WGS system indicated Denmark as country of origin of the food samples and of the processing environmental sample.

The remaining two profiles (one from Norway and one from France) were obtained from *L. monocytogenes* isolated from samples of raw salmon collected in 2014 and 2018, not linked to food products associated with RASFF notifications.

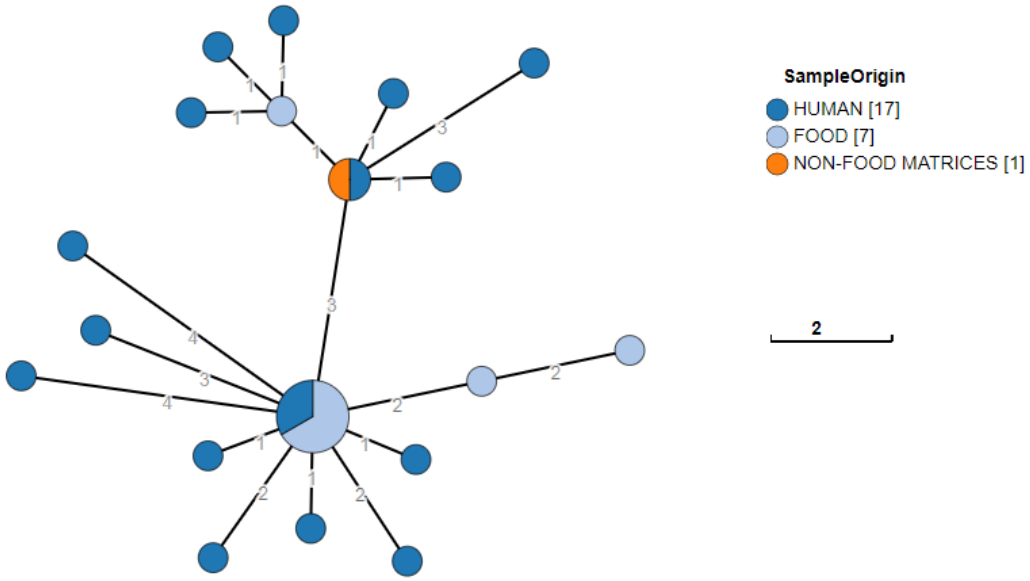
Both the minimum spanning tree (MST) and the single-linkage cluster tree show the genetic closeness between human and non-human isolates as well as across countries (Figures 3 and 4).

Figure 3. Single linkage clustering tree of 17 human and eight non-human *L. monocytogenes* ST1607 isolates by country, year, sample origin, and sample matrix in the molecular typing tool in EpiPulse (cluster code: 2023-08.LIST.60.), as of 22 April 2024



Source: *ROA Listeria monocytogenes ST1607 linked to fish products (microreact.org)*

Figure 4. cgMLST-based minimum spanning tree of 17 human and eight non-human *L. monocytogenes* ST1607 isolates by sample origin, as of 22 April 2024



ECDC and EFSA risk assessment for the EU/EEA

A prolonged genomic cluster of 20 human *Listeria monocytogenes* ST1607 infections has been reported to ECDC with cases identified in Denmark (17), Germany (1), and Italy (2) since 2019. The number of cases has sharply increased since 2021. The most recent case was reported in March 2024 in Denmark, indicating an ongoing risk of infections. Of 20 listeriosis cases, five have died (one due to a cause other than *L. monocytogenes* infection), indicating high severity of infection, particularly among elderly people with underlying chronic conditions. Based on national investigations, RTE fish products were identified as possible vehicles of infection, and nine of 15 interviewed cases (60%) reported consumption of RTE fish products.

Overall, the national investigations in Italy and in Denmark, the traceability analysis, and the sharing of the genomic data revealed the detection of five matching *L. monocytogenes* ST1607 isolates from four sliced smoked salmon products (four batches). These products had been produced by the Danish Processing Plant A between 2021 and 2024. These contaminated products were distributed to the three countries (Denmark, Germany, and Italy) reporting human cases to ECDC. In addition, the available genomic data from an isolate from raw fish material indicates that the outbreak strain is circulating in the fish supply chain since at least 2014.

The identification of the outbreak strain from the environment of the Danish Processing Plant A in 2023 and in the products since 2021 indicates the persistence of the *L. monocytogenes* ST1607 within the plant and suggests that the point(s) of the contamination in the plant has not been identified and controlled. Even though control measures had been implemented at the plant (followed up by the food safety authority in Denmark) and there have been the withdrawals and recalls of the contaminated batches, new batches of contaminated products could be placed into the market until the site(s)of the contamination at the plant and the root(s) of the contamination upstream into the fish production chain are identified and properly controlled.

Based on available information from microbiological analyses (human and food), traceability analysis, and case interviews, the conclusion is that sliced smoked salmon products are the likely sources of infection. New cases could occur in EU/EEA countries, particularly among vulnerable people (such as those with underlying health problems and elderly people) until the root(s) of contaminations are identified and corrective measures are implemented.

In general, following of the HACCP (Hazard Analysis Critical Control Points) principles (e.g. testing of incoming raw materials for *L. monocytogenes*), good hygiene practices and good manufacturer practices within the whole food supply chain should reduce the risk of contamination. Storing food at refrigerator temperatures, exercising proper handling, refraining from consuming food past its expiration date, and following the labelling instructions can further reduce the risk of infection.

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 event 2023-FWD-00003 in EpiPulse should new cases continue to be reported.
- Countries are encouraged to investigate 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* ST1607 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* ST1607 isolates from any kind of food, feed, animal and related environment to the EFSA One Health WGS System.
- Countries are invited to conduct and 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.

Source and date of request

ECDC sent a request to EFSA on 11 April 2024 to produce a Joint Rapid Outbreak Assessment (ROA). EFSA accepted the request on 12 April 2024.

Consulted experts and national contact points

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Public health experts consulted for data and facts validation:

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Germany: Holzer Alexandra (Robert Koch-Institut FG35), Sven Halbedel (Robert Koch-Institut, FG11);
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EFSA staff (in alphabetical order): Sofia Fusco, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, Frank Verdonck.

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National experts consulted by the RASFF contact points:
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Country Officers of the EFSA One Health WGS system consulted: Denmark, France, Italy, Norway

National experts consulted by the Country Officer of the:

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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 data 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.

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

Denmark

On 18 March 2024, the food safety authority in Denmark reported in RASFF (2024.2029) the detection (<10 CFU/g) of *L. monocytogenes* matching the outbreak strain (per centralised WGS cluster analysis) from an official sample of chilled cold-smoked Norwegian salmon (dry salted and sliced) (Product A Batch A). The smoked salmon was sampled on 29 February 2024 at manufacturer level (Danish Processing plant A) and was marked with an expiry date of March 2024 (2024.2029, *fup1*). Product A Batch A was manufactured with raw materials (fresh salmon) supplied by the Norwegian Producer A (2024.2029, *fup6).*

Following the positive findings, the Danish Processing plant A withdrew the product sold within Denmark. In addition, the Danish Processing plant A contacted its recipients in Italy (Italian Wholesaler A and Italian Wholesaler B) to inform about the positive detection (2024.2029, *fup1, fup2, fup9*).

Between December 2023 and March 2024, the Danish Processing plant A had delivered various batches to the Italian wholesalers, including Batch A, that had been delivered also to Germany (2024.2029, *fup2*). Batch A was distributed by the Danish Wholesaler E only to the German Retailer A (2024.2029, *fup8*).

Following the detection in Italy of *L. monocytogenes* in smoked salmon products manufactured by the Danish Processing plant A, on 13 July 2023, on 23 December 2022, and on 10 May 2021, the food safety authority in Denmark reported in RASFF the trace forward information of Product B Batch B, Product C Batch C, and Product G Batch D. These products had been delivered only to the Italian Wholesaler C, Italian Wholesaler F, and the Italian Wholesaler G, respectively. Therefore, there was no distribution to other food business operators. The batches had been withdrawn (2023.4705, *fup1*; 2022.7482, *fup1;* 2021.2299, *fup3-4*).

The food safety authority in Denmark was informed of the national investigation in Italy, including the WGS typing's results, on 27 July 2023.

Germany

On 18 March 2024, the food safety authority in Germany notified in RASFF (2024.2029) the implementation of voluntary control measures taken regarding the chilled smoked salmon (sliced) Product D Batch A from the Brand A manufactured by the Danish Processing plant A with fish farmed in Norway. Product D Batch A had reached the German market via the Danish Wholesaler E. The control measures were implemented by the German Retailer A on 14 March 2024 after having been alerted by its wholesaler (Danish Wholesaler E). The measures consisted of informing the authorities, withdrawals, and recalls (customer notices, social media, and customer phone calls). The recalled batch was marked with an expiry date of April 2024 (RASFF 2024.2029).

Italy

On 10 April 2024, after having been notified by the Danish authorities in RASFF about the national investigation (2024.2029, *fup1*), the food safety authority in Italy informed that the Italian Wholesaler A had implemented some control measures regarding the smoked salmon products (Product E) from Batch A manufactured by the Danish Processing plant A. The control measures consisted of the detention of the remaining smoked salmon products not sold yet. Product E from Batch A was marked with an expiry date in April 2024 (2024.2029, *fup4*).

In addition, the food safety authority informed that the Italian Wholesaler A delivered smoked salmon Product F from Batch A and marked with an expiry date in March 2024 to the Italian Wholesaler D, which further sold the majority of them to the final consumers. Those products not sold were returned to the Italian Wholesaler A (2024.2029, *fup4*).

Moreover, the food safety authority in Italy informed that the Italian Wholesaler B had received Product H Batch A from the Danish Processing plant A and had further distributed it locally (2024.2029, *fup9*).

On 27 July 2023, and in the frame of national outbreak investigations, the food safety authority in Italy contacted the food safety authority in Denmark. On 16 October 2023, the food safety authority in Denmark informed that an official environmental sample collected on 6 September 2023 at the Processing plant A tested positive for *L. monocytogenes* ST1607 matching the outbreak strain (2024.2029, *fup11*).

On 12 July 2023, the food safety authority in Italy opened a RASFF notification (2023.4705) to inform about the detection (<10 CFU/g, pH=5.92, Aw=0.97) of *L. monocytogenes* matching the outbreak strain (per centralised

WGS cluster analysis) from a sample of chilled smoked Norwegian salmon (sliced) (Product B Batch B). The smoked salmon product was sampled at wholesale level (Italian Wholesaler C) in the frame of an official control performed on 13 June 2023. Product B Batch B had been manufactured by the Danish Processing plant A with fish farmed in Norway. The product was marked with an expiry date of August 2023 (RASFF 2023.4705). On 4 August 2023, the food safety authority reported that products were sent for destruction as animal-by-product category 1 (2023.4705, *fup2*).

On 21 December 2022, the food safety authority in Italy opened a RASFF notification (2022.7482) to inform about the detection (<10 CFU/g, pH=6.03, Aw=0.97) of *L. monocytogenes* matching the outbreak strain (per centralised WGS cluster analysis) from an official sample of chilled smoked Norwegian salmon (sliced) (Product C Batch C). The smoked salmon product was sampled on 12 December 2022 at wholesale level (Italian Wholesaler F) and manufactured by the Danish Processing plant A with fish farmed in Norway. The product was marked with an expiry date of January 2023. The food safety authority reported that some products from Batch C were seized at the wholesaler while some others were blocked at customers level (RASFF 2022.7482).

On 7 May 2021, the food safety in Italy opened a RASFF notification (2021.2299) to inform about the detection (<10 CFU/g, Aw=0.95) of *L. monocytogenes* matching the outbreak strain (per centralised WGS cluster analysis) from an official sample of chilled cold-smoked salmon (sliced) (Product G Batch D). The smoked salmon product was sampled on 29 April 2021 at retail level (Italian Retailer B (the Italian Wholesaler G's retailers)) and manufactured by the Danish Processing plant A with salmon fished in the Pacific Northeast area (FAO fishing area 67). The product was marked with an expiry date in June 2021. The food safety authority reported that product was recalled on 6 May 2021 by the retailer (2021.2299, *fup3*).

Annex 2. Background information on *L. monocytogenes*

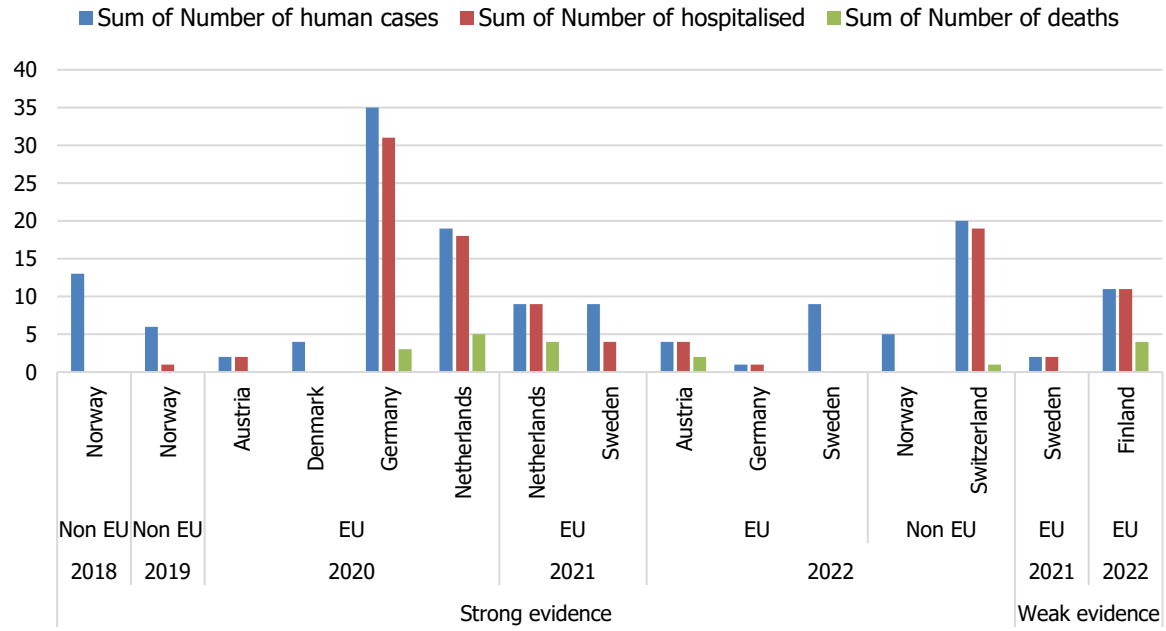
Food-borne outbreaks caused by *L. monocytogenes*

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); and 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 4 deaths reported (Figure 5).

Figure 5. 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, 114 975 total units were tested for *Listeria* 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, Slovenia, Slovakia, Spain, and Sweden). There were 76 570 units tested for the detection method, resulting in 2 923 units positive (3.82%). There were 47 153 units tested for the enumeration method, resulting in 297 units positive (0.63%) with *L. monocytogenes* ≤100 UFC/g, and in 121 units positive (0.26%) with *L. monocytogenes* >100 CFU/g.

Regarding the non-EU countries (Albania, Iceland, Montenegro, Republic of North Macedonia, and Serbia), an amount of 234 total units were tested for *Listeria* in fish and fish products. There were 201 units tested for the detection method, resulting in 12 units positive (5.97%). There were 34 units tested with the enumeration method resulting in no units positive for *L. monocytogenes* ≤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.