

JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Prolonged multi-country cluster of *Listeria monocytogenes* ST155 infections linked to ready-to-eat fish products

13 December 2023

Abstract

A genomic cluster of *Listeria monocytogenes* sequence type (ST) 155, serogroup IIa, infections has been identified in the European Union/European Economic Area (EU/EEA) and the United Kingdom (UK). Based on genomic similarity, the cluster can be divided into three sub-clusters, of which only cases due to sub-cluster 1 continue to be reported. Sub-cluster 1 is therefore the focus of this assessment, with 64 cases reported in five EU/EEA countries between 2016 and 2023, of which 17 were in 2022 and 2023 (one in Austria, one in Belgium, eight in Italy, six in Germany, and one in the Netherlands). It includes 10 fatal cases between 2019 and 2023. Sub-clusters 2 and 3 are historical, with 30 cases reported between 2011 and 2021. Based on case interviews, ready-to-eat (RTE) fish products have been implicated as vehicles of infection.

National food investigations, traceability, and genomic data identified 34 *L. monocytogenes* isolates from 12 fish products and one isolate from a fish processing environment within sub-cluster 1. Sequencing analysis identified a link with two processing plants in Lithuania. In 2022–2023, contaminated fish products from these plants had reached retail markets in Germany and Italy, but there was no information on the product distribution in the other three countries reporting cases. The recurrent detection of the sub-cluster 1 strain from marketed sealed RTE fish products revealed the persistence of the strain in one processing plant over eight years.

Further targeted investigation in the RTE fish production chain is needed to identify the point(s) of contamination. The interruption of the production of RTE fish products in one of the processing plants is likely to reduce infections, but until all sources and sites of contaminations are properly controlled new cases are expected to occur, particularly among vulnerable people (the immunosuppressed and those aged over 75 years).

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Event background

On 9 March 2020, **Germany** reported 15 different listeriosis clusters from 2010 to 2020 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 to salmon products [1].

After the alert from Germany, other European Union/European Economic Area (EU/EEA) countries reported cases with genetically close *Listeria monocytogenes* isolates, confirming that several of these clusters had a multi-country nature.

Of the reported multi-country clusters, ECDC and the European Food Safety Authority (EFSA) prepared a Joint Notification Summary (JNS) of a cluster named 'Omikron1' according to the nomenclature of the Robert Koch Institute, Germany. The JNS was distributed directly to public health and food safety authorities on 16 April 2020 to inform about ongoing risk of *Listeria monocytogenes* infections linked to certain fish products. The JNS was updated on 13 November 2020.

Since 2020, and as of 28 November 2023, listeriosis cases have continued to be reported in the 'Omikron1' cluster, suggesting possible active source(s) in the EU/EEA. As this 'Omikron1' cluster (2023-FWD-00023) involves several countries, has a high total number of severe and fatal cases, and has been active for several years, indicating a prolonged risk for *L. monocytogenes* infections caused by this specific strain in the EU/EEA, in August 2023 ECDC and EFSA decided to further produce and publish this joint outbreak assessment (Rapid Outbreak Assessment, or ROA).

Outbreak strain characterisation

The 'Omikron1' outbreak strain belongs to serogroup IIa, clonal complex (CC) 155, sequence type (ST) 155 and cluster type (CT) 1128 (Ridom, SeqSphere) [2]. According to the Institut Pasteur scheme [3], the isolate is assigned to a code 'L2-SL155-ST155-CT842/CT5098, IIa'. The strain is negative for LIPI3 and LIPI4.

Representative German *L. monocytogenes* strains of the 'Omikron1' cluster are available at European Nucleotide Archive (ENA) [4] with codes ERR2261647 (from 2016, falls into sub-cluster 3) and ERR7113321 (from 2020, falls into sub-cluster 1).

European outbreak case definition

The European outbreak case definition is the following:

A confirmed outbreak case in the genetic 'Omikron1' cluster:

A laboratory-confirmed *Listeria monocytogenes* case with disease onset on or after 1 January 2022 (date of sampling or date of receipt by the laboratory if date of onset is not available).

AND

Fulfilling the following laboratory criteria:

- clustering within seven allelic differences (ADs) by cgMLST in a centralised single-linkage WGS analysis, OR
- clustering within seven ADs by cgMLST in a national pipeline.

A historical confirmed outbreak case in the genetic 'Omikron1' cluster:

A laboratory-confirmed *Listeria monocytogenes* case with disease onset before 1 January 2022 (date of sampling or date of receipt by the laboratory if date of onset is not available).

AND

Fulfilling the following laboratory criterion:

- clustering within seven ADs (cgMLST) in a centralised single-linkage WGS analysis, OR
- clustering within seven ADs (cgMLST) in a national pipeline.

A genetic sub-cluster of 'Omikron1' was defined using a cut-off of four ADs in a single-linkage analysis among confirmed outbreak cases.

The genetic sub-cluster 1 within 'Omikron1' was assigned using a cut-off of four ADs in a single-linkage analysis among confirmed outbreak cases. Additional cases were added to sub-cluster 1 if the isolates were within four ADs in the national pairwise comparison to the German reference strain ERR7113321 (from 2020).

Epidemiological and microbiological investigations of human cases

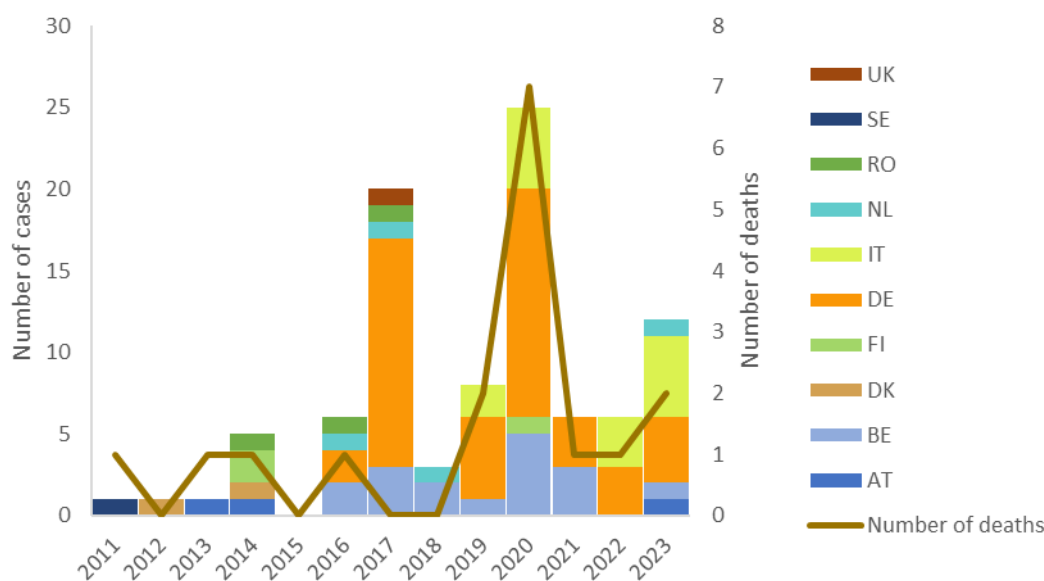
ECDC invited countries to report cases using a standard line list and submitting sequences of *L. monocytogenes* ST155 isolates to ECDC. The collected data covered also historical cases that fulfilled the European case definition. The descriptive epidemiology below includes recent and historical cases, thus presenting the overall magnitude of 'Omikron1' cluster.

As of 5 December 2023, 94 confirmed cases of *L. monocytogenes* ST155 in the cluster 'Omikron1' have been reported in nine EU/EEA countries and the United Kingdom (UK) since 2011 (Table 1, Figure 1).

Table 1. Number of all confirmed cases of *L. monocytogenes* ST155 in 'Omikron1' cluster by country and year of statistics in nine EU/EEA countries and the UK (n=94), as of 5 December 2023

Country	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Austria	0	0	1	1	0	0	0	0	0	0	0	0	1	3
Belgium	0	0	0	0	0	2	3	2	1	5	3	0	1	17
Denmark	0	1	0	1	0	0	0	0	0	0	0	0	0	2
Finland	0	0	0	2	0	0	0	0	0	1	0	0	0	3
Germany	0	0	0	0	0	2	14	0	5	14	3	3	4	45
Italy	0	0	0	0	0	0	0	0	2	5	0	3	5	15
Netherlands	0	0	0	0	0	1	1	1	0	0	0	0	1	4
Romania	0	0	0	1	0	1	1	0	0	0	0	0	0	3
Sweden	1	0	0	0	0	0	0	0	0	0	0	0	0	1
United Kingdom	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Total	1	1	1	5	0	6	20	3	8	25	6	6	12	94

Figure 1. Number of all confirmed cases of *L. monocytogenes* ST155 and reported deaths in the 'Omikron1' cluster by country and year of statistics in nine EU/EEA countries and the UK (n=94), as of 5 December 2023

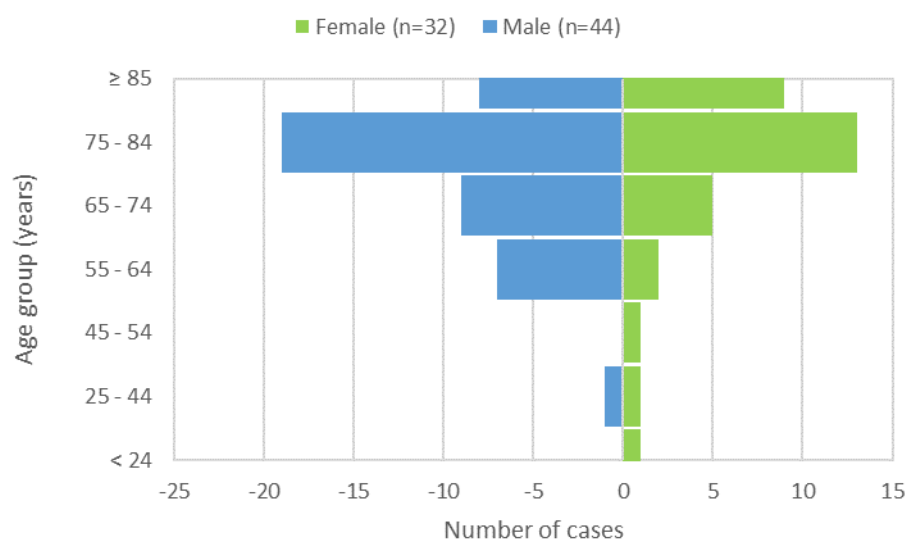


AT: Austria; BE: Belgium; DK: Denmark; FI: Finland; DE: Germany; IT: Italy; NL: the Netherlands; RO: Romania; SE: Sweden; UK: the United Kingdom.

Data on age and sex were available for 76 cases from six countries (Figure 2). The age range of patients was 13 to 93 years, with a median of 78 years. The most affected age group was 75–84-year-olds (42.7%), followed by those aged ≥ 85 years (22.7%). There was no difference by sex.

Of 54 cases with known information, 52 (96.3%) were hospitalised and 17 cases have died due to or with *Listeria* infection in Austria (2), Belgium (1), Germany (12), Italy (1), and Sweden (1). The age range of fatal cases was 26 to 90 years (median 78). Of 12 Italian cases with known information, four developed meningitis and eight septicaemia.

Figure 2. Number of all confirmed cases of *L. monocytogenes* ST155 in the 'Omikron1' cluster by age and sex in six EU/EEA countries and the UK (n=76), as of 5 December 2023



Sources: Austria, Belgium, Germany, Italy, the Netherlands, and Sweden

Information from patient interviews

In **Germany**, four of five interviewed German cases reported consumption of RTE fish products within 14 days before illness. Of these, one case is from 2022.

In **Italy**, three of the five listeriosis cases reported in 2023 had consumed RTE fish products (smoked salmon) within 30 days before illness. One of these was a case who developed meningitis in July 2023 and reported consumption of a salmon product (Product J) prior to symptoms. No food history information was available for the other two cases reported in 2023.

In **the Netherlands**, the one case, to date, from 2023 reported consumption of fish products prior to disease onset.

Genetic sub-clusters of *L. monocytogenes* ST155, 'Omikron1'

In a centralised ECDC and EFSA One Health WGS analysis, 144 *L. monocytogenes* ST155 isolates met the EU case definition criteria, involving 90 human and 54 non-human isolates between 2011 and 2023. According to the European case definition for sub-clusters, five German and two Italian cases were added, and one duplicate isolate of a German case was counted only once, giving a total of 96 human cases. Of these, two isolates could not be assigned to any sub-cluster.

Further analysis of 144 *L. monocytogenes* ST155 isolates (plus five German and two Italian cases) revealed three sub-clusters covering 94 human cases in sub-cluster 1 (n=64), sub-cluster 2 (n=15), and sub-cluster 3 (n=15). The human isolates in sub-clusters varied by number of countries and temporal period, sub-cluster 1 being the only one still active in 2022–2023 (Figure 3). In terms of number of countries, the sub-cluster 2 had the broadest geographical spread with seven EU/EEA countries and the UK reporting cases between 2011 and 2021 (Figure 4), whereas sub-cluster 3 involved three countries with cases reported between 2016 and 2020 (Figure 5).

In sub-cluster 1, the 64 cases were reported in Austria (1), Belgium (12), Germany (34), Italy (15), and the Netherlands (2) between 2016 and 2023 (Figure 3). There were 17 cases reported in 2022–2023, all belonging to sub-cluster 1. Of these, one case was reported in Austria, one in Belgium, eight cases in Italy, six in Germany, and one in the Netherlands (Figure 3).

In sub-cluster 1, 10 fatal cases were reported: in 2019 (2), 2020 (5), and one each in 2021, 2022, and 2023. Of 10 fatal cases, eight were reported in Germany, and one each in Belgium and Italy. In sub-cluster 2, five fatal cases were reported: one in Sweden in 2011, two cases in Austria in 2013 and 2014, and two cases in Germany in 2020. In sub-cluster 3, one death was recorded in Germany in 2016.

In this ROA, the focus is on 'Omikron1' sub-cluster 1, which is ongoing with cases reported in 2022–2023, has several severe and fatal infections, and affects more than one country. The sub-clusters 2 and 3 seem to be historical at the time of this assessment.

Figure 3. Number of all confirmed cases of *L. monocytogenes* ST155 in the 'Omikron1' sub-cluster 1 by reporting country and year of statistics in five EU/EEA countries (n=64), as of 5 December 2023

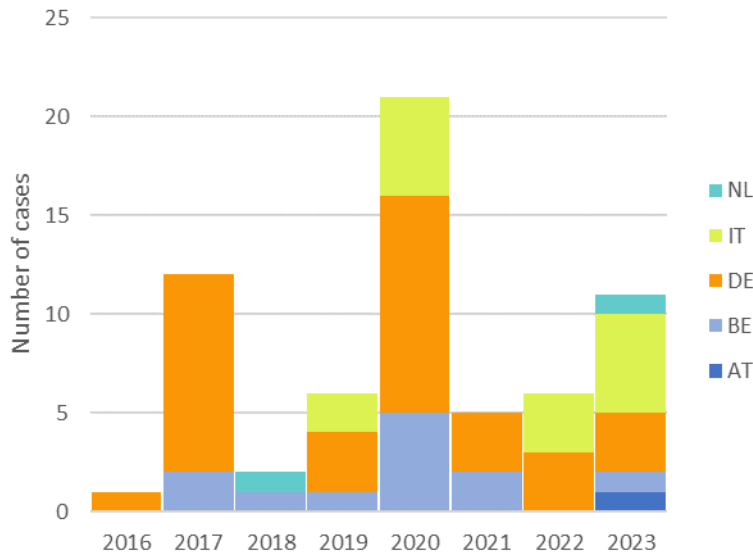


Figure 4. Number of all confirmed cases of *L. monocytogenes* ST155 in the 'Omikron1' sub-cluster 2 by reporting country and year of statistics in seven EU/EEA countries and the UK (n=15), as of 5 December 2023

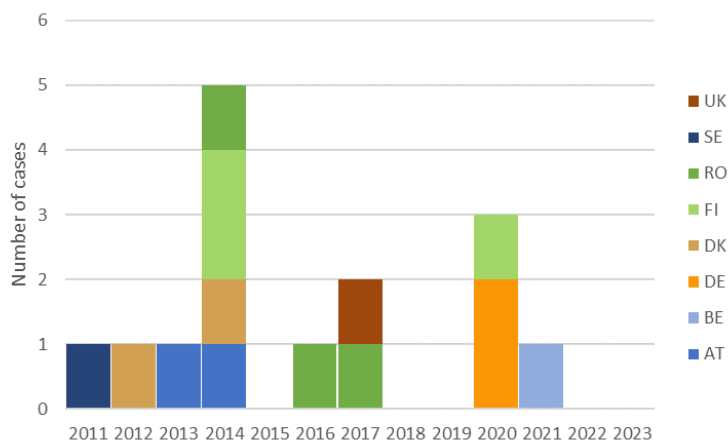
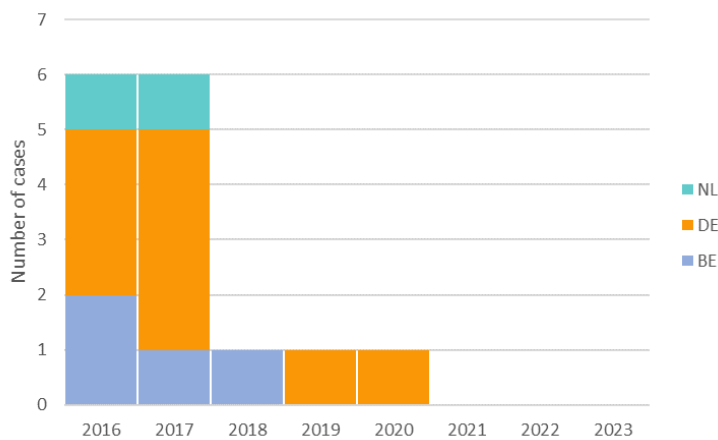


Figure 5. Number of all confirmed cases of *L. monocytogenes* ST155 in the 'Omikron1' sub-cluster 3 by reporting country and year of statistics in three EU/EEA countries (n=15), as of 5 December 2023



Microbiological and environmental investigations of food and control measures

Product J and Product C (RASFF notifications 2023.5976 and 2019.4292)

The following section refers to:

- three *L. monocytogenes*-positive smoked salmon RTE products, namely **Product J** from **Batch J** sampled in 2023, **Product J** from **Batch P** sampled in 2022, and **Product J** from **Batch N** sampled in 2018, microbiologically linked to the Epi-Pulse event 2020-FWD-00012 and 2023-FWD-00023 and reported in the notification RASFF 2023.5976 (5 EC validated follow up-*fup*, as of 27 November 2023).
- an historical *L. monocytogenes*-positive smoked salmon product sampled in 2016 (**Product C Batch C**) microbiologically linked to the Epi-Pulse event 2020-FWD-00012 and 2023-FWD-00023 and reported in the notification RASFF 2019.4292 (13 EC *fup*, as of 5 December 2023).

These smoked salmon RTE products were manufactured by the **Lithuanian Processing Plant C**.

A visual representation of their traceability is displayed in Figure 6.

Italy

Following the occurrence of a meningitis case due to *Listeria monocytogenes* ST155 infection in July 2023 in Italy, the food safety authority reported in RASFF (2023.5976) that two sampling units of the same smoked salmon RTE product (sealed packages) (**Product J**) collected chilled at the patient's home tested positive for *L. monocytogenes* ST155 (3 000 000 CFU/g and 820 000 CFU/g).

The two smoked salmon products were collected on 7 August 2023 and belonged to **Batch J** with expiring date in July 2023. Three *Listeria* isolates were detected and whole genome sequenced, and the cluster analysis performed at national level showed a genetic similarity with the isolate from the Italian case (sub-cluster 1) (2023.5976).

As part of the national investigation, the food safety authority performed an official sampling (17 August 2023) at the retailer (Retailer A) where the case had purchased the smoked salmon products on 12 July 2023. A sample of Product J belonging to another batch (Batch K) was collected chilled and tested negative for *L. monocytogenes*.

Products J Batch J and Batch K were manufactured by the Lithuanian Processing Plant C with salmon from Norway (salmon origin available in RASFF only for Batch K) and distributed in Italy by the Italian Wholesaler A.

In addition, the food safety authority informed that **Product J** from **Batch P** sampled at wholesale level (Wholesaler D) in November 2022 tested positive for the matching *L. monocytogenes* ST155 (<10 CFU/g) (sub-cluster 1 and sub-cluster 2). Product J Batch P was manufactured by the Lithuanian Processing Plant C with salmon from Norway and distributed in Italy by the Italian Wholesaler A (*fup5*, 2023.5976).

On 20 November 2023, the food safety authority also informed that an historical *L. monocytogenes*-positive smoked salmon product (sealed package of **Product J Batch N**) sampled chilled in 2018 (official sample) tested positive for the matching *L. monocytogenes* ST155 (sub-cluster 1). Product J Batch N was collected on 7 May 2018 at retail level (Italian Retailer F), manufactured by the Lithuanian Processing Plant C with salmon from Norway, and distributed in Italy by the Italian Wholesaler A (*fup1*, *fup4* 2023.5976).

Lithuania

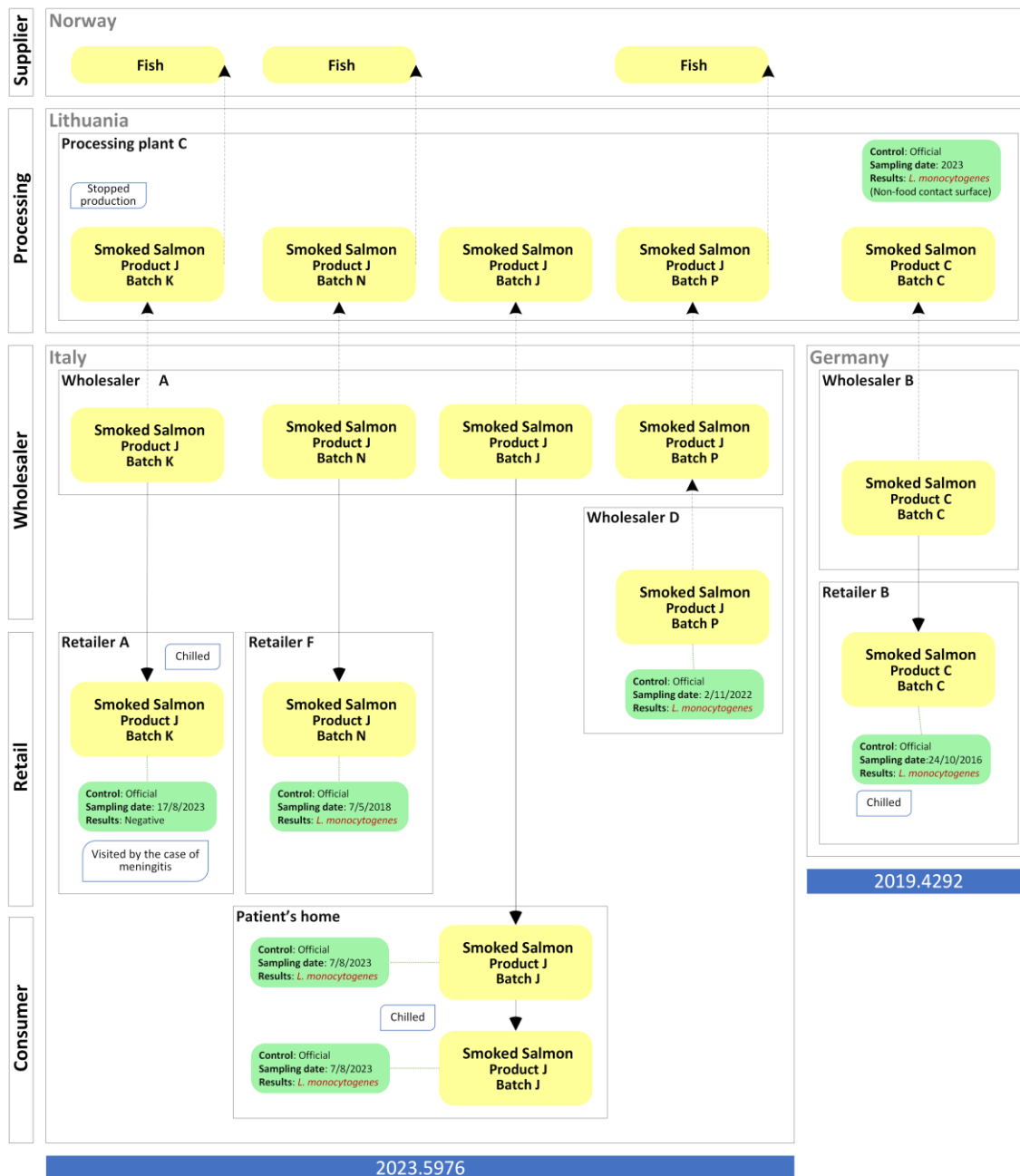
On 15 September 2023, following the outcome of the Italian investigation, the food safety authority informed that the Lithuanian Processing Plant C had stopped the production (*fup2*, 2023.5976). The food safety authority also informed that food (cold smoked salmon) and environmental samples were collected and tested for *Listeria*. *L. monocytogenes* was not detected in the food samples. One processing environment sample (non-food contact surface) tested positive for the matching *L. monocytogenes* ST155 (*fup3*, 2023.5976).

Germany

On 20 May 2020, the food safety authority in Germany reported in RASFF (2019.4292) that a chilled smoked salmon product (sealed package) (**Product C Batch C**) collected in October 2016 at retail level (German Retailer B) tested positive for *L. monocytogenes* ST155 (sub-cluster 1) (*fup4*, 2019.4292).

Product C Batch C was manufactured by the Lithuanian Processing Plant C and distributed in Germany by the German Wholesaler B (*fup4*, 2019.4292). Further traceability information was not available in RASFF.

Figure 6. Graphical representation of traceability and microbiological analysis of the *L. monocytogenes*-positive food (RTE smoked salmon Product J and Product C), as reported by the countries involved under RASFF notifications 2023.5976 (5 EC validated follow up-*fup*, as of 27 November 2023) and 2019.4292 (13 EC *fup*, as of 5 December 2023)



L. monocytogenes in red= *L. monocytogenes* ST155 cluster 'Omikron1' according to the national cluster analysis

Product G, Product A, and Product K (RASFF notification 2019.4292)

The following section refers to:

- a *L. monocytogenes*-positive smoked salmon RTE product sampled in 2023 (**Product G Batch G**) microbiologically linked to the Epi-Pulse event 2023-FWD-00023 and 2020-FWD-00012 and reported in the notification RASFF 2019.4292 (13 EC *fup*, as of 5 December 2023).
- an historical *L. monocytogenes*-positive smoked salmon product sampled in 2017 (**Product K Batch M**) microbiologically linked to the Epi-Pulse event 2023-FWD-00023 and 2020-FWD-00012 and reported in the notification RASFF 2019.4292 (13 EC *fup*, as of 5 December 2023).
- an historical *L. monocytogenes*-positive smoked salmon product sampled in 2016 (**Product A Batch A**) microbiologically linked to the Epi-Pulse event 2020-FWD-00012 and reported in the notification RASFF 2019.4292 (13 EC *fup*, as of 5 December 2023) is described too.

These smoked salmon RTE products were manufactured by **Lithuanian Processing Plant A**.

A visual representation of their traceability is displayed in Figure 7.

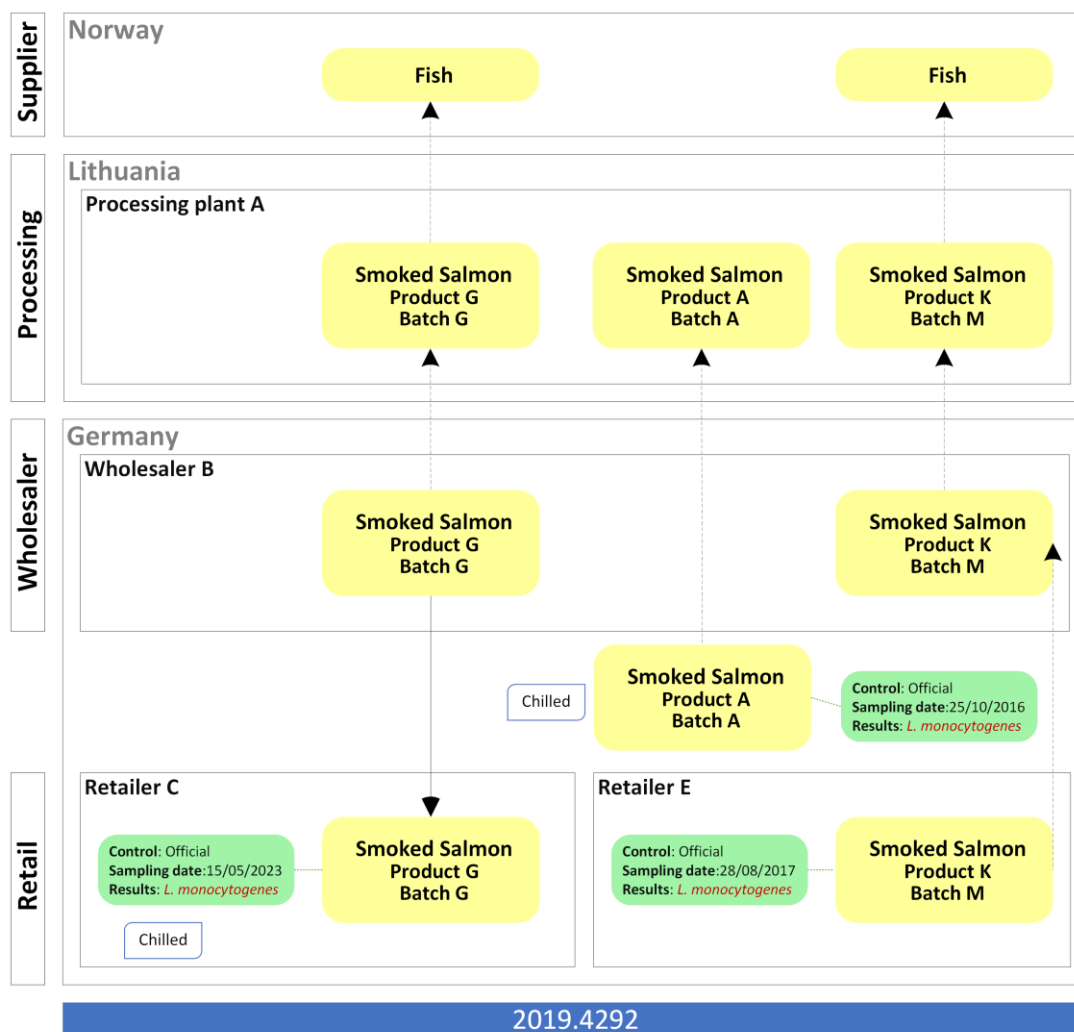
Germany

On 18 September 2023, the food safety authority in Germany reported in RASFF (2019.4292) that an official sample of chilled smoked salmon (sealed package) (**Product G Batch G**) tested positive for *L. monocytogenes* ST155 matching the German representative human strain (sub-cluster 1) (*fup11*, 2019.4292). The sample was collected in May 2023 at retail level (German Retailer C). Product G Batch G was manufactured by the Lithuanian Processing Plant A with salmon from Norway and distributed in Germany by the German Wholesaler B (*fup11*, 2019.4292).

Earlier, the food safety authority reported in RASFF (2019.4292) that a matching isolate of *L. monocytogenes* ST155 (sub-cluster 3) was also detected in an official sample of chilled smoked salmon product (**Product A Batch A**) (sealed package) collected on 25 October 2016. Also, Product A Batch A was manufactured by the Lithuanian Processing Plant A (RASFF 2019.4292). Further information including the place of sampling and traceability was not available from RASFF.

Later, an official sample of smoked salmon product (**Product K Batch M**) (sealed package) was collected on 28 August 2017 and tested positive for the matching *L. monocytogenes* ST155 ('Omikron1' cluster) on 4 November 2019. The sample was collected at retail level (German Retailer E). Product K Batch M was manufactured by the Lithuanian Processing Plant A with salmon from Norway and distributed in Germany by the German Wholesaler B (*fup13*, RASFF 2019.4292).

Figure 7. Graphical representation of traceability and microbiological analysis of the *L. monocytogenes*-positive food (RTE smoked salmon Product G, Product A, and Product K), as reported by the countries involved under RASFF notification 2019.4292 (13 EC *fup*, as of 5 December 2023)



L. monocytogenes in red= *L. monocytogenes* ST155 cluster 'Omikron1' according to the national cluster analysis

Product B, Product H, and Product I (RASFF notifications 2019.4292 and 2021.4990)

The following section refers to:

- an historical *L. monocytogenes*-positive smoked salmon RTE product sampled in 2017 (**Product B Batch B**)
- an historical *L. monocytogenes*-positive smoked salmon RTE product sampled in 2020 (**Product H Batch H**)
- an historical *L. monocytogenes*-positive smoked salmon RTE product sampled in 2020 (**Product I Batch I**).

These smoked salmon RTE products are microbiologically linked to the Epi-Pulse event 2020-FWD-00012 and reported in the notification RASFF 2019.4292 (13 EC *fup*, as of 5 December 2023) and 2021.4990 (2 EC validated *fup*, as of 18 October 2021). These smoked salmon RTE products were manufactured by **Lithuanian Processing Plant B**.

A visual representation of their traceability is displayed in Figure 8.

Germany

Within a national investigation on a cluster of human infections (2016-2019) caused by *L. monocytogenes* ST155, the food safety authority reported (RASFF 2019.4292) that a matching isolate of *L. monocytogenes* ST155 (sub-cluster 3) was detected in an official sample of a chilled smoked salmon product (**Product B Batch B**) (sealed package) collected on 13 July 2017. Product B Batch B was manufactured by the Lithuanian Processing Plant B with salmon from Norway. Additional sampling information including the place of sampling and traceability information was not available from RASFF.

Lithuania

Following the information shared in December 2019 by Germany with regard to Product B Batch B, on 2 January 2020 the food safety authority in Lithuania reported in RASFF the outcome of an official control performed at Lithuanian Processing Plant B that had manufactured the product. According to the food safety authority, the results of the own-check sampling in 2018 – 2019 (samples from manufactured products and food processing environment) and of the shelf-life studies complied with the requirements of the legislation (*fup1*, 2019.4292).

Belgium

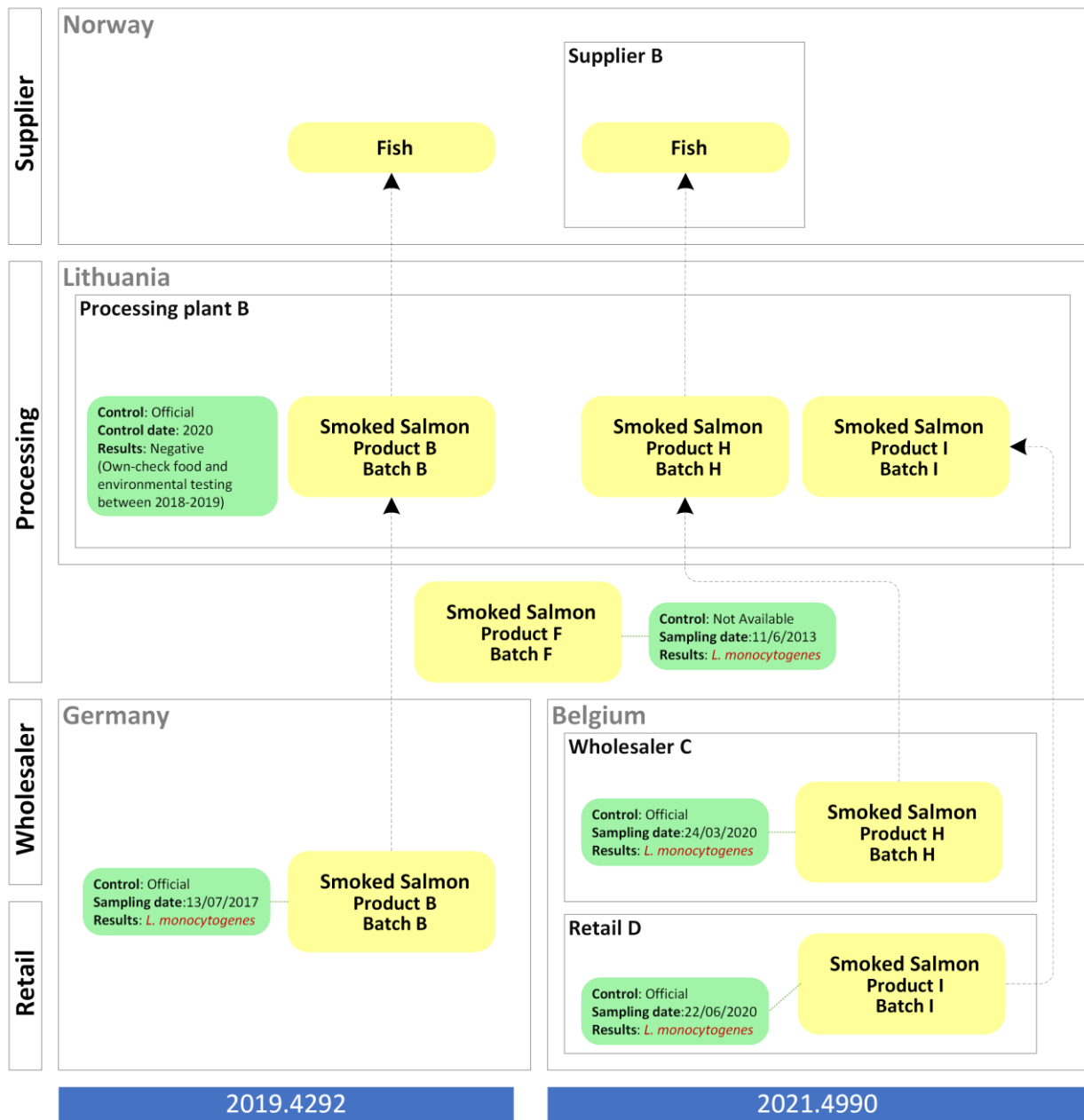
In the frame of a national research project, three historical *L. monocytogenes* food isolates from smoked salmon products were found to match the German *L. monocytogenes* ST155 representative human strain ('Omikron1' cluster) (RASFF 2021.4990). On 17 September 2021 the food safety authority in Belgium reported in RASFF the traceability information of two out of the three historical food isolates mentioned above. The two isolates were collected from two smoked salmon products (Product H Batch H and Product I Batch I) (*fup2*, 2021.4990). The remaining food isolate was detected from the smoked salmon Product F Batch F.

Product H Batch H was collected on 24 March 2020 at wholesale level (Wholesaler C) and tested positive for *L. monocytogenes* ST155 with less than 40 CFU/g (sub-cluster 1). This smoked salmon product was manufactured for the Belgian Processing Plant E by the Lithuanian Processing Plant B with salmon from Norway (Norwegian Supplier B) (*fup2*, 2021.4990).

Product I Batch I was collected on 22 June 2020 at retail level (Belgian Retailer D) and tested positive for *L. monocytogenes* ST155 with 80 CFU/g (sub-cluster 1). This smoked salmon product was manufactured for the Belgian Processing Plant F by the Lithuanian Processing Plant B (*fup2*, 2021.4990).

Product F Batch F was collected on 11 June 2013 at processing level and tested positive for *L. monocytogenes* ST155 with less than 10 CFU/g (sub-cluster 3). The plant was not available in RASFF, however the food safety authority informed that this plant is not active since 2019. Further traceability information was not available in RASFF.

Figure 8. Graphical representation of traceability and microbiological analysis of the *L. monocytogenes*-positive food* (RTE smoked salmon Product B, Product H, and Product I), as reported by the countries involved under RASFF notifications 2019.4292 (13 EC *fup*, as of 5 December 2023) and 2021.4990 (2 EC validated *fup*, as of 18 October 2021)



L. monocytogenes in red = *L. monocytogenes* ST155 cluster 'Omikron1' according to the national cluster analysis

* An additional food product (smoked salmon manufactured by the Lithuanian Processing Plant B) was collected in 2020 in France at retail level and tested positive for *L. monocytogenes* ST155 (sub-cluster 1) (RASFF 2020.2970) (Table 2, Annex 2).

Annex 1 describes the traceability of RTE fish products sampled in 2020 and reported to be positive for *L. monocytogenes* ST155 (sub-cluster 2).

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

ECDC performed an active case finding exercise inviting countries to report sequences of *L. monocytogenes* isolates matching within seven ADs to at least one of the two representative German outbreak strains. Publicly available isolates matching the criteria were retrieved from ENA. By 28 November 2023, 90 sequences of human isolates were matching the EU case definition in a centralised WGS analysis from nine EU/EEA countries and the UK. Sequences of cases' isolates were available from Austria (3), Belgium (17), Denmark (2), Finland (3), Germany (43, including one duplicate), Italy (13), the Netherlands (4), Romania (3), Sweden (1), and the UK (1).

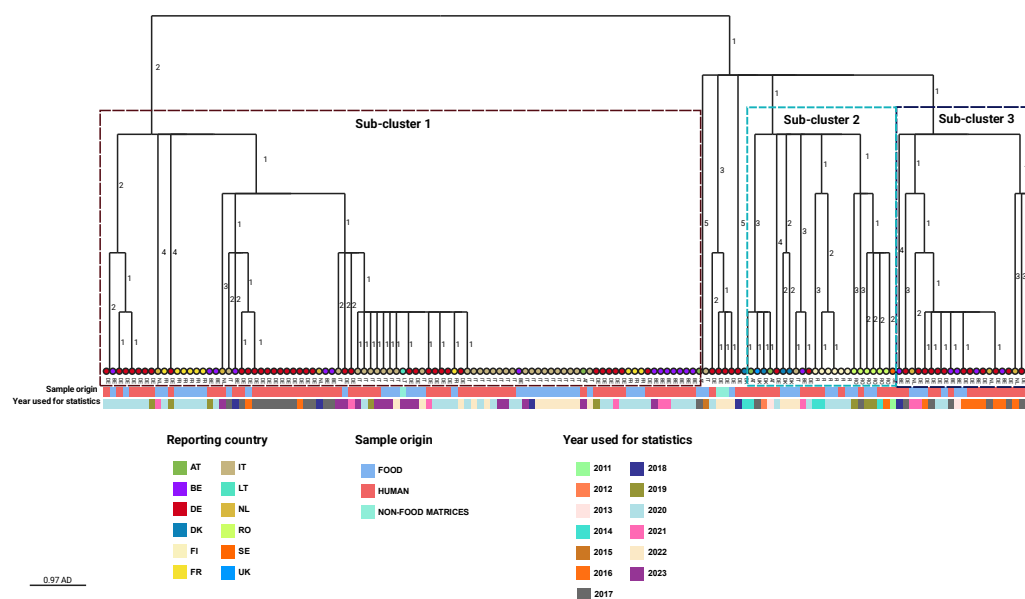
EFSA launched different calls for data since July 2023, inviting all EU and EEA Member States to submit genomic information to the EFSA One Health WGS System regarding *L. monocytogenes* ST155 ('Omikron1' cluster) food isolates collected between 2020 and 2023, focusing on isolates collected from RTE fish products. By 27 November 2023, a total of 1125 profiles of *L. monocytogenes* non-human isolates had been successfully shared in the EFSA One Health WGS system by 26 EU/EEA countries.

For cross-sectoral analysis, the cgMLST single-linkage analysis was performed by ECDC and by EFSA as previously described [5]. 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 has < 1% missing loci (< 17 missing loci over a total of 1748 loci).

ECDC sought matches in the EFSA One Health WGS System on 27 November 2023, using 90 reference genomes of *L. monocytogenes* ST155 isolated from human cases belonging to cluster 'Omikron1'. As a result of the queries, 54 submitted profiles of *L. monocytogenes* ST155 non-human isolates (51 food and three environmental) clustered within seven ADs in a single-linkage cluster analysis with the human isolates, giving a total of 144 *L. monocytogenes* ST155 isolates in the joint isolate dataset, including one duplicate isolate from a case in Germany. Countries sharing non-human data matching the outbreak strain and included in the centralised analysis were consulted for validation of the genomic data. The samples related to the 54 non-human isolates were collected between 2015 and 2023 from Austria, Belgium, Germany, Denmark, Finland, France, Italy, Lithuania, the Netherlands, and Romania. Epidemiological information submitted to the EFSA One Health WGS system indicated as country of origin of the food samples positive for the 'Omikron1' *L. monocytogenes* the following countries: Estonia, Germany, Lithuania, Poland, and Romania. Details of the non-human isolates are available in Annex 2.

The cross-sectoral WGS analysis revealed three sub-clusters at maximum four ADs (see above 'Genetic sub-clusters of *L. monocytogenes* ST155') (Figure 9). Of these, only sub-cluster 1 was still active with human cases and non-human isolates reported in 2022-2023. Thus, the focus of this risk assessment is on this active sub-cluster 1.

Figure 9. Overview of the three genetic sub-clusters of *L. monocytogenes* ST155 isolates in the cluster 'Omikron1' at a maximum four allelic differences in a single-linkage tree (n=144*), as of 5 December 2023



*Including one duplicate isolate from a case in Germany.

Available at: <https://microreact.org/project/5BrqNREs9rU2faXEPUVb5Z-roa2023-fwd-00023listeriosisomikron1>

Analysis of active sub-cluster 1

The cross-sectoral, centralised WGS analysis with available sequences for sub-cluster 1 consisted of 92 *L. monocytogenes* ST155 isolates, of which 58 were from humans (one duplicate), 33 from food and one from processing environment (non-food matrices). Based on national WGS analysis, five German and two Italian cases were added to sub-cluster 1 and of the duplicate isolates, only one was included in the descriptive analysis (Figure 10). A detailed single-linkage tree of sub-cluster 1 with available sequences is presented in Figure 11.

Figure 10. Distribution of *L. monocytogenes* ST155 isolates/cases in sub-cluster 1 of 'Omikron1' by sample origin and year of statistics (n=98), as of 5 December 2023

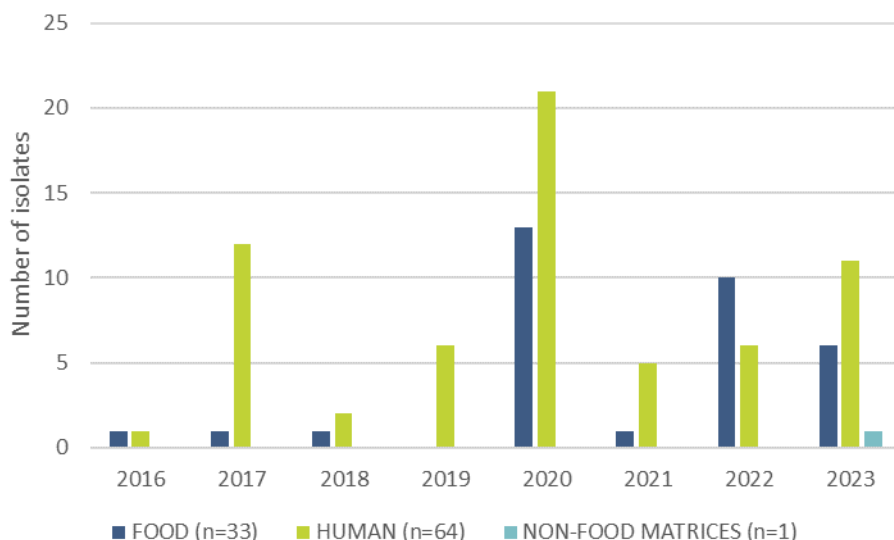
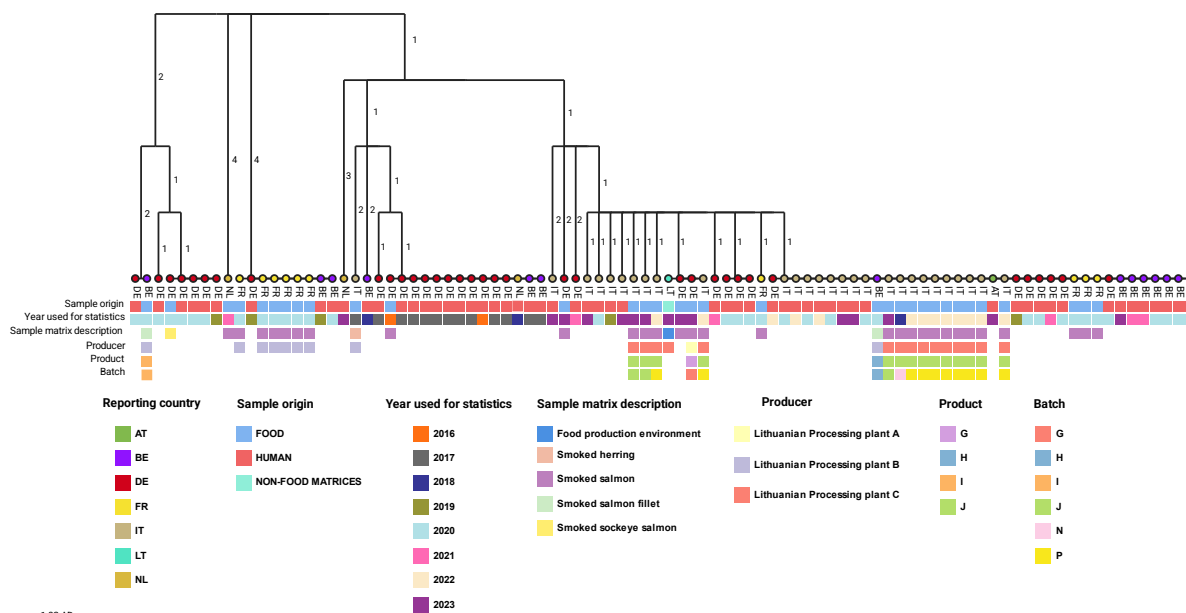


Figure 11. cgMLST-based single-linkage tree of *L. monocytogenes* ST155 isolates in sub-cluster 1 of 'Omikron1' by country, sample origin, year of statistics, sample matrix description, producer, product, and batch (n=92*), as of 28 November 2023



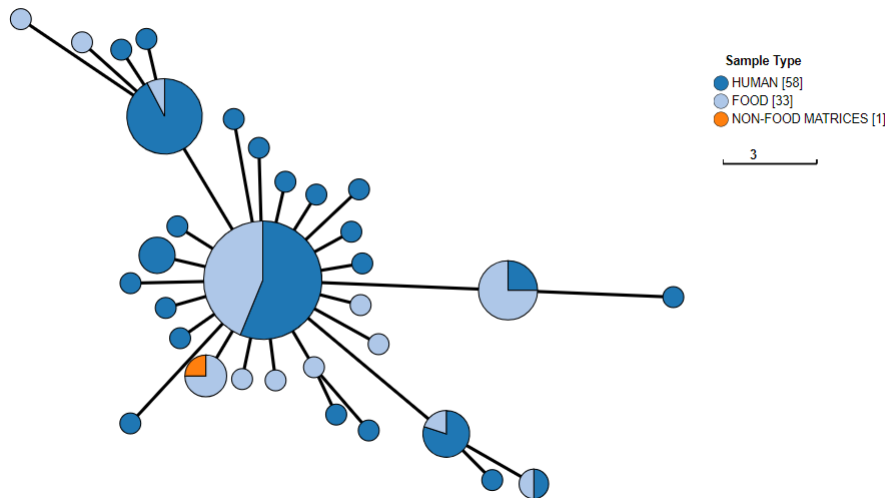
*Including one duplicate isolate from a case in Germany.

Available at: <https://microreact.org/project/5BrqNREs9rU2faXEPUVb5Z-roa2023-fwd-00023listeriosisomikron1>

The joint WGS analysis indicates that sub-cluster 1 of 'Omikron1' has been active since 2016 with a peak in reported human listeriosis cases and detected non-human *L. monocytogenes* ST155 isolates in 2020 (Figure 10). Most recent isolations in non-human samples have been linked to producers A (one in 2023) and C (10 in 2022 and four in 2023). Most recent human isolates in sub-cluster 1 (17) are from Austria (1), Belgium (1), Germany (6), Italy (8), and the Netherlands (1) in 2022-2023.

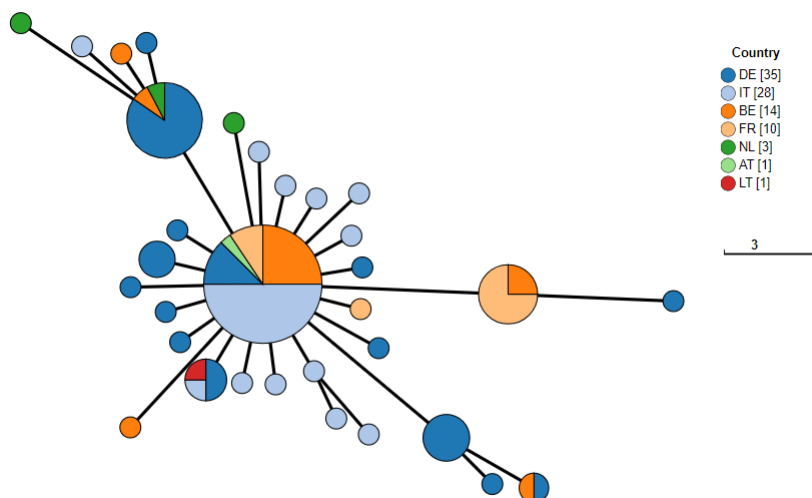
The minimum spanning trees of *L. monocytogenes* ST155 isolates from human and non-human samples show genetic closeness between human and non-human isolates (Figure 12) as well as across countries (Figure 13).

Figure 12. cgMLST-based minimum spanning tree of human and non-human *L. monocytogenes* ST155 isolates in sub-cluster 1 of 'Omikron1' by source (n=92*), as of 28 November 2023



*Including one duplicate isolate from a case in Germany.

Figure 13. cgMLST-based minimum spanning tree of human and non-human *L. monocytogenes* ST155 isolates in sub-cluster 1 of 'Omikron1' by reporting country (n=92*), as of 28 November 2023



*Including one duplicate isolate from a case in Germany.

ECDC and EFSA risk assessment for the EU/EEA

A genomic cluster of *Listeria monocytogenes* ST 155, serogroup IIa, infections has been identified in the EU/EEA and the UK. Based on genomic similarity, the cluster can be divided into three sub-clusters, of which sub-cluster 1 is the only sub-cluster for which cases continue to be reported, with 64 cases reported in five EU/EEA countries in 2016–2023. The sub-clusters 2 and 3 are historical with altogether 30 human cases reported in 2011–2021. Of 64 cases in sub-cluster 1, 17 (26.6%) were reported in 2022–2023. Of these, one case was reported in Austria, one in Belgium, eight cases in Italy, six in Germany, and one in the Netherlands. In sub-cluster 1, 10 (15.6%) fatal cases were reported in 2019 (2), 2020 (5), and one each in 2021, 2022, and 2023. The case fatality rate is similar to the reported background data of *L. monocytogenes* serogroup IIa infections in 2018–2022 (Annex 3). Based on case interviews and national investigations, RTE fish products have been implicated as vehicles of infection.

Extensive national investigation in Germany, including cases in the cluster 'Omikron1', pointed contaminated smoked and 'gravad' (cured) salmon products as a serious risk for *Listeria* infections in humans [1]. For this assessment, limited detailed exposure information was available: eight of 11 interviewed cases in 2022–2023 confirmed consumption of RTE fish products (salmon) within 14–30 days prior to illness. One of these was an Italian case of meningitis in July 2023 reporting consumption of salmon products before illness. Retrieving a food history, covering 30 days before symptom onset, from severely ill elderly persons is difficult and subject to significant recall bias. Therefore, consumption history can be considered as supportive information. Quantitative modelling performed by EFSA has suggested that about 90% of invasive human *L. monocytogenes* infections are caused by ingestion of RTE food containing > 2 000 CFU/g and one third of cases are due to growth of *Listeria* at consumers' phase [6]. *Listeria* growth at chilled temperatures implicates that even initial low-level contamination prior to refrigeration may pose a risk for infections, particularly for immunosuppressed and elderly persons.

Overall, the national investigations, traceability analysis, and call for genomic data revealed the detection of 54 *L. monocytogenes* isolates clustering with the two outbreak reference genomes of 'Omikron1' from 31 fish products (34 isolates from 12 fish products within sub-cluster 1) and three isolates clustering with the two outbreak reference genomes of 'Omikron1' from fish processing environments (one within sub-cluster 1). Epidemiological and microbiological data from food and environmental samples revealed the occurrence of the outbreak strains of 'Omikron1' in some fish processing plants over the years 2015–2023.

Within the active sub-cluster 1, there were 6 RTE fish products manufactured by three processing plants sited in Lithuania (Processing Plant C, fish products positive in 2023, 2022, and 2018; Processing Plant B fish products positive in 2020, 2017; and Processing Plant A, a fish product positive in 2023). The manufacturer was not available for the remaining 6 fish products testing positive between 2016–2023. There is one environmental sample, within sub-cluster 1, obtained from a non-food contact surface sampled at the Processing Plant C in 2023. Out of the three processing plants implicated, the sequence-based analysis with higher resolution (maximum four ADs) indicates the presence of two known active sources of contaminated fish products in Lithuania, Processing Plant A (2023) and Processing Plant C (2018–2023). In 2022 and 2023, contaminated fish products from these two processing plants had reached the retail market in Germany and in Italy, but there was no information on the distribution of those products to the other countries where human cases have been reported (namely Austria, Belgium, and the Netherlands).

The detection in 2023 of the sub-cluster 1 strain from a sealed chilled RTE salmon product (Product J Batch J) collected from the fridge of the Italian case of meningitis and manufactured in the Processing Plant C pointed towards the Lithuanian company (Processing Plant C) as the source of infection for the case of meningitis in Italy. The recurrent detection of the sub-cluster 1 strain from sealed RTE fish products in the EU countries and environmental samples revealed the persistence of the strain in at least the Processing Plant C over the years 2016–2023.

The possible common origin of the contamination with the sub-cluster 1 strain in the involved plants is suggested by the microbiological data but needs further investigation of the suppliers of the incoming raw materials of the RTE fish products positive in 2022 and 2023. The identification of the origin of the contamination will allow the implementation of targeted control measures and mitigation actions. Moreover, further efforts should be done for targeted sampling around the production of fish products and environmental sites to identify the point(s) of contamination.

The interruption of production in Processing Plant C is likely to reduce the likelihood of infections but new cases are expected to occur in the EU/EEA countries, particularly among vulnerable persons (immunosuppressed and elderly), until all the sources and sites of contaminations are properly controlled.

In general, following of the HACCP (Hazard Analysis Critical Control Points) principles, the good hygiene practices and of the good manufacturer practices within the whole food supply chain can reduce the risk of contamination. Ensuring refrigerator temperatures, exercising proper handling, and refraining from consuming food past its expiration date can further reduce the risk of infection.

Recommendations and options for response

- Member States are encouraged to share sequences of human *L. monocytogenes* isolates with ECDC as part of the EU/EEA-wide WGS-enhanced listeriosis surveillance. ECDC can provide sequencing support for recently isolated human *L. monocytogenes* strains.
- Member States are invited to update the event 2023-FWD-00023 in EpiPulse should new cases continue to be reported.
- Member States 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.
- Member States are invited to share the sequence of the *L. monocytogenes* ST155 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* ST155 isolates from any kind of food, feed, animal and related environment to the EFSA One Health WGS System.
- Member States are invited to share in RASFF the outcome of their investigations to identify the sources and the point(s) of contamination.

Source and date of request

ECDC sent a request to EFSA on 18 August 2023 to produce a Joint ROA. EFSA accepted the request on 18 August 2023.

Consulted experts and national contact points

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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.

Annex 1. Trace-back analysis, products D and E

Product D, and Product E (RASFF notification 2020.3822)

The following section refers to:

- two historical *L. monocytogenes*-positive smoked and 'gravad' (cured) rainbow trout RTE products sampled in 2020 (**Product D Batch D** and **Product E Batch E**) microbiologically linked to the Epi-Pulse event 2020-FWD-00012 and reported in the notification RASFF 2020.3822 (7 EC *fup*, as of 15 October 2021).

These rainbow trout RTE products were manufactured in Estonia (**Estonian Processing Plant D**).

A visual representation of their traceability is displayed in Figure 14.

Finland

Within a national investigation on a cluster of human infections (2014–2020) caused by *L. monocytogenes* ST155, the food safety authority reported (RASFF 2020.3822) that two matching food isolates of *L. monocytogenes* ST155 were detected in June 2020 in Finland (places of sampling not available) from own-check samples of a chilled sliced cold-smoked rainbow trout (**Product D Batch D**) (sub-cluster 2) and of a chilled sliced 'gravad' (cured) rainbow trout (**Product E Batch E**) (sub-cluster 2).

Product D Batch D and Product E Batch E had been manufactured by the Estonian Processing Plant D which was supplied with raw materials (trout fillets) by the intermediate Finnish Supplier C (*fup2*, *fup3*, 2020.3822).

Estonia

Following the national investigations in Finland, the food safety authority in Estonia reported in RASFF that the two positive trout products (Product D Batch D and Product E Batch E) manufactured at the Estonian Processing Plant D were sliced on different slicing lines.

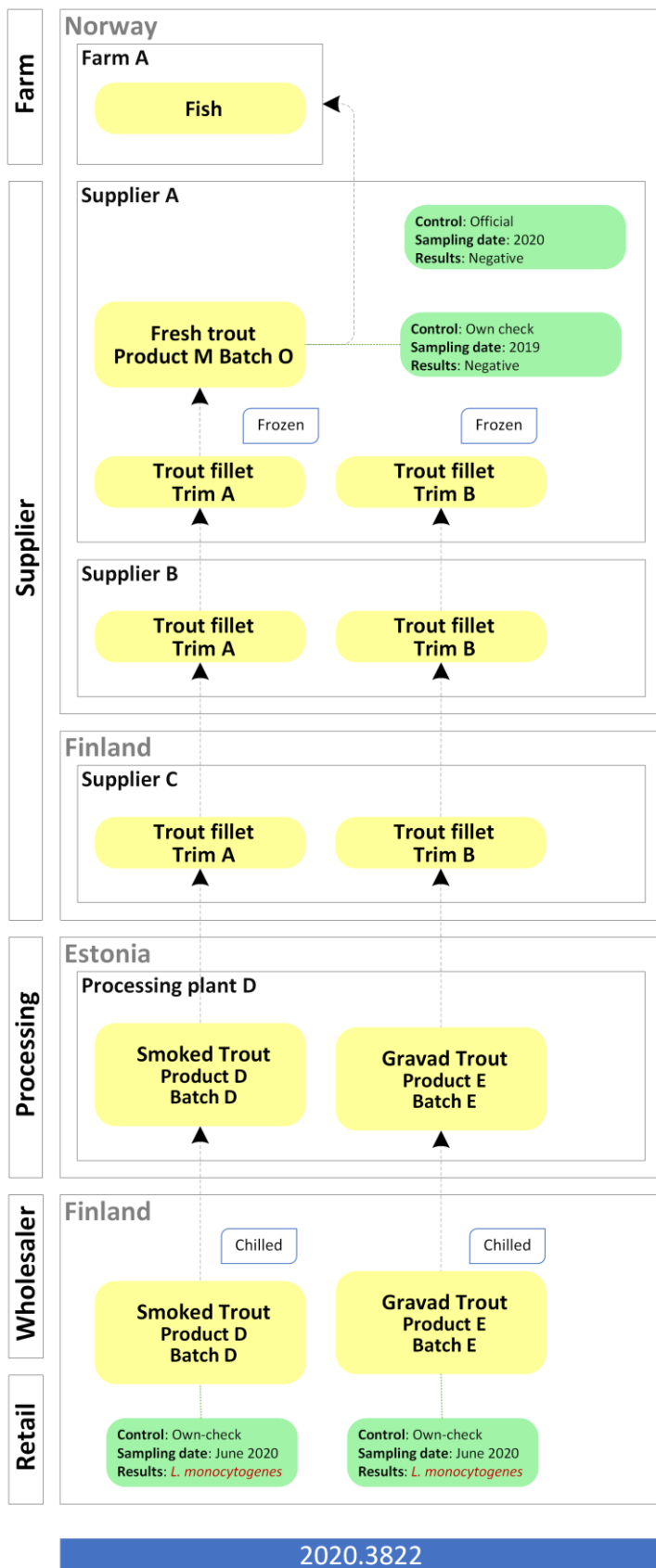
Trim A and Trim B (frozen rainbow trout fillets) were used as raw materials to produce Product D Batch D and Product E Batch E, respectively. Both Trim A and Trim B originated from the Norwegian Supplier A. The Estonian Processing Plant D had received both trims (Trim A and B) from the Norwegian Supplier B via the intermediate Finnish Supplier C (*fup2*, *fup3*, 2020.3822).

The food safety authority informed that at the Estonian Processing Plant D the fillets are processed in one part of the production area (fillet department) and the final product is processed in another part of the production area (slicing department) – these rooms are separated from each other and there is no direct movement between the rooms (neither products nor people). On each day of production, the equipment and premises are cleaned and disinfected after the end of the working day. During production, after each break an intermediate disinfection of lines is carried out (*fup2*, 2020.3822).

Norway

On 13 October 2020, the food safety authority in Norway informed about the outcome of an official control performed at the Norwegian Supplier A that had supplied the raw materials (trout fillets Trim A and Trim B) used for the production of the positive trout products (*fup4*, 2020.3822). The Norwegian Supplier A produced the trout fillets (Trim A and Trim B) in September 2019 (*fup4*). Trim A was produced starting from fresh trout (Product M Batch O farmed at the Norwegian Farm A) and no detection of *L. monocytogenes* was reported in the fillets of trout and whole slaughtered trout (Product M Batch O) (*fup4*, 2020.3822). Information on Trim B was not available in RASFF. Five official samples (further information not available) were collected at the Norwegian Supplier A during the inspection in 2020 and tested negative for *Listeria* (*fup4*, 2020.3822).

Figure 14. Graphical representation of traceability and microbiological analysis of the *L. monocytogenes*-positive food (RTE smoked and 'gravad' (cured) rainbow trout Product D and Product E), as reported by the countries involved under RASFF notifications 2020.3822 (7 EC *fup*, as of 15 October 2021)



L. monocytogenes in red = *L. monocytogenes* ST155 cluster 'Omikron1' according to the national cluster analysis

Annex 2. Non-human isolates by sub-cluster

Table 2. Details of the epidemiological data by sub-clusters associated with the non-human profiles of the 54 *L. monocytogenes* ST155 isolates* matching the outbreak strain ('Omikron1' cluster) obtained from 32 samples collected in 10 EU countries

1 Sampling Country	Year	Sample matrix description	Sampling point	Processing plant	Product/ Batch (RASFF)	N. Isolates
Subcluster 1						
Belgium	2020	smoked salmon fillet		Lithuanian Processing Plant B	H/H (2021.4990)	1
Belgium	2020	smoked salmon fillet		Lithuanian Processing Plant B	I/I (2021.4990)	1
France	2020	smoked salmon	Retail			4
France	2020	smoked salmon	Retail	Lithuanian Processing Plant B	(2020.2970)	6
Germany	2016	smoked salmon				1
Germany	2023	smoked salmon		Lithuanian Processing Plant A	G/G (2019.4292)	1
Germany	2023	smoked salmon				1
Germany	2023	smoked salmon				1
Germany	2020	smoked sockeye salmon				1
Italy	2022	smoked salmon	Wholesaler	Lithuanian Processing Plant C	J/P (2023.5976)	10
Italy	2023	smoked salmon	Household	Lithuanian Processing Plant C	J/J (2019.4292) (2023.5976)	3
Italy	2018	smoked salmon	Storage	Lithuanian Processing Plant C	J/N (2019.4292) (2023.5976)	1
Italy	2017	smoked herring	Retail	Lithuanian Processing Plant B		1
Lithuania	2023	Food production environment	Fish processing	Lithuanian Processing Plant C		1
Netherlands	2021	smoked salmon	Retail			1
Subcluster 2						
Denmark	2022	fresh salmon				2
Finland	2020	chilled sliced 'gravad' (cured) rainbow trout		Estonian Processing Plant D	E/E (2020.3822)	2
Finland	2020	chilled sliced cold-smoked rainbow trout		Estonian Processing Plant D	D/D (2020.3822)	1
Italy	2022	smoked salmon	Wholesaler	Lithuanian Processing Plant C	J/P (2023.5976)	1
Romania	2019	chilled sliced smoked salmon	Fish processing			1

1 Sampling Country	Year	Sample matrix description	Sampling point	Processing plant	Product/Batch (RASFF)	N. Isolates
Romania	2019	chilled cold smoked salmon	Retail			1
Romania	2019	chilled cold smoked salmon	Industry sampling			1
Subcluster 3						
Belgium	2013	smoked salmon fillet			F/F	1
Germany	2016	smoked salmon			A/A**	1
Germany	2020	smoked salmon				1
Germany	2016	smoked salmon				1
Germany	2021	smoked salmon				1
Netherlands	2021	smoked salmon				1
Not assigned						
Austria	2022	Salmon				1
Germany	2022	smoked fish				1
Germany	2022	Food production environment				1
Germany	2022	Food production environment				1
Italy	2015	Smoked salmon	Retail			1

* On 4 December 2023, Germany informed that additional profiles were shared in the OH WGS System but were not included in the joint analysis. They belonged to isolates retrieved from Product B, Product C, and an additional food sample (without epidemiological data). Further analysis revealed that Product B belongs to sub-cluster 3 and Product C and the additional food sample belong to sub-cluster 1.

** On 4 December 2023, Germany provided further epidemiological data linking the shared profile to Product A.

Annex 3. Disease background

Disease characteristics

Background information about listeriosis can be found on the websites of ECDC, the US Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO) [1].

Surveillance of listeriosis in the EU/EEA

L. monocytogenes (serogroup IIa) isolation in humans

Listeriosis is a notifiable disease in the EU/EEA. Notification is mandatory in 29 countries, and voluntary in one. The surveillance systems of listeriosis have full national coverage in 28 EU/EEA countries. The EU case definition is used in 26 countries, whereas four (France, Germany, Italy, and Liechtenstein) use other, unspecified case definitions.

From 2018 to 2022, a total of 12 313 confirmed *L. monocytogenes* cases were reported to the European Surveillance System (TESSy) (mean number of cases per year 2 463, range from 1 928 to 2 772) by 30 EU/EEA countries. Although a decrease in the number of *L. monocytogenes* cases was observed in the EU/EEA in 2020 due to the COVID-19 pandemic, the overall trend for listeriosis between 2018 and 2022 did not show a significant decrease or increase.

During this period, *L. monocytogenes* serogroup IIa was the second most commonly reported serogroup (41%), from 382 to 442 cases per year reported by 16 EU/EEA countries. France, Germany and Sweden accounted for 39%, 22% and 10% of the reported of serogroup IIa cases, respectively. The median age of cases with information available was 75 years (interquartile range IQR=65–83). In the age group 15–44 years, a high proportion (75%) of cases were women and 65% of the infections with known data were pregnancy-associated. Overall case fatality of serogroup IIa cases was 16%. The majority (84%) of the fatal cases were in age group >65 years, and 55% of the cases in this age group were males. The majority (99%) of the cases were of domestic origin.

Further information can be found in ECDC's Annual epidemiological report [10] and the online *Surveillance atlas of infectious diseases* [11].

Food-borne outbreaks caused by *L. monocytogenes*

This section summarises country-specific data on food-borne outbreaks associated with *L. monocytogenes* from fish and fish products as reported between 2017 and 2021 to EFSA by the EU Member States and EFTA countries (Norway) in accordance with the Zoonoses Directive 2003/99/EC.

During these five years, overall, 14 foodborne outbreaks were caused by *L. monocytogenes* with overall 150 human cases reported, 70 hospitalisations, and 12 deaths.

Out of the 14 outbreaks, **13 strong-evidence foodborne** outbreaks were reported by **five EU Member States** namely, Austria (n=1), Denmark (n=3), Germany (n=1), the Netherlands (n=4), Sweden (n=2), and by Norway (n=2). There were overall 103 human cases reported, 68 hospitalisations, and 12 deaths. The reported food vehicles in details and when available included cold smoked salmon, smoked rainbow trout, trout fillet, eel, mackerel, salmon, and fermented fish.

In the same period, **one EU Member State** reported **one weak-evidence foodborne outbreak** caused by *L. monocytogenes* (Sweden, n=1). There were overall two human cases reported and two hospitalisations. The reported food vehicles in detail included salmon.

Occurrence of *L. monocytogenes* in ready-to-eat (RTE) fish

This section summarises country-specific data on the occurrence of *L. monocytogenes* for the matrix 'Food-RTE' for the category fish and fish products from 2017 to 2021 as reported to EFSA by the EU Member States and non-EU Member States in accordance with the Zoonoses Directive 2003/99/EC.

During these five years, an amount of 43 535 total units were tested for *Listeria* in fish and fish products as reported by 24 EU Member States (Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, France, Greece, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Poland, Portugal, Sweden, Slovenia, and Slovakia). There were 29 885 units tested only for the detection method, resulting in 1 319 units positive (4.41%) for *L. monocytogenes*. There were 21 359 units tested only for the enumeration method, resulting in 399 units positive (1.87%) with *L. monocytogenes* ≤ 100 UFC/g, and in 90 units positive (0.42%) with *L. monocytogenes* > 100 CFU/g.

Regarding the non-EU Member States (n=4, i.e., Iceland, Montenegro, Republic of North Macedonia, Serbia), an amount of 146 total units were tested for *Listeria* in fish and fish products. There were 110 units tested for the detection method, resulting in 5 units positive (4.55%) for *L. monocytogenes*. There were 36 units tested with the enumeration method that resulted in no units positive for *L. monocytogenes* \leq 100 CFU/g and *L. monocytogenes* $>$ 100 CFU/g.

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

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