



# Multi-country outbreak of *Listeria monocytogenes* sequence type 8 infections linked to consumption of salmon products

25 October 2018

## Conclusions

A multi-country outbreak of 12 listeriosis cases caused by *Listeria monocytogenes* sequence type (ST) 8 has been identified through whole genome sequencing (WGS) analysis in three EU/EEA countries: Denmark (6 cases), Germany (5) and France (1). Four of these cases have died due to or with the disease. It is likely that the extent of this outbreak has been underestimated since the outbreak was identified through sequencing and only a subset of the EU/EEA countries routinely use this advanced technique to characterise *L. monocytogenes* isolates. The first case was sampled in October 2015 in Denmark and the most recent case was reported in May 2018 in Germany.

In August 2017, Denmark identified the first cluster of cases, which was investigated and linked to the consumption of ready-to-eat cold-smoked salmon produced in Poland [1]. Control measures were implemented and the Member States and competent authorities were informed. In October 2017, France reported the identification of a matching *L. monocytogenes* strain in food isolates from marinated salmon originating from the same Polish processing company as identified in the Danish outbreak investigation. This supports the hypothesis that contamination may have occurred at the processing company in Poland. However, due to the lack of WGS data on the isolates found in the environmental and food samples taken at the Polish processing plant, it is not possible at present to confirm the contamination with the *L. monocytogenes* ST8 outbreak strain at the suspected Polish plant. Moreover, until detailed information on the Norwegian primary producers of the salmon used in the contaminated batches is reported and assessed, possible contamination at primary production level cannot be excluded either.

Although control measures were implemented following the Danish outbreak investigation in September 2017, the identification of the same strain in a salmon product in France and a new human case in Germany suggest that the source of contamination is still active and contaminated products have been distributed to other EU countries than Denmark. Until the source of infection has been eliminated, new invasive listeriosis cases may still occur. Pregnant women, the elderly and immunocompromised individuals are at increased risk of invasive listeriosis, which is associated with severe clinical course and potentially death.

## Options for response

Competent authorities are encouraged to report new human cases associated with this event and the findings of public health investigations to the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD) and consider interviewing new and recent listeriosis cases that are possibly related to this event about the consumption of ready-to-eat salmon products.

ECDC is supporting WGS analysis of human *L. monocytogenes* isolates from cases possibly related to this outbreak and reported in countries that are not routinely performing WGS. Since the European case definition of this outbreak is also based on the ECDC cgMLST pipeline, ECDC suggests that countries with sequenced isolates share with ECDC *L. monocytogenes* sequences differing by a maximum of 15 alleles from the representative outbreak strains (available in EPIS-FWD) to increase the sensitivity for finding isolates possibly linked to this outbreak (i.e. within 7 cgMLST allelic differences [7] from any other outbreak isolate part of the multi-country outbreak).

The European Union Reference Laboratory for *L. monocytogenes* (EURL-*Lm*) is providing support to Member States that do not have WGS capacity to perform WGS analysis of non-human isolates for strains possibly related to this outbreak. In order to identify the source of contamination, the involved Member States are advised to carry out environmental and food sampling and testing at critical sites along the production lines in processing plant and primary production facilities.

Competent public health and food safety authorities in affected EU countries should share information at the European level on epidemiological, microbiological and environmental investigations (including tracing information) and issue relevant notifications using the Early Warning and Response System (EWRS)<sup>1</sup> and Rapid Alert System for Food and Feed (RASFF)<sup>2</sup>.

## Source and date of request

ECDC proposed producing this Rapid Outbreak Assessment (ROA) to EFSA on 19 September 2018 and the proposal was accepted by EFSA on 24 September 2018.

## Public health issue

This document provides an assessment of the cross-border public health risk related to this outbreak of *L. monocytogenes* infections linked to consumption of salmon.

## Consulted experts

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- European Union Reference Laboratory for *Listeria monocytogenes* (EURL-*Lm*): Benjamin Felix, Jean-Charles Leblanc.

Public health external experts representing national authorities (in alphabetical order of countries):

- Denmark: Susanne Schjørring, Luise Müller (Staten Serum Institut)
- France: Mathieu Tourdjman (Santé publique France), Alexandre Leclercq, Mylène Maury, Marc Lecuit (Institut Pasteur)
- Germany: Sven Halbedel, Alexandra Holzer (Robert Koch Institut).

RASFF contact points in Denmark, France, Germany, Norway and Poland were consulted by EFSA to clarify and validate their national data on food and environmental investigations.

<sup>1</sup> EWRS is a rapid alert system for notifying alerts at EU level in relation to serious cross-border threats to health of biological, chemical, environmental or unknown origin. EWRS enables the European Commission and competent authorities of the Member States to be in permanent communication for the purposes of alerting, assessing public health risks and determining measures that may be required to protect public health. National competent authorities should notify an alert in EWRS when the development or emergence of a serious cross-border threat to health fulfils the criteria listed in Article 9 of Decision 1082/2013/EU.

<sup>2</sup> RASFF is the official EU system for sharing information on hazards found in food and feed, trade of potentially contaminated batches between Member States and tracing of such batches. RASFF notifications should be completed with information on exposure to food for related human cases, as well as traceability information on the suspected food vehicles and analytical results to support traceability investigations.

## Disclaimer

ECDC issued this outbreak assessment document in accordance with Article 10 of Decision No 1082/13/EC and Article 7(1) of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC), and with the contribution of EFSA 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 (EFSA) and laying down procedures in matters of food safety.

In the framework of ECDC's mandate, the specific purpose of an ECDC-EFSA outbreak assessment is to present different options on a certain matter, with their respective advantages and disadvantages. The responsibility on the choice of which option to pursue and which actions to take, including the adoption of mandatory rules or guidelines, lies exclusively with EU/EEA Member States. In its activities, ECDC strives to ensure its independence, high scientific quality, transparency and efficiency.

This report was written under the coordination of an internal response team at ECDC, with contributions from EFSA, at the behest of the European Commission based on a mandate requesting scientific assistance from EFSA in the investigation of multinational food-borne outbreaks (Ares (2013) 2576387, Mandate M-2013-0119, 7 July 2013).

All data published in this rapid outbreak assessment are correct to the best of our knowledge on 22 October 2018. Maps and figures published do not represent a statement on the part of ECDC, EFSA or its partners on the legal or border status of the countries and territories shown.

## Disease background information

### *Listeria monocytogenes* isolation in humans

From 2013 to 2017, between 1 905 and 2 527 listeriosis cases have been reported to TESSy annually by 30 EU/EEA countries [2]. Germany, France and Spain accounted for 26%, 17% and 10% respectively of the reported cases in this period. Severe *L. monocytogenes* infections were more common in males (54%) and among persons over 65 years of age (65% of cases) in both genders. The majority of the cases (98%) were of domestic origin [3].

Background information about listeriosis can be found in disease fact sheets from ECDC, CDC and WHO [4,6].

### Foodborne outbreaks caused by *Listeria monocytogenes*

This section presents information on foodborne outbreaks caused by *L. monocytogenes* reported to EFSA under the framework of Directive 2003/99/EC. Although mandatory, not all the Member States report the complete information on foodborne outbreaks to EFSA and consequently the information summarised in this section may not be exhaustive for certain countries.

From 2010 to 2017, three *L. monocytogenes* outbreaks associated with the consumption of salmon were reported to EFSA by Denmark (2) and the Netherlands (1) involving 18 human cases.

Denmark reported two food-borne outbreaks associated with the consumption of gravad (cured) salmon and cold smoked salmon in 2010 and 2017, respectively. The Danish outbreak in 2017 was caused by *L. monocytogenes* ST8 and involved six human cases related to the multi-country outbreak assessed in the present rapid outbreak assessment. For these two outbreaks, evidence supporting the association between human cases and the consumption of salmon was reported to be strong.

In 2015, the Netherlands reported one weak-evidence outbreak associated with the consumption of smoked salmon involving three human cases.

### *Listeria monocytogenes* isolation in food

*L. monocytogenes* is widely distributed in the environment and can enter food-processing settings via incoming raw materials and the movement of personnel and equipment. *L. monocytogenes* can colonise in the form of biofilms on food-processing equipment and food-contact surfaces and can therefore persist for prolonged periods in food-processing environments. Hence, a wide range of foodstuffs can become contaminated during various stages of food production and distribution, particularly during the food-processing stage. Food business operators perform their own checks to monitor and control possible contamination by *L. monocytogenes* of the food-processing environment and the final product [7].

European monitoring data on *L. monocytogenes* in foods that are provided by Member States to EFSA mostly originate from sampling conducted under EU Regulation (EC) No 2073/2005 on microbiological criteria, which lays down the food safety criteria for *L. monocytogenes* in ready-to-eat (RTE) foods and which has been in force since 1 January 2006.

In 2016, among the different RTE food categories and across all sampling stages, *L. monocytogenes* was most frequently detected in 'fishery products' (5.6%) and 'fish' (4.7%), followed by 'pork meat products other than fermented sausages' (3.1%) and 'soft and semi-soft cheeses made from raw milk' (2.5%) [7]. As in previous years, RTE fish and fishery products remained the food categories with the highest level of non-compliance at processing.

This section focuses on the reporting of *L. monocytogenes* in fish and fishery products, which represent the suspected food category in this investigation.

Table 1 of the annex summarises the information reported on *L. monocytogenes* in fish and fishery products from 2010 to 2016, related to both ready-to-eat (RTE) and non-RTE food products, regardless to the sampling stage. Only results obtained using the detection method (presence or absence of *L. monocytogenes*) are presented in Table 1 (see annex). In 2016, 251 *L. monocytogenes* isolations (based on the detection method only) were reported in fish and fishery products (163 isolates from 'fish' and 88 isolates from 'fishery products'). *L. monocytogenes* positive units were mostly sampled at retail (55.0%) and at processing plant (33.5%), while only few isolations were reported from samples collected at catering facilities (5), at border control (5) and at wholesaler (3). The sampling stage was unspecified for 16 isolations (6.4%). The majority of *L. monocytogenes* isolations reported in 2016 were from smoked fish and fishery products (including hot and cold smoked fish) (24.3%), followed by marinated fish (22.0%) and other RTE fishery products (20.0%). The fish and fishery product was unspecified in 15.5% of the *L. monocytogenes* isolations reported in 2016. The following 15 Member States and one non-Member State reported *L. monocytogenes* isolations based on the detection method in 2016: Austria (6), Belgium (8), Bulgaria (40), Denmark (3), France (27), Estonia (7), Germany (53), Greece (1), Hungary (5), Ireland (5), Italy (53), Luxembourg (11), the Netherlands (3), Spain (13), Sweden (11) and Norway (5). Further details on the number of positive units reported between 2010 and 2016 are presented by food category in Table 2 of the annex.

Information on MLST is usually not reported in the context of monitoring zoonoses and zoonotic agents in food based on Directive 2003/99/EC. Specifically, no data on *L. monocytogenes* ST8 have been reported to EFSA (this information is not mandatory and is only reported on a voluntary basis).

## Event background information

On 31 August 2017, Denmark reported in EPIS-FWD an outbreak of listeriosis. Between May and September 2017, Danish authorities identified five cases with *L. monocytogenes* ST8 isolates belonging to the same cluster delineated by whole genome sequencing (WGS). One additional historical case from 2015 was later identified. The Danish epidemiological, microbiological and food investigations provided strong evidence that the outbreak was associated with consumption of salmon products produced in an EU Member State.

Following the Danish alert, additional human *L. monocytogenes* isolates, matching with the cluster by WGS-based core genome MLST analysis within 7 allelic differences (Moura et al., 2016) [8], have been identified from October 2015 to May 2018 in Denmark, France and Germany.

This ROA is linked to the EPIS FWD urgent inquiry UI-426 and RASFF notifications 2017.1319 and 2017.1546.

## Multi-country investigations

### EU outbreak case definition

Confirmed outbreak case:

- Patient with laboratory-confirmed invasive listeriosis, with symptoms onset on or after 1 January 2017 (date of sampling or date of receipt by the reference laboratory if date of onset is not available); and
- Fulfilling the additional laboratory criterion: with a *Listeria monocytogenes* isolate within 7 cgMLST allelic differences (Moura et al. 2016) [8] from any other outbreak isolate part of the multi-country outbreak (representative sequence uploaded in EPIS-FWD) based on the ECDC pipeline.

Historical confirmed outbreak case:

- Patient fulfilling the microbiological criteria for a confirmed outbreak case with symptoms onset before 1 January 2017 (date of sampling or date of receipt by the reference laboratory if date of onset is not available); and
- Fulfilling the additional laboratory criterion: with a *Listeria monocytogenes* isolate within 7 cgMLST allelic differences (Moura et al., 2016) [8] from any other outbreak isolate part of the multi-country outbreak (representative sequence uploaded in EPIS-FWD) based on the ECDC pipeline.

## Epidemiological and microbiological investigations of humans

As of 8 October 2018, three EU countries had identified 10 confirmed cases reported on or after 1 January 2017 and 2 historical confirmed cases reported from 2015 to 2016 (Table 1), four of the cases died due to or with the disease.

**Table 1. *Listeria monocytogenes* outbreak cases by country and case classification, EU, 2014 to 2018, as of 8 October 2018**

Reporting country	Confirmed cases (reported on or after 1 January 2017)		Historical confirmed cases (reported before 1 January 2017)		Total number of cases
	2018	2017	2016	2015	
Denmark	0	5	0	1	6
France	0	0	1	0	1
Germany	1	4	0	0	5
<b>Total</b>	<b>1</b>	<b>9</b>	<b>1</b>	<b>1</b>	<b>12</b>

The five Danish confirmed cases had onset of disease between May and August 2017 and the historical confirmed case had onset of disease in October 2015. The five patients identified in 2017 were between 59 and 96 years of age. Three were female and two were male. One died within 30 days of diagnosis.

The five confirmed German cases were identified between August 2017 and May 2018. The five patients were from four different federal states and had onset of symptoms in August 2017 (3 cases), December 2017 (1) and May 2018 (1). The patients' ages ranged from 22 to 82 years, with a median age of 78 years. Three patients were male and two were female. Three patients, including the patient who had disease onset in May 2018, died of listeriosis.

The French patient was a female over 80 years of age who presented with meningitis in June 2016.

Austria, the Czech Republic, Ireland, Luxembourg, the Netherlands, Norway, Slovenia, Spain, Sweden and the United Kingdom reported no cases suspected to be related to this outbreak.

## Information from patient interviews

Four Danish patients with symptoms onset in 2017 confirmed consumption of cold smoked salmon. A fifth Danish patient with symptom onset in 2017 had consumed marinated salmon. Four cases bought salmon products at retail stores belonging to Danish wholesaler A.

Of the three German patients identified in August 2017, two died and could not be interviewed. The third patient reported eating salmon regularly. The patient identified in December 2017 was an asylum seeker who was lost to follow-up. The latest case in May 2018 died due to the disease. An interview with relatives was not possible.

Information on other cases in affected Member States could not be retrieved from patients classified as historical confirmed cases due to the long delay between their onset and the investigation in September 2017.

## Microbiological and environmental investigations of food

This section summarises country-specific information on food and environmental investigations associated with this outbreak that have been reported by the national competent authorities through RASFF until 22 October 2018 (references of the relevant RASFF notifications: 2017.1319 and 2017.1546).

### Denmark

Overall, four food isolates closely related to the multi-country outbreak strain from the following batches of sliced cold smoked salmon (2017 production season) have been notified by Denmark (RASFF alert 2017.1319):

- Batches A, B and C of cold smoked salmon originating from Poland.

On 30 August 2017, Denmark reported the finding of *L. monocytogenes* ST8 above 100 CFU/g in two batches of sliced cold smoked salmon (batches A and B). These isolates (one from batch A and two from batch B) were closely related to the human outbreak strain ( $\leq 2$  allelic differences using cgMLST, as described in section 'European whole genome sequencing analysis of human and non-human isolates'). Batch A was sampled on 12 July 2017 at a retail store (retailer A) belonging to the Danish wholesaler A, where the contaminated batch B was sampled on 11 August 2017. Both batches A and B originated from Polish processing company A (RASFF alert 2017.1319, original notification). The salmon used to produce batches A and B was reared in Norway and distributed to the Danish wholesaler A by two different Norwegian exporters (exporters A and B, respectively; RASFF alert 2017.1319, follow-ups 11 and 19).

Other food and environmental samples resulted positive for *L. monocytogenes*, but none of the isolates matched the outbreak human strain (RASFF alert 2017.1319, original notification).

On 30 August 2017, the wholesaler A, upon request from the Danish Veterinary and Food Administration (DVFA), recalled all batches of cold smoked salmon produced by the Polish processing company A still within their shelf life. The DVFA initially decided to follow up on these findings by imposing reinforced checks on the next 5 batches of cold smoked salmon from the Polish processing company A (RASFF alert 2017.1319, original notification). However, on 18 September 2018, following the review of information received from Poland on the sampling activities carried out at the Polish processing company A (RASFF 2017.1319, follow-up 4), Denmark informed on the final decision of the DVFA not to impose the reinforced checks on products from the Polish company A (RASFF alert 2017.1319, follow-ups 5).

On 31 August 2017, official samples from eight additional batches (four batches of cold smoked and four batches of gravad salmon) originating from Polish company A were taken at Danish wholesaler A and all samples tested negative for *L. monocytogenes* in 25g (RASFF alert 2017.1319, follow-ups 5 and 9).

On 22 October 2018, Denmark provided information on *L. monocytogenes* ST8 finding (<10 cfu/g) in an official sample collected in the context of 'customer complaint and outbreak investigation' from a batch of cold smoked salmon scraps (batch C) sampled on 31 August 2017 at wholesaler A. Contaminated batch C originated from Polish processing company A, which received the salmon used for this batch from Norwegian exporter B (RASFF alert 2017.1319, follow-up 22). The isolate from batch C was included in the joint WGS analysis described in this report and found closely related ( $\leq 2$  allelic differences) to the human outbreak strain (see specific section on 'European whole genome sequencing analysis of human and non-human isolates').

## France

One food isolate closely related to the multi-country outbreak strain from the following batch of marinated salmon (2017 production season) has been notified by France (RASFF alerts 2017.1546 and 2017.1319):

- Batch D of marinated salmon originating from Poland.

On 27 September 2017, France reported (RASFF alert 2017.1546, original notification) the finding of *L. monocytogenes* (460 CFU/g) in an official sample from a batch of chilled marinated salmon (batch D) collected on 6 September 2017 at a French retail shop (retailer B). Contaminated batch D was presumably no longer on the market at the time of notification. The product was distributed by the French wholesaler B and manufactured by Polish company A.

The salmon used for producing batch D was reared in Norway and distributed by Norwegian exporter B (RASFF alert 2017.1319, follow-ups 11 and 19). The only information indicated on the packaging of the products received from Poland referred to Polish processing company A. The final product was labelled as kosher.

On 26 October 2017, France informed that the *L. monocytogenes* isolate from batch D was closely related to the Danish outbreak strain (RASFF alert 2017.1546, follow-up 1; RASFF 2017.1319, follow-up 6) as confirmed by the joint WGS analysis described in this report (see specific section on 'European whole genome sequencing analysis of human and non-human isolates').

## Poland

### Information on Polish company A

Polish processing company A produces four salmon-type products (RASFF 2017.1319, follow-up 11):

- Cold smoked salmon and gravad salmon (dried/marinated fish with salt, sugar and dill + drying)
- Hot smoked salmon
- Frozen salmon; and
- Fresh salmon

These products can support the growth of *L. monocytogenes* and they do not undergo any treatment able to inhibit the growth of bacteria during the production process. The shelf life period was established for each product using appropriate tests, then shortened to meet the requirements of the country where the product was intended to be commercialised. For the Danish market, 30- and 24-day shelf lives were established for cold smoked and gravad salmon respectively. For the French market, a 40-day shelf life was established for both cold smoked and gravad salmon. Currently, Polish processing company A is involved in the processing of salmonids such as Atlantic salmon (*Salmo Salar*) and salmon trout (*Oncorhynchus mykiss*).

The processing plant of company A has one pretreatment line at the preprocessing hall, where all the raw fish manufactured in the plant undergoes heading, mechanical or manual filleting, trimming, gutting, bone removal and skinning (optional). Following the pretreatment line, there are three production lines at the slicing hall that operate simultaneously by processing one batch of salmon at a time and where it is possible to produce maximum three different products types (RASFF 2017.1319, follow-ups 4 and 11). There are no dedicated lines for a specific type of product. The processing of one product takes place on three lines at the same time. Cleansing and disinfecting operations are carried out between the processing of various assortments. Both cold smoked and gravad salmon undergo similar production steps, consisting of salting (seasonings are added only to gravad salmon), sorting, ripening,

curing (including drying, brining and smoking, the latter only for cold smoked salmon), cooling, cutting (some products can already be sold as cured or smoked cuts for food purposes, e.g. salads), skinning, slicing, weighting, packaging/labelling, metal detection, shock-freezing (optional), box packaging, cool storage (0–4 °C) or deep-freeze storage (-18 °C), distribution. Similar production steps as the ones described above are also applied for hot-smoked salmon, with the main exception of the hot-smoking step.

Fresh salmon (i.e. without heat treatment) undergoes only filleting and slicing and can be sold with or without skin as chilled fish. After the skin removal process or without removal, the fresh salmon is put in a bag, vacuum packed, marked and moved on the trolley to the shock chamber for freezing. Production of the fresh salmon takes place only on the pre-processing hall.

Polish processing company A has its own laboratory in which food samples are regularly tested for food safety criteria.

## Information on food and environmental sampling and testing (2017 to 2018)

In September 2017, the Polish competent authorities started investigating the possible source of contamination of batches A and B reported by Denmark on 30 August 2017 (RASFF 2017.13.19). Official samples of the products available at Polish processing company A were taken from September 2017 to September 2018. Findings of *L. monocytogenes* in food and environmental official samples collected at Polish company A are presented in Table 2 (RASFF 2017.1319 follow-up 11). *L. monocytogenes* was not detected in any of the remaining official food (105) and environmental (35) tested samples collected from September 2017 to September 2018 (data not included in Table 2). The *L. monocytogenes* isolates from food and environmental samples were not typed.

**Table 2. Findings of *L. monocytogenes* in food and environmental official samples collected at Polish company A from September 2017 to September 2018 (RASFF 2017.1319 follow-up 11, issued on 5 October 2018)**

Product	Tested samples	Batch code	Sampling context	Sampling date	Production date	Lm*	Positive samples
Cold smoked salmon (scraps)	5	E	Official	4.09.2017	4.09.2017	Present in 25 g	1
Cold smoked salmon (scraps) 500 g	5	F	Official	6.09.2017	5.09.2017	Present in 25 g	1
Marinated salmon (scraps) 500 g	5	G	Official	6.09.2017	5.09.2017	Present in 25 g	1
Cold smoked salmon (sliced) 200 g	5	H	Official	6.09.2017	6.09.2017	Present in 25 g	1
Cold smoked salmon (scraps) 500 g	5	I	Official	6.09.2017	6.09.2017	Present in 25 g	1
Swab samples taken at the table top of line 3 and the fish tray	24	NA	Official	7.09.2017	NA	Present**	2
Cold smoked salmon (sliced) 200 g	5	L	Official	7.09.2017	7.09.2017	Present in 25 g	1
Marinated salmon (scraps) 500 g	5	M	Official	7.09.2017	7.09.2017	Present in 25 g	1
Swab from the blue tape and roll of line 3	10	NA	Official	21.03.2018	NA	Present**	1
Cold salmon fillet of Norwegian smoke (sliced) 300 g	5	N	Official	10.04.2018	10.04.2018	Present in 25 g	1
Cold smoked salmon (sliced) 300 g	5	O	Official	24.07.2018	24.07.2018	Present in 25 g	1

Lm\*: *Listeria monocytogenes*

\*\**: present on the surface*

NA: *not applicable.*

In 2017, own-check sampling and testing were carried out at Polish company A, with a specific focus on *L. monocytogenes* (RASFF 2017.1319, follow-up 11). Sanitary swabs were taken from all production areas of the facility, including the filleting, ripening, refrigerating, smoking slicing and reception of raw materials areas. Swabs were also taken from the skin of raw fish, workers' shoes and hands, seasoning packaging, machines and equipment. Of the 1 360 environmental swab samples analysed, eight confirmed the presence of *L. monocytogenes*, representing 0.59% of all analysed swab tests. *L. monocytogenes* contamination was confirmed in the following areas:

- Reception of raw materials – pallet lift, floor
- Ripening area – sewage grille
- Slicing area – tapes and rolls by the weighing lines
- Slicing area – slicer; and
- Filleting area – foreman’s office, filleting department.

In all cases where irregularities were found, corrective measures were undertaken (see next section). Following the implementation of corrective measures, new samples were taken and no irregularity was found (RASFF 2017.1319, follow-up 11).

In addition, 4 385 own-check laboratory tests were conducted in 2017 on finished products sampled at Polish processing company A. *L. monocytogenes* was not detected in any of these own-check tests.

Levels of *L. monocytogenes* <10 cfu/g were found in a reference sample from contested batch B that was stored by Polish company A and tested at the end of product’s shelf life in an external accredited laboratory.

On 22 October 2018, Poland confirmed that contaminated batch C of cold smoked salmon reported by Denmark was manufactured at Polish processing company A (RASFF 2017.1319, follow-up 21). The salmon used for the production of batch C was fresh gutted salmon with head delivered by Norwegian exporter B (RASFF 2017.1319, follow-up 21).

## Corrective measures implemented by Polish company A

On 6 September 2017, Poland informed that processing company A was requested by the competent authority to withdraw suspected batches A and B from the market (RASFF 2017.1319, follow-up 4).

Since 1 September 2017, the following corrective measures were implemented at the plant of Polish processing company A (RASFF 2017.1319, follow-ups 15 and 21):

- Production stoppage (from 3 to 14 September 2017)
- Additional treatments for cleaning and disinfecting equipment and production rooms
- Thermal fogging treatments
- Modernisation of equipment on line 3 (one of the three production lines at the slicing hall, which was considered by the Polish Competent Authority and the Company as the probable source of *L. monocytogenes* contamination)
- Increased frequency of sampling and testing activities in both own and official laboratory

During the corrective actions, only trial production was carried out, the production of which was subjected to laboratory analysis, then destroyed. Trial production was conducted until satisfactory results were obtained, guaranteeing product safety. After obtaining results consistent with both the finished product and environmental swabs, products from 15 September 2017 were placed on the market. Products produced before this date were destroyed.

- Since September 2017, each product sampled at the plant of the Polish company A is not distributed until the testing results are obtained. Therefore, none of the products found to be contaminated with *L. monocytogenes* has been placed on the market.

The plant of Polish processing company A is currently in production activity (RASFF 2017.1319, follow-up 21).

## Information on origin of salmon and distribution of suspected products

According to the information notified by Poland on 5 and 22 October 2018 (RASFF alert 2017.1319, follow-ups 11 and 21), the salmon used to produce contaminated batches A, B, C and D was reared in Norway and distributed by Norwegian exporters A, which distributed the salmon used in batch A, and exporter B, which distributed the salmon used to produce batches B, C and D (RASFF alert 2017.1319, follow-ups 19 and 21). No detailed information has been provided on the primary producers where the salmon used to produce batches A, B, C and D was reared.

On 16 October 2018, Poland informed that from August 2017 to 4 October 2018, Polish company A sold its products (other than the suspected batches) to the following countries (RASFF alert 2017.1319, follow-up 15):

- Cold smoked salmon: Poland, Germany, France, Denmark, Greece
- Gravad salmon: Poland, Germany, France, Denmark, Greece
- Hot smoked salmon: Poland, Germany
- Frozen salmon: Poland, Germany, France, Denmark; and
- Fresh salmon: Poland.

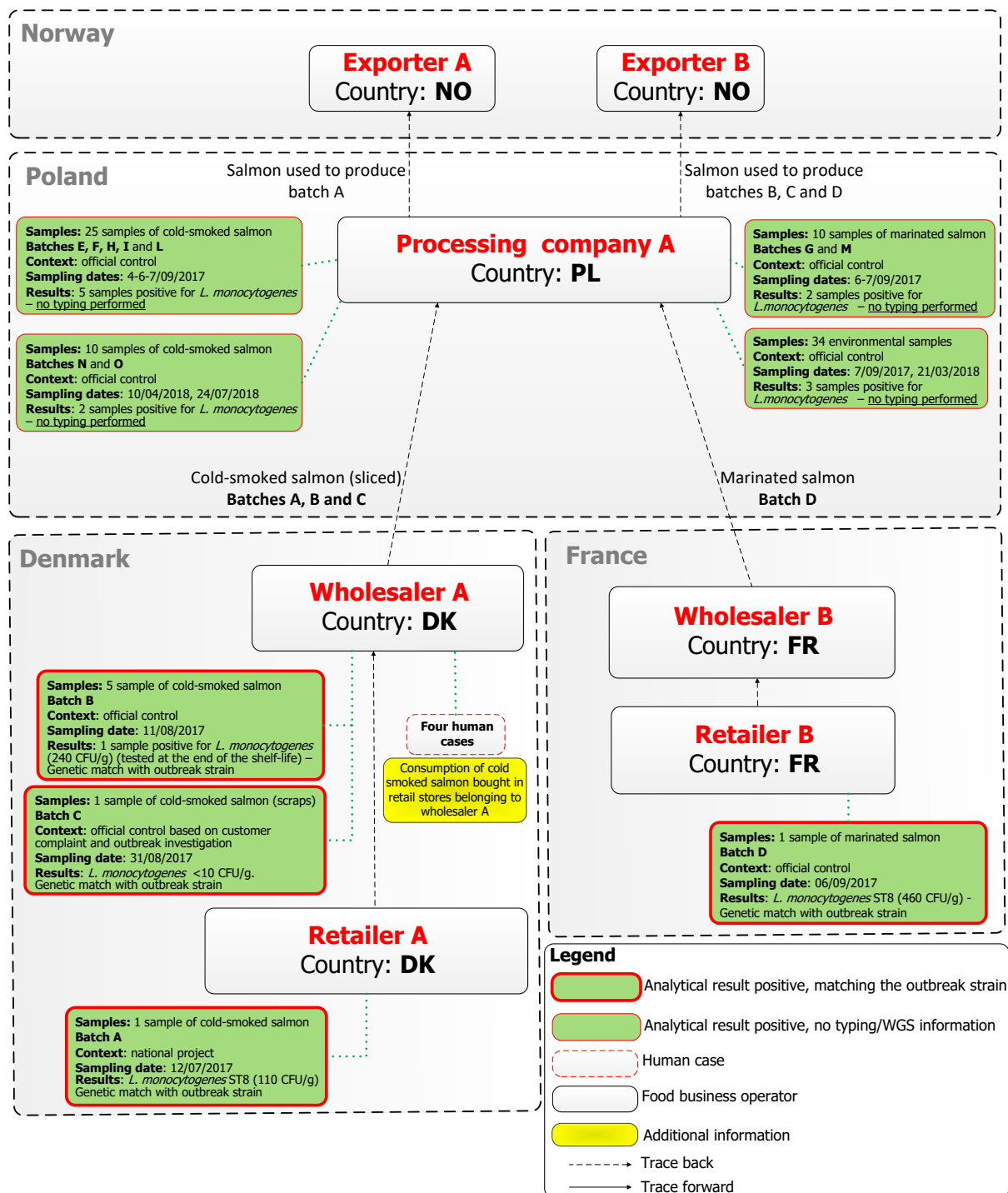
However, it is important to underline that, as confirmed by Poland, suspected batches A and B of smoked salmon were only delivered to Danish wholesaler A, while implicated batch D of marinated salmon was delivered only to French wholesaler B.

## Norway

On 19 October 2018, the Norwegian competent authority clarified that Norwegian companies A and B are exporters of salmon, not primary producers (RASFF 2017.1319, follow-up 19).



**Figure 1. Graphical representation of traceability and testing information reported by Member States in RASFF, as of 22 October 2018**



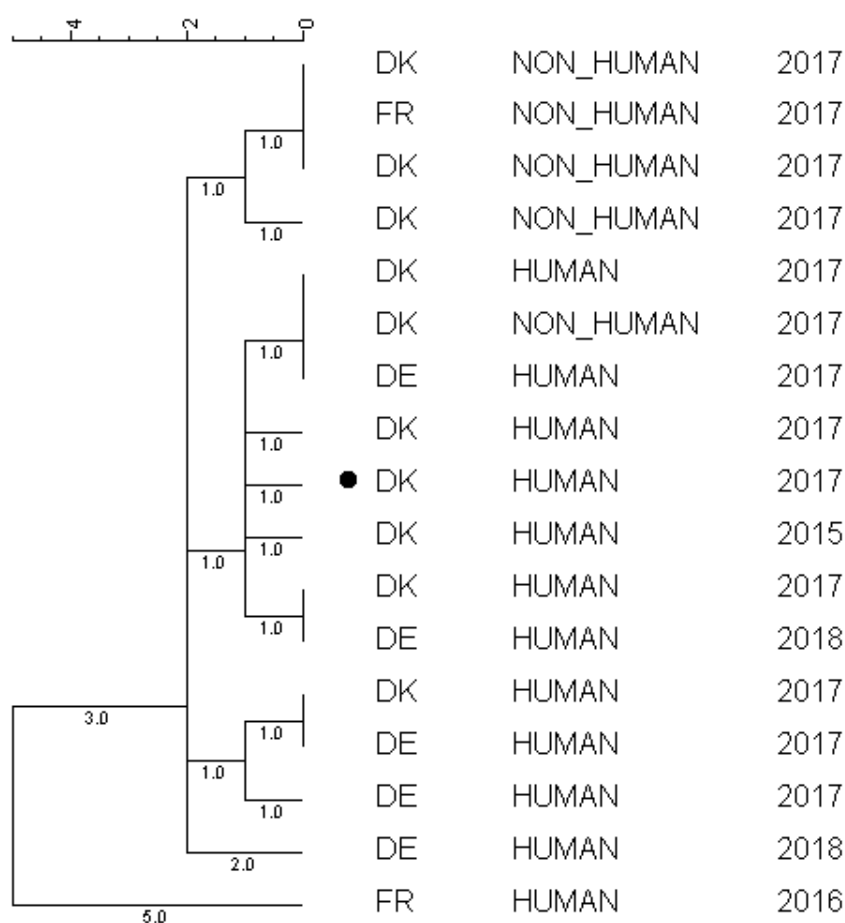
## European whole genome sequencing analysis of human and non-human isolates

Initial WGS-based analysis for identifying possible outbreak-related isolates was performed in the Member States’ public health institutes and national reference centres using national WGS pipelines. Raw sequence data (Denmark) or assemblies (France, Germany) from human *L. monocytogenes* isolates (12) matching the European case definition were collected by ECDC from national reference laboratories (NRLs)/centres of the FWD network. The EURL-*Lm* collected sequence data on five non-human isolates from the Danish (4) and French (1) reference centres and NRLs. WGS data analysis of human and non-human isolates was performed jointly by ECDC and the EURL-*Lm* using the same software and harmonised parameters. Sequences were analysed with BioNumerics version 7.6.3 (Applied-Maths, Sint-Martens-Latem, Belgium). The analysis of raw reads included trimming using the default Bionumerics 7.6.3 settings; *de novo* assembly using SPAdes v.3.7.1; post-assembly optimisation by mapping reads back onto the assembly and keeping the consensus. The default settings of BLAST parameters for allele calling were used, with the exception of identity percentage 70. cgMLST analysis was performed using assembly-based allele calling with the Pasteur scheme (Moura et al. 2016) in BioNumerics [7]. Isolates were retained in the analysis if at least 1 661 (95%) of the 1 748 core loci were detected. Isolates differing by seven or less cg alleles from any other outbreak isolate were considered as confirmed cases.

The Danish representative outbreak strain (assembly provided in EPIS) had 1 744 core genome loci (99.8%) and 1 704 of the 1 748 core genome loci (97.5%) were shared by all isolates, i.e. the unique loci were detected in each of the 17 isolates.

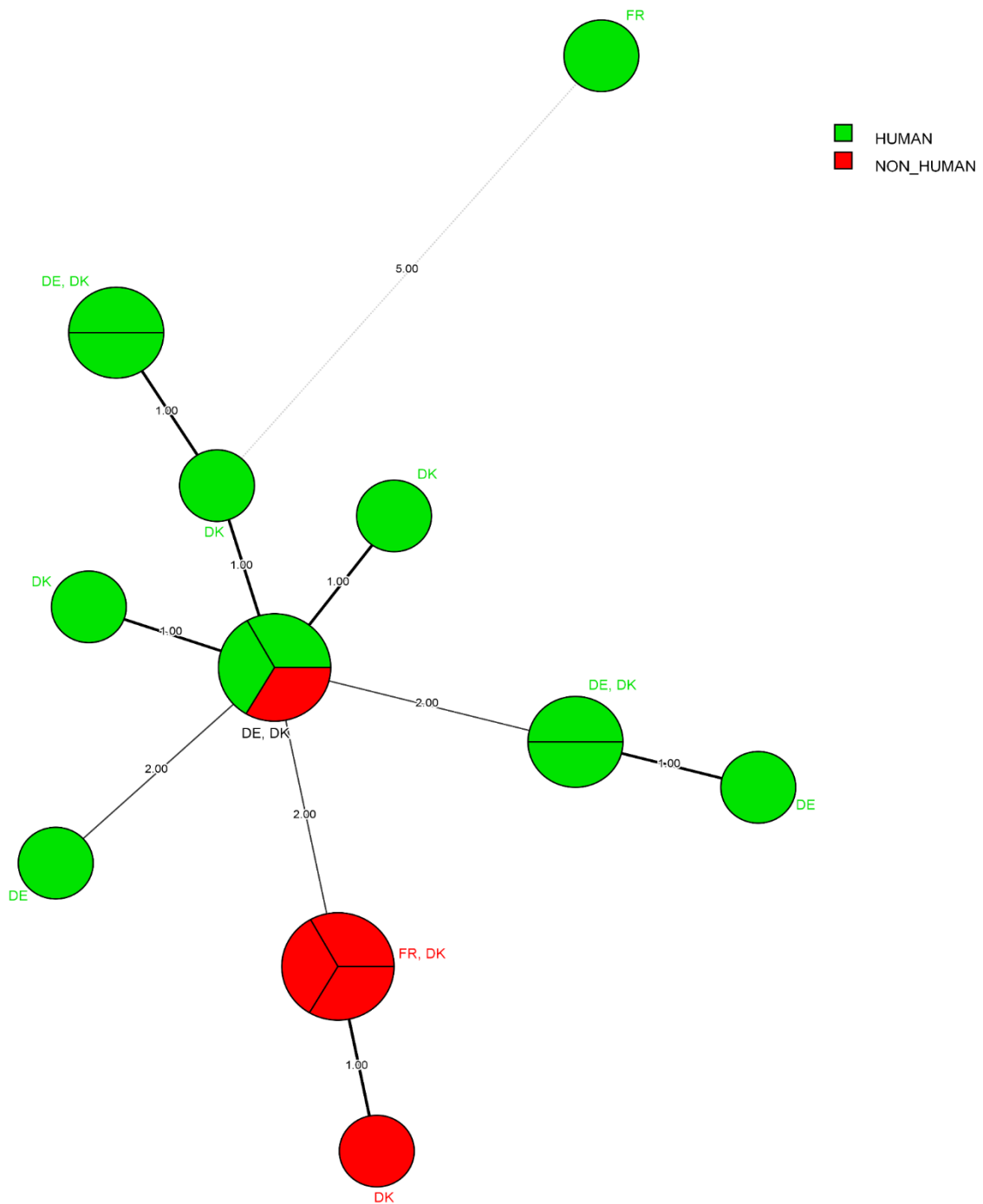
The single-linkage tree including all human (n=12) and non-human (n=5) isolates (Figure 2) shows that all of them are within 5 cg-allelic differences, indicating close genetic relatedness.

**Figure 2. cgMLST-based (Pasteur scheme) single-linkage tree including sequences from 12 human *L. monocytogenes* isolates and five non-human isolates from two countries, EU/EEA, 2015 to 2018**



Danish representative outbreak sequence indicated with a point.

**Figure 3.** cgMLST-based (Pasteur scheme) minimum spanning tree including sequences from 12 human *L. monocytogenes* isolates and five non-human isolates from two countries, EU/EEA, 2015 to 2018



Each circle represents a particular cgMLST type. The size of each circle is proportional to the number of isolates within the cgMLST type. The branches show genetic divergence between the circles. The divergence is given in number of allelic differences and is indicated on the branch.

## ECDC and EFSA threat assessment for the EU/EEA

WGS-based analysis identified 12 patients with onset of symptoms between October 2015 and May 2018 and isolates matching the outbreak strain: six in Denmark, one in France and five in Germany. Cases belong to the same cgMLST cluster within seven allelic differences. Four of these patients have died. The investigation findings suggest a common source of contamination.

*L. monocytogenes* ST8 strains may have a high pathogenic potential [9]. *L. monocytogenes* may persist in food processing facilities for years and has also been documented for *L. monocytogenes* sequence type ST8 [10]. Persistence in food processing facilities represents a serious threat to food safety as food products are the primary source for human *L. monocytogenes* -infection. Contamination of ready-to-eat fish products typically occurs in the processing plant environment but the strains enter the processing facility with the raw material from primary production and the movement of personnel and equipment [11]. Persistence of *L. monocytogenes* in food processing environments is considered to be the major source of RTE food contamination. Persistence appears to be the result of both improper hygiene conditions and the high adaptive capacity of these bacteria against physical and chemical factors such as biofilm-forming capacity [11].

In 2017, a subset of five human cases was investigated in Denmark and found to be associated with consumption of salmon products produced in Poland [1]. Four *L. monocytogenes* ST8 isolates closely related to the human outbreak strain were found in three batches of sliced cold smoked salmon sampled at a Danish wholesaler and at a retail store belonging to the same wholesaler. Immediate control measures were implemented to remove the contaminated food from the market and avoid new infections in humans. Later in 2017, French competent authorities detected a food isolate falling within the cgMLST cluster of the Danish outbreak. This food isolate derived from an official sample collected at retail from a batch of marinated salmon originating from the same Polish company as the one identified in the Danish trace-back investigations. This supports the hypothesis that contamination may have taken place at the processing company in Poland. However, due to the lack of WGS data on the isolates found in the environmental and food samples taken at the Polish processing plant, it is not possible at present to confirm the contamination with the *L. monocytogenes* ST8 outbreak strain at the suspected Polish plant. Moreover, until detailed information on the Norwegian primary producers of the salmon used in the contaminated batches is reported and assessed, possible contamination at the primary production level cannot be excluded either. WGS analysis in human and non-human isolates suggests a common vehicle of infection for the Danish and French cases.

Germany reported listeriosis cases associated with this outbreak with onset of disease between August 2017 and May 2018. However, the limited availability of epidemiological information, as well as the lack of data on the microbiological link between the non-human *L. monocytogenes* isolates and the outbreak strain, does not allow to draw any conclusion on the food vehicle and its origin associated with the German cases.

This appears as a prolonged intermittent common source food-borne outbreak linked to salmon products with a shelf life of about three to six weeks that has been ongoing between 2015 and 2018. Although control measures were implemented following the Danish outbreak investigation in September 2017, the identification of the same strain in France in a salmon product and a new human case in Germany suggest the possibility that the source of contamination is still active and contaminated products have been distributed to other EU countries besides Denmark. Until the source of contamination is identified and controlled, new invasive *L. monocytogenes* infections associated with this outbreak may occur in humans. It is also likely that the extent of this outbreak has been underestimated since the outbreak was identified through sequencing and only a subset of the EU countries routinely use this advanced technique to characterise *L. monocytogenes* isolates.

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## Annex

**Table 1. Isolations of *L. monocytogenes*\* from fish and fishery products reported to EFSA under the framework of Directive 2003/99/EC, EU/EFTA countries, 2010 to 2016**

Source	Number of positive units, 2010	Number of positive units, 2011	Number of positive units, 2012	Number of positive units, 2013	Number of positive units, 2014	Number of positive units, 2015	Number of positive units, 2016	Total positive units, 2010 to 2016
<b>Fish</b>								
Smoked	189	944	1 228	1 175	1 205	65	45	4 851
Cold smoked	16	5	12	11		5	2	51
Hot smoked			8	40		10	2	60
Gravad/slightly salted		4		4	6	26	9	49
Marinated	1		11	28			55	95
Raw*	19	24	54	66	9	21	5	198
Cooked*	0	0	40	1	0	0	2	43
Other*	13	82	14	22	21	19	29	200
Unspecified	2	174	57	1	13	6	14	267
<b>Total isolations in fish</b>	<b>240</b>	<b>1 233</b>	<b>1 424</b>	<b>1 348</b>	<b>1 254</b>	<b>152</b>	<b>163</b>	<b>5 814</b>
<b>Fishery products</b>								
Smoked	29	2	6		8	4	12	61
Other ready-to-eat	93	34	10	14	44	58	50	303
Non-ready-to-eat	0	1	0	5	0	3	0	9
Raw*	6	1	1	1	9	1	1	20
Cooked*	6	0	1	0	2	2	0	11
Unspecified*	410	551	60	33	154	68	25	1 301
<b>Total isolations in fishery products</b>	<b>544</b>	<b>589</b>	<b>78</b>	<b>53</b>	<b>217</b>	<b>136</b>	<b>88</b>	<b>1 705</b>
<b>Total isolations in fish and fishery products</b>	<b>784</b>	<b>1 822</b>	<b>1 502</b>	<b>1 401</b>	<b>1 471</b>	<b>288</b>	<b>251</b>	<b>7 519</b>

\*: *L. monocytogenes* isolations from detection method are included. Information on both ready-to-eat (RTE) and non-RTE food is included regardless of the sampling stage.

'Raw fish' includes 'raw fish', 'raw fish – chilled' and 'raw fish – frozen'.

'Cooked fish' includes 'cooked fish' and 'cooked fish – chilled'.

'Other fish' includes 'fish (food)', 'fish - fishery products from fish species associated with a high amount of histidine not enzyme matured', 'fish – fishery products which have undergone enzyme maturation treatment in brine', 'fish – unspecified – chilled' and 'fish – unspecified – frozen'.

'Other ready-to-eat (RTE) fishery products' includes unspecified RTE fishery products, 'unspecified RTE fishery products – chilled', 'unspecified RTE fishery products – frozen' and 'unspecified fishery products – seafood pâté'.

'Non RTE fishery products' includes unspecified non RTE fishery products, 'unspecified non RTE fishery products – chilled' and 'unspecified non RTE fishery products – frozen'.

'Cooked fishery products' include 'unspecified fishery products – cooked' and 'unspecified fishery products – cooked - chilled'.

'Raw fishery products' include 'unspecified fishery products – raw', 'unspecified fishery products – raw - chilled' and 'unspecified fishery products – raw – frozen'.