

JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of *Listeria monocytogenes* sequence type 6 infections linked to ready-to-eat meat products

25 November 2019

Abstract

Twenty-one cases of *Listeria monocytogenes* IVb sequence type ST 6 infections have been reported from the Netherlands (19 cases) and Belgium (two cases). This outbreak was identified using whole genome sequencing (WGS) analysis.

The patients had onset of illness between 2017 and August 2019. Three patients have died and one suffered a miscarriage due to the infection. The close genetic relatedness of the strains (≤ 3 allelic differences), and the temporal distribution of the cases suggest a prolonged, intermittent, common source foodborne outbreak which occurred in at least two EU Member States.

Nine isolates from six sliced ready-to-eat (RTE) meat products, produced between 2017 and 2019 by the Dutch Manufacturing Company A, were found to be contaminated with *L. monocytogenes* strains matching the outbreak strain (≤ 3 allelic differences). Although the exact points of contamination have not been identified yet, the results of the investigation suggest that the contamination may have happened at the Dutch Manufacturing Company A, which represents the only common manufacturing point of the contaminated products. The Dutch Manufacturing Company A distributed products to several EU countries as well as to countries outside the EU.

Following the detection in food of *L. monocytogenes* isolates matching the outbreak strain, and the discovery of the environmental contamination with other *L. monocytogenes* strains, the Dutch Manufacturing Company A stopped the production in October 2019, and finalised the withdrawals and recalls of all RTE meat products. This measure decreases the risk of new cases occurring possibly associated with products from this company.

Pregnant women, the elderly and immunocompromised people are at higher risk of invasive listeriosis, which is associated with severe clinical course and potential death. Therefore, specific attention should be paid to the administration of RTE meat products to people in hospitals, nursing homes and those belonging to vulnerable population groups.

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Event background

On 1 August 2019, the Netherlands reported a cluster of 18 invasive listeriosis cases to the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD). The cluster was identified through whole genome sequencing (WGS) analysis and included one non-human isolate from food. In the following weeks, Belgium reported two human cases of *L. monocytogenes* infections to EPIS-FWD, which shared identical (0 allelic difference) sequences with the Dutch isolates.

This joint ECDC-EFSA outbreak assessment is linked to the EPIS FWD urgent inquiry UI-583 and Rapid Alert System for Food and Feed (RASFF) notification 2019.3490.

Multi-country investigations

EU outbreak case definition

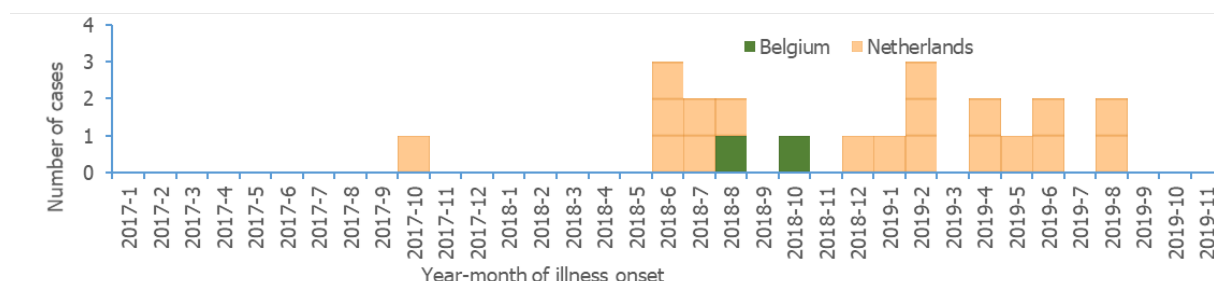
Outbreak-confirmed case

- A resident of the European Union/European Economic Area (EU/EEA) 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 *L. monocytogenes* isolate within 3 cgMLST allelic differences (Moura et al. 2016 [1]) from at least one of the 5 representative sequences shared in EPIS-FWD UI-583 by the Netherlands (NL2019_29_CT90, NL2019_20_CT5162, NL2017_88_CT90, NL2018_37_CT5162 or NL2018_67_CT90), based on the ECDC pipeline.

Epidemiological and microbiological investigations of humans

Based on the EU case definition as of 14 November 2019, there are 21 confirmed cases associated with this outbreak, of which 19 are in the Netherlands and two in Belgium. The cases were reported in 2017 (1), 2018 (8) and 2019 (12) (Figure 1).

Figure 1. Distribution of outbreak-confirmed listeriosis cases by country and month of illness onset*, EU, 2017–2019, as of 14 November 2019 (n=21)



* Month of sampling or month of receipt by the reference laboratory if month of onset unavailable

Two of the 19 Dutch patients were pregnant women in their 30s. The other 17 patients had a median age of 78 years, ranging from 64 to 94 years, and 10 were men. All patients were hospitalised, three patients died and one had a miscarriage.

The two patients reported by Belgium were a 97-year-old woman and a perinatal case of a Dutch mother (diagnosed in Belgium).

The 21 isolates from the outbreak-confirmed cases cluster within ≤ 3 allelic difference by single linkage clustering, and belong to serogroup IVb and sequence type (ST) 6. Of the 19 Dutch isolates, 17 were of SeqSphere cluster type ST6-CT90 and two were ST6-CT5162. Analysis of the LIPI-3 and LIPI-4 pathogenicity island associated with hypervirulence was performed on the five Dutch representative isolates: all five harboured the LIPI-3 island, but were LIPI-4 negative [2].

Austria, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Norway, Spain, the United Kingdom, Switzerland and the United States reported no *L. monocytogenes* isolates within 3 allelic differences from the Dutch outbreak strain.

Information from patient interviews

In the Dutch investigation, the available information on cases' food exposure could not point towards a specific source. Of the 19 Dutch patients, 15 reported having consumed cold meat products, three did not reply to the question and one reported not having eaten any cold meat product. When asked about the type of meat product consumed, different types of meat products were reported.

No food history information is available for the two cases reported in Belgium.

Microbiological and environmental investigations of food

This section summarises country-specific information on food and environmental investigations, and traceability analyses (Figure 2 in Annex) of products positive for *L. monocytogenes*, as reported through RASFF notification 2019.3490 (25 follow-ups: last access 18 November 2019).

Overall, nine isolates of *L. monocytogenes* IVb (PCR-based serotype) and ST 6 (MLST-based sequence type) - showing less than or equal to 3 allelic differences in cgMLST with the representative outbreak strain (according to the EU outbreak case definition and the EU WGS analysis), were detected in nine samples of six ready-to-eat (RTE) meat-based products prepared between 2017 and 2019 by the Dutch Manufacturing Company A:

- one sample of Product A
- one sample of Product B
- four samples of Product C
- one sample of Product D
- one sample of Product E
- one sample of Product F.

In addition, one isolate of *L. monocytogenes* IVb (PCR-based serotype) and ST 6 (MLST-based sequence type) showing 6 AD in cgMLST with the closest representative outbreak strain (according to the EU WGS analysis), was detected in one sample of one additional type of RTE meat-based product prepared in 2010, also by the Dutch Manufacturing Company A:

- One sample of Product G.

Moreover, other *L. monocytogenes* isolates from different serogroups and STs, and not clustering with the representative outbreak strain, were detected in 15 samples of RTE meat products prepared in 2019 and in four environmental samples collected at two sites within the Dutch Manufacturing Company A in 2019.

Information on the Dutch Manufacturing Company A

The Dutch Manufacturing Company A produces approximately 650 different types of sliced RTE meat products for the retail market and the catering industry, intended to be stored at a temperature below or equal to 7°C until consumption. The Dutch Manufacturing Company A receives frozen and pre-packed sausages (about 200 different meat products) from approximately 60 meat suppliers. Just prior to slicing, the sausages are unpacked. Subsequently, the frozen sausages enter the RTE production line that consists of the following steps: slicing (sausages are sliced frozen), portioning, and packaging that are carried out in the 'high care hall'; they then undergo the automated labelling that is performed in the 'low care hall' of the company. The final RTE meat products are then transferred to transport boxes.

Information on *L. monocytogenes* positive RTE meat-based products clustering with the representative isolates of the outbreak strain according to the EU WGS analysis

In October 2019, following the identification on 31 July 2019 of a national cluster of human infections caused by *L. monocytogenes*, the Dutch Food Authority reported in RASFF 2019.3490 (4 October 2019) on the outcome of a national foodborne outbreak investigation that was performed. After the initial signal detection (31 July 2019), one single sequence from a food isolate was found to cluster with the human isolates from the outbreak cases. This food isolate originated from a sample of Product A that was prepared in 2017 by the Dutch Manufacturing Company A and sampled chilled at retail level (Retailer E). The Dutch Food Authority reported that on 3 October 2017 Retailer E implemented a recall. Product A was obtained from raw pre-packed sausages that originated from a Dutch Supplier C. They were sliced in 2017 by the Dutch Manufacturing Company A along the slicing line 3, and distributed as RTE meat product to the stores of the group Dutch Retailer A.

The Dutch Food Authority reported that additional samples of RTE meat-based products (namely the Product B, Product C, Product D, Product E and Product F), collected in the frame of own-check controls at the Dutch Manufacturing Company A, tested positive for *L. monocytogenes* IVb - ST 6 (analyses started between 16 August and 30 August 2019). The isolates were sent for whole genome sequencing on 20 September 2019 and were found to cluster with the representative outbreak strain by SNP analyses. Product F and Product B were obtained from boiled pre-packed sausages which originated from the Dutch meat Supplier A and from the Dutch meat Supplier B, respectively. Product C, Product D, and Product E were obtained from boiled pre-packed sausages delivered by the Dutch Supplier C. All the five products were sliced by the Dutch Manufacturing Company A along the slicing line 1 and were distributed as RTE meat products to the stores of the group Dutch Retailer A. These RTE sliced foods were produced between 16 July 2019 and 26 August 2019 by the Dutch Manufacturing Company A.

Furthermore, from the dataset of *L. monocytogenes* isolates collected from the NRL network, the EURL-*Lm* identified one isolate showing less than 7 allelic differences in cgMLST with the representative outbreak strain. The Dutch Food Authority reported that the isolate originated from the RTE meat Product G which was sampled in the frame of an official control in 2010 and tested positive on 11 August 2010. Product G was obtained from boiled pre-packed sausage(s) that originated from the Dutch meat Supplier D, sliced in 2010 by the Dutch Manufacturing Company A along the slicing line 2 (located in a different building with respect to the other lines involved in positive products), and was distributed as RTE meat products to the stores of Retailer B.

Information on other *L. monocytogenes* positive RTE meat-based products not clustering with the representative outbreak strain according to the EU WGS analysis

The Dutch Food Authority reported in RASFF that samples of RTE meat-based products (Annex – Table 1) were collected in the course of official and own-check controls at the Dutch Manufacturing Company A in 2017 (Product H), in 2018 (Product I), and between March–October 2019 (Products J to V). They tested positive for different *L. monocytogenes* serogroups (e.g. IIa, IIc, IVb) and sequence types (e.g. ST 8, ST 9). The Dutch Food Authority reported that isolates, for which WGS analysis was performed, did not cluster with the representative outbreak strain. The trace-back and microbiological analyses of these positive RTE meat-based products is provided in the Annex, Table 1.

The products were manufactured in different processing lines in the Dutch Manufacturing Company A, where some of the lines were found to be positive for multiple *L. monocytogenes* strains. Specifically, one line (line 3) was also used for manufacturing one product found positive for *L. monocytogenes* ST 6 clustering with the human isolates from the outbreak cases. Moreover, the Dutch Food Authority clarified that all food products collected in the frame of official controls were sampled after the packaging step, and that most of the food products collected in the frame of own-check controls (by the Dutch Manufacturing Company A) were sampled after the slicing step, with no available information on the package status of the sample.

Distribution of RTE meat-based products to other countries

On 4 October 2019, the Dutch Food Authority reported in RASFF 2019.3490, that as result of a national foodborne outbreak investigation, the food product consisting in cooked sliced beef (Product Z) were recalled. Product Z was produced by the Dutch Manufacturing Company A and delivered to the stores of the Belgian Retailer D. On 8 October 2019 the Belgian Food Authority communicated (*fup9*) that the Belgian Retailer D initiated a withdrawal and a recall of all the RTE meat products belonging to Product Z. The Belgian Food Authority reported in RASFF (*fup9*) that the RTE meat-based products belonging to Product Z were further distributed to the stores of the same Retailer D located in Luxembourg. The Food Authority in Luxembourg reported that a recall was initiated on 4 October 2019 and a press release was issued on their website (*fup11*).

The Dutch Food Authority also reported in RASFF (*fup4*, *fup15*) the type and number of RTE meat-based products that were delivered by the Dutch Manufacturing Company A to several food business operators (i.e. wholesalers, retailers, and catering industry) located in Belgium (*fup10*), in Luxembourg (*fup15*), in Germany (*fup1*), and additionally in Suriname, Saint Maarten and Curacao (*fup4*). The Dutch Food Authority also reported in RASFF (*fup8*) an additional list of RTE meat-based products delivered to Belgium. The Belgian Food Authority reported in RASFF (*fup16*) that additional withdrawals and recalls of RTE meat-based products originating from the Dutch Manufacturing Company A were performed as a precautionary measure by the food business operators involved in the delivery. The German Food Authority requested the single recipient of the RTE meat-based products originating from the Dutch Manufacturing Company A to apply the control measures (*fup25*) on 8 October 2019.

On 5 October 2019, the Dutch Food Authority listed the RTE meat-based products that were delivered by the Dutch Manufacturing Company A in RASFF (*fup2*) to retailers sited in Spain and in Aruba (*fup2*). The Spanish Food Authority (*fup19*) reported that withdrawals and recalls and/or destruction (*fup23*) of the RTE meat-based products related to the RASFF alert were initiated by the food business operators involved. Public warnings were also displayed at the involved Spanish retailers.

Recipients located in Suriname, Saint Maarten, Curacao (*fup4*) and Aruba (*fup2*) were also informed of the event.

Information on environmental sampling and testing

The Dutch Food Authority reported that hundreds of samples were collected and analysed for *L. monocytogenes* during the national foodborne outbreak investigation. In August 2019, four environmental samples collected from two sites of the Dutch Manufacturing Company A tested positive for *L. monocytogenes*. Specifically, one swab sample was collected by the Dutch Food Authority in the context of an official control from a drainage situated between line 3 and line 4, and the isolate was typed as *L. monocytogenes* IIa –ST 8. Three samples were collected in the frame of own-check controls from the equipment (form clamp, wrench, and pressing machine) before the cleaning in line 5, and the isolates were typed as *L. monocytogenes* IIc –ST 9.

Control measures implemented by the Dutch Food Authority

The Dutch Food Authority reported that control measures were implemented at the Dutch Manufacturing Company A before the decision to interrupt the production had been taken. Measures consisted of an increased frequency in food and environmental samplings, and intensified local inspections performed by the Dutch Food Authority.

The Dutch Food Authority requested that the Dutch Manufacturing Company A stop production (October 2019) and initiate a consistent withdrawal and recall of all the RTE meat-based products whose use-by-date was not yet exceeded as a preventive measure. This followed the detection of *L. monocytogenes* isolates clustering with the outbreak strain in the food products, the continuous detection of environmental *L. monocytogenes* isolates (although not clustering with the representative isolates of the outbreak strain), and the identification of several gaps in hygienic procedures in the Dutch Manufacturing Company A. Online public warnings were also issued by the Dutch Manufacturing Company A.

The trace-forward exercise involved the withdrawal and recall of around 400 different type of sliced RTE meat-based products corresponding to circa 300 tons, and involved circa 10 000 food business operators located mainly in the Netherlands and Belgium but also across continental (Germany, Luxembourg, and Spain) and non-continental (Aruba was advised via INFOSAN; Curacao, San Maarten) Europe and Suriname as listed in RASFF 2019.3490 (*fup1*, *fup2*, *fup4*, *fup5*, *fup6*, *fup8*, *fup9*, and *fup10*).

The Dutch Food Authority reported that human and non-human isolates of *L. monocytogenes* are routinely subjected to WGS (cgMLST and SNP) analyses in the Netherlands, and that isolates are routinely shared across the two sectors (i.e. human and food). This practice will ensure a faster and more efficient response by both sectors in the Netherlands.

At the time of publication of this document, the Dutch Manufacturing Company A was still inactive.

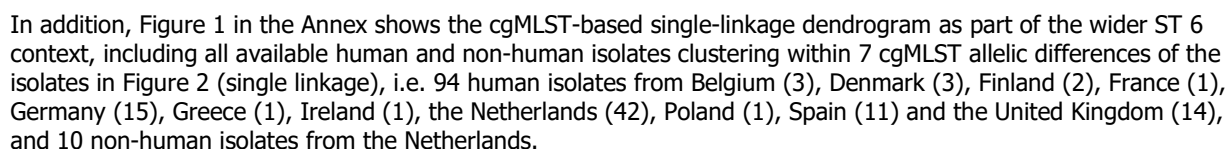
European whole genome sequencing analysis of human and non-human isolates

Initial WGS-based searches for identifying possible outbreak-related *L. monocytogenes* isolates were performed in the Member States' public health institutes and national reference centres using the five Dutch representative assemblies shared through EPIS FWD and national WGS pipelines. In total, 30 closely related *L. monocytogenes* isolates, as reported by countries in EPIS, were identified by the Belgian (2), Danish (1), French (5) and German (22) public health institutes and national reference centres. Raw sequence data or assemblies of these isolates were collected by ECDC from national reference laboratories (NRLs)/centres of the FWD network for inclusion in the multi-country analysis. In addition, ECDC searched for possible outbreak-related isolates in The European Surveillance System and identified isolates from five additional EU Member States that clustered with the Dutch reference isolates within 7 cgMLST alleles in single linkage analysis.

The EURL-*Lm* launched a consultation to Member States for submitting sequences of *L. monocytogenes* ST 6 from food, feed and animals. In total five countries submitted 17 genome sequences to EURL-*Lm* which performed cgMLST analysis using BioNumerics version 7.6.3 (Applied-Maths, Sint-Martens-Latem, Belgium). A total of 10 non-human isolates from the Netherlands showed < 7 AD in cgMLST with the representative human isolates of the outbreak strain and were included in the joint EU WGS analysis.

Sequences were analysed by ECDC 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 v3.7.1; post-assembly optimisation by mapping reads back onto the assembly and keeping the consensus (using MismatchCorrector implemented in SPAdes v3.7.1). The default settings of BLAST parameters for allele calling were used. Assembly-based allele calling was performed using the Institut Pasteur core genome scheme as implemented in BioNumerics, resulting in a cgMLST allelic profile per isolate. Isolates were excluded from further analysis if less than 1 661 (95%) of the 1 748 core loci were detected.

Figure 2. Minimum spanning tree (cgMLST, Institut Pasteur scheme) including sequences from 21 human *L. monocytogenes* isolates and nine non-human isolates from two countries, EU/EEA, 2017 to 2019



Disease characteristics

Disease surveillance for invasive listeriosis in the EU

Listeriosis in humans

Food-borne outbreaks caused by pathogen *L. monocytogenes*

6

The food reported as the cause of the strong-evidence and weak-evidence outbreaks belonged to the following categories 'Bovine meat and products thereof', 'Buffet meals', 'Cheese', 'Crustaceans, shellfish, molluscs and products thereof', 'Fish and fish products', 'Meat and meat products', 'Mixed food', 'Other food', 'Other or mixed red meat and products thereof', 'Pig meat and products thereof', 'Vegetables and juices and other products thereof' and 'Unknown'.

Occurrence of *L. monocytogenes* in RTE food

In accordance with the Zoonoses Directive 2003/85/EC, for the year 2013-2017 a total 27 countries reported data on the occurrence of *L. monocytogenes* in RTE foods, with an overall occurrence of 1.93% (514,581 tested units). The following RTE food categories were reported: 'fish RTE' and 'Fishery, RTE'; 'Milk, RTE', 'Soft and semi-soft cheese, RTE', 'Hard cheese, RTE', 'Other dairy products, RTE'; RTE Food intended for infants and for medical purposes; 'RTE Products of meat origin, fermented sausage' and 'RTE Products of meat origin other than fermented sausage'; 'Other RTE products'. Detailed information can be found in the 'European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2017' [7].

Risk assessment questions

This assessment provides an overview of the cross-border public health risk in EU/EEA related to the outbreak of *L. monocytogenes* IVb ST 6 infections in the Netherlands and Belgium with a link to consumption of RTE meat products.

ECDC and EFSA threat assessment for the EU/EEA

This report is about a cluster of *L. monocytogenes* IVb ST 6 cases with illness onset from 2017 to 2019. WGS-based analyses performed at the national level and confirmed by ECDC identified a total of 21 cases from the Netherlands (19) and Belgium (two) with isolates clustering within 3 allelic differences using single linkage analysis. Three cases were related to pregnancies and 18 were in adults older than 60 years of age. At least three patients died and one had a miscarriage due to or with the disease. All five representative isolates of the outbreak strain harboured LIPI-3 virulence gene cluster.

The close genetic relatedness suggests a common source of infection. The temporal distribution of cases indicates a prolonged, intermittent, common-source outbreak took place in at least in two EU Member States. Since disease onset in the last patient was in August 2019, the source of contamination during this outbreak has been active until very recently.

Interviews with patients found that a large number (15/19) of the Dutch cases consumed cold meat cuts. However, patient's interviews could not point at a single food vehicle, as exposure to several meat products was reported. At the time of publication of this report there was no specific information on the brands and batches of these products to verify a direct epidemiological link to a specific food exposure.

L. monocytogenes is ubiquitous in the environment (e.g. moist environments, soil, and water) and it may colonise and persist in food processing facilities for years, representing a risk for food safety, especially in RTE food products, and is a serious threat to public health [8,9]. Environmental factors (e.g. hard-to-clean facilities and equipment) and intrinsic strain characteristics (e.g. biofilm formation capability and better adaptation to environmental stress) can contribute to the persistence of *L. monocytogenes* in food processing plants [10]. Furthermore, *L. monocytogenes* strains may possess virulence genes and thereby increase the risk of invasive listeriosis [10].

The Dutch food competent authority and the Dutch public health institute jointly found nine *L. monocytogenes* IVb ST 6 isolates clustering with those from the outbreak cases in different types of sliced RTE meat products prepared by the Dutch Manufacturing Company A. The isolates matching the human cluster (according to the EU outbreak case definition) were obtained from six products which were manufactured between 2017 and August 2019 from both boiled and raw sausages originating from different suppliers. Official and own-check environmental samplings performed at the Dutch Manufacturing Company A resulted in the detection of *L. monocytogenes* ST 8 and ST 9 isolates from the equipment located in, or near the slicing lines, that did not match the outbreak human strains or any *L. monocytogenes* isolated from meat products sampled at the Dutch Manufacturing Company A. However, inspections performed by the Dutch competent authority identified gaps in hygiene procedures in the company, which could have led to plausible cross-contamination during the production. Although the exact points of contamination along the RTE production line with *L. monocytogenes* matching the outbreak strain has not been identified yet, these findings suggest that the contamination most likely happened during the processes performed at the Dutch Manufacturing Company A, which represents the only common point of manufacturing of the contaminated products.

Based on the results of the national investigation, the Dutch competent Food Authority requested the Dutch Manufacturing Company A to stop the production, and as a preventive measure, to initiate the withdrawal and recall of all the meat products whose use-by-date had not yet past. The products have been sold in different countries within and outside Europe involving more than 10 000 food business operators. At the time of the publication, the Dutch Manufacturing Company A was still inactive, and the recalls were finalised.

The 21 Belgian and Dutch human isolates and the nine Dutch non-human isolates belong to a larger cluster of *L. monocytogenes* ST 6 including a previously reported international groups of isolates classified into the same cgMLST type (Institut Pasteur cgMLST type L1-SL6-ST6-CT443) [1]. Within this cluster an additional non-human isolate was identified by the EURL-*Lm*. This isolate originated from an RTE meat product prepared by the Dutch Manufacturing Company A in August 2010. There is a possibility that part of the human isolates in the larger cluster are related to the Dutch Manufacturing Company A; however further information is necessary to assess this possibility.

Given the long incubation period of invasive listeriosis in some risk groups (up to 70 days), possible delay in diagnosis and reporting, and any possible delay in returning the contaminated products to the point of sale, new cases may still be identified in the coming weeks/months. Pregnant women, the elderly and immunocompromised people are at higher risk of invasive listeriosis, which is associated with severe clinical course and potential death. Therefore, specific attention should be paid to the administration of RTE meat products to people in hospitals, nursing homes and to those belonging to vulnerable population groups.

Options for response

Competent authorities are encouraged to report new human cases associated with this event by food consumption history and WGS (as well as the findings of public health investigations) to EPIS-FWD. They should also consider interviewing new and recent listeriosis cases that are possibly related to this event. In order to assess exposure history, interviews should include questions about the consumption of cold meat products, including brand information. ECDC supports the WGS analysis of human *L. monocytogenes* isolates from cases possibly related to this outbreak and reported in countries that are not routinely performing WGS. Countries that routinely perform WGS are kindly requested to share sequences (reads) from possibly related isolates with ECDC for inclusion in the multi-country analysis. Sequences from representative human isolates of the outbreak strain are available in EPIS FWD UI-583.

The European Union Reference Laboratory for *L. monocytogenes* (EURL-*Lm*) provides support to Member States who do not have WGS capacity to perform WGS of non-human isolates for strains possibly related to this outbreak. In order to identify the source(s) 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 plants and primary production facilities.

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

Source and date of request

The Directorate General for Health and Food Safety of the European Commission requested the production of an ECDC-EFSA joint outbreak assessment on 4 October 2019.

¹ 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.

² 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.

Consulted experts

ECDC experts (in alphabetic order): Erik Alm, Sergio Brusin, Saara Kotila, Daniel Palm, Ettore Severi, Johanna Takkinen, Ivo Van Walle.

EFSA experts (in alphabetic order): Valentina Rizzi, Mirko Rossi, Eleonora Sarno.

European Union Reference Laboratory for *Listeria monocytogenes* (EURL-Lm) (in alphabetic order): Karine Capitaine, Benjamin Felix, Jean-Charles Leblanc, Maroua Sayeb.

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

- Belgium: Wesley Mattheus, An Van den Bossche, Dieter Van Cauteren, Sarah Denayer (Sciensano)
- Denmark: Laura Espenhain and Susanne Schjørring (Staten Serum Institut)
- Greece: Kassiani Mellou (Hellenic National Public Health Organisation)
- Netherlands: Ingrid Friesema, Eelco Franz (RIVM)

All public health experts have submitted declarations of interest, and a review of these declarations did not reveal any conflict of interest.

RASFF contact points in Belgium, Germany, Luxembourg, Spain and the Netherlands were consulted by EFSA to clarify and validate their national data on food and environmental 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 853/2004 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. 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 ECDC's and EFSA's knowledge as of 25 November 2019. 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.

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Annex

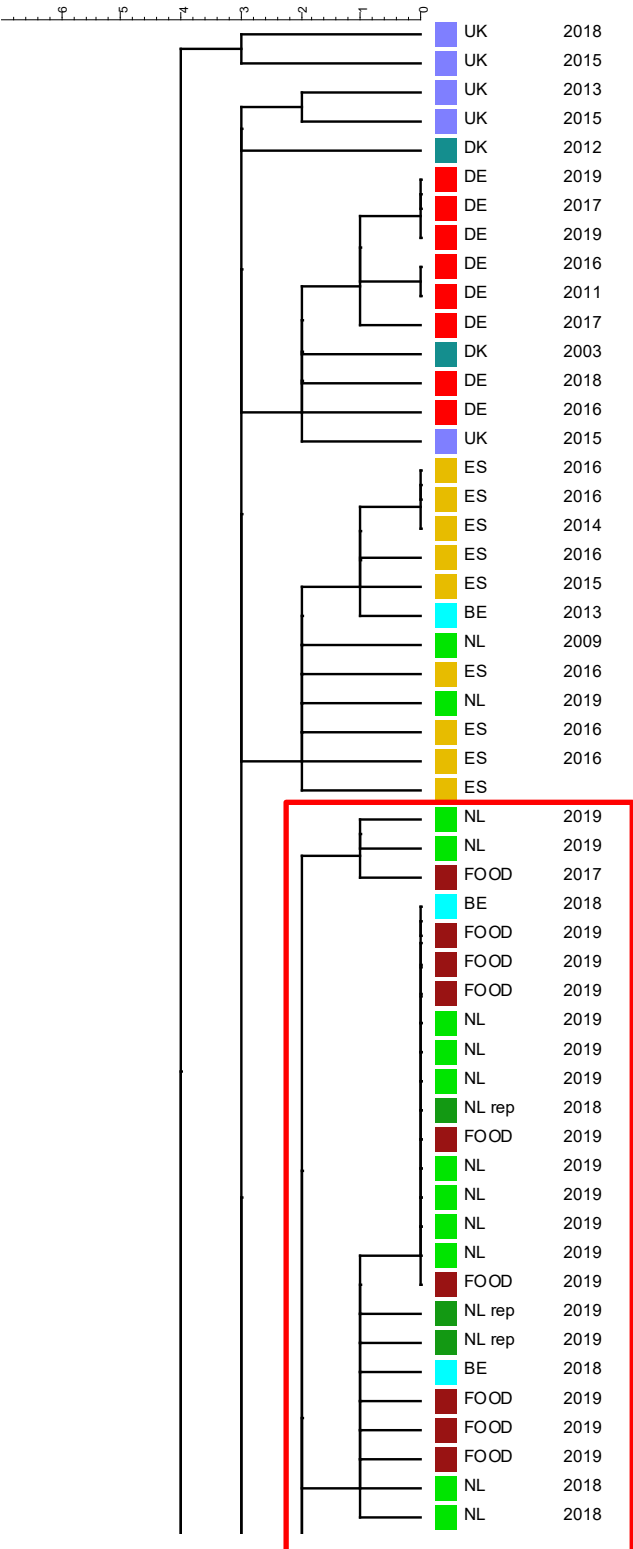
Table 1. Overview of *Listeria monocytogenes* positive RTE meat-based products produced by the Dutch Manufacturing Company A

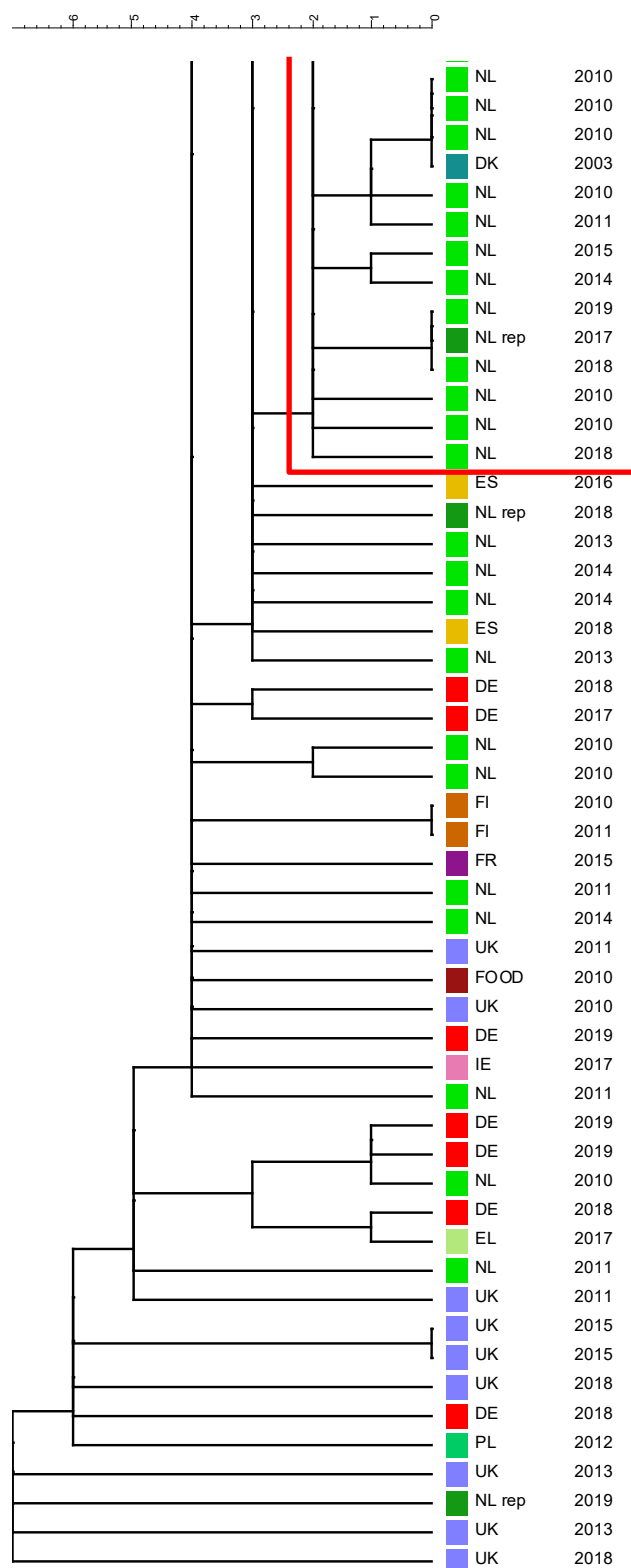
Type of Control	RTE meat-based product sampled	Production year	Meat supplier (country)	Slicing line	Detection (cfu/g)	Serogroup (Sequence Type)	EU WGS analysis (AD)
Official	Product A	2017	Supplier C (NL)	Line 3	Detected (na)	IVb (na)	≤3 AD
Own-check	Product B	2019	Supplier B (NL)	Line 1	Detected (na)	IVb (ST 6)	≤3 AD
Own-check	Product C	2019	Supplier C (NL)	Line 1	Detected (na)	IVb (ST 6)	≤3 AD
Own-check	Product D	2019	Supplier C (NL)	Line 1	Detected (na)	IVb (ST 6)	≤3 AD
Own-check	Product E	2019	Supplier C (NL)	Line 1	Detected (na)	IVb (ST 6)	≤3 AD
Own-check	Product F	2019	Supplier A (NL)	Line 1	Detected (270 000cfu/g)	IVb (ST 6)	≤3 AD
Official	Product G	2010	Supplier D (NL)	Line 2	Detected (na)	na (na)	6 AD
Own-check	Product H	2017	Supplier C (NL)	Line unknown	Detected (<100cfu/g)	na (na)	na
Official	Product I	2018	Supplier C (NL)	Line 3	Detected (na)	IIc (na)	na
Official	Product J	2019	Supplier C (NL)	Line 3	Detected (na)	IIa (na)	na
Own-check	Product K	2019	Suppliers unknown (NL)	Line unknown	Detected (na)	na (na)	na
Own-check	Product L	2019	Suppliers unknown (NL)	Line unknown	Detected (na)	na (na)	na
Own-check	Product M	2019	Supplier D (NL)	Line 5	Detected (>15 000cfu/g)	IIc (ST9)	na
Official	Product N	2019	Supplier E (NL)	Line 3	Detected (na)	IIa (ST8)	na
Own-check	Product O	2019	Supplier D (NL)	Line unknown	Detected (na)	na (na)	na
Own-check	Product P	2019	Supplier C (NL) and Supplier E (NL)	Line 6	Detected (<100cfu/g)	IVb (na)	na
Own-check	Product Q	2019	Supplier D (NL)	Line 7	na	IIa (na)	na
Own-check	Product R	2019	Supplier D (NL)	Line 6	Detected (<100cfu/g)	IVb (na)	na
Own-check	Product S	2019	Supplier F (unknown)	Line 8	Detected (<100cfu/g)	IIa (na)	na
Own-check	Product T	2019	Suppliers unknown (unknown)	Line 9	Detected (na)	na (na)	na
Own-check	Product U	2019	Suppliers C (NL) and Supplier E (NL)	Line 9	Detected (<100cfu/g)	na (na)	na
Own-check	Product V	2019	Supplier D (NL)	Line 9	Detected (na)	na (na)	na

na=not available; cfu=colony forming unit; AD=allelic differences in cgMLST with the representative outbreak strain according to the EU WGS analysis of human and non-human isolates.

Figure 1. Single-linkage dendrogram (cgMLST, Institut Pasteur scheme) including sequences from 94 human *L. monocytogenes* isolates and 10 non-human isolates from eleven countries, EU/EEA, 2003 to 2019.

The figure is split over two pages.





The cluster including the representative isolates are indicated using a red box.

Table 2. Distribution of human isolates clustering within 7 allelic differences from the outbreak cluster (single linkage), by country and time range of detection, EU 2003-2019 (n=94)

Reporting country	Time range of detection	Number of isolates
Belgium	2013-2018	3
Denmark	2003-2012	3
Finland	2010-2011	2
France	2015	1
Germany	2011-2019	15
Greece	2017	1
Ireland	2017	1
Netherlands	2009-2019	42
Poland	2012	1
Spain	2014-2018	11
United Kingdom	2010-2018	14
Total	2003-2019	94

Figure 2. Graphical representation of traceability, testing information and control measures reported by Member States under the RASFF notification 2019.3490, as of 20 November 2019

