

JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of monophasic *Salmonella* Typhimurium sequence type (ST) 34 linked to chocolate products

12 April 2022

Abstract

On 17 February 2022, the United Kingdom (UK) reported a cluster of cases with monophasic *Salmonella* Typhimurium sequence type 34 infection. By 8 April 2022, 150 cases had been reported in nine EU/EEA countries and the UK. Most cases are below 10 years of age and many children have been hospitalised. The strain exhibits resistance to seven antimicrobial classes but remains susceptible to azithromycin, ciprofloxacin, meropenem, and cephalosporins. Case interviews and epidemiological investigations suggest specific chocolate products of Brand A, produced by Company A from Processing Plant B in Belgium as likely vehicles of infection.

Monophasic *Salmonella* Typhimurium matching the human outbreak strain had been identified at Plant B in December 2021 in own-check samples. The processing step involving buttermilk was identified as the possible contamination point, and hygiene measures were implemented. Plant B distributed the implicated chocolate products across Europe and globally after negative *Salmonella* testing. Public warnings have been issued by the competent national authorities in different countries. On 8 April 2022, based on the official controls, the food safety authority in Belgium assessed that Plant B was not able to guarantee the safety of its products. As a result, the authorisation for production was withdrawn. Simultaneously, Company A decided to extend the recall to all batches of all products of Brand A produced at Plant B regardless of lot number or expiration date.

This outbreak is rapidly evolving, and children have so far been most at risk for severe infection among reported cases. The recalls and withdrawals launched worldwide will reduce the risk of further infections. However, further investigations are needed at the production site to identify the root cause, timing, and possible factors behind the contamination, including the evaluation of the possibility of the wider use of contaminated raw material in other processing plants.

Event background

On 17 February 2022, the United Kingdom reported in the European Centre for Disease Prevention and Control's (ECDC's) EpiPulse system (event ID 2022-FWD-00014) a 5-single nucleotide polymorphism (SNP) cluster of 18 cases with monophasic *Salmonella* Typhimurium infection of eBURST Group 1 (eBG1) with SNP designations using the United Kingdom Health Security Agency's (UKHSA) whole genome sequencing (WGS) pipeline: 1.1.1.124.6096.7575.%.

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Two representative UK isolates are publicly available in the European Bioinformatics Institute/European Nucleotide Archive (EBI/ENA) with genome codes SRR17830210 and SRR18021617. The Enterobase cgMLST hierarchical clustering designation for the outbreak isolates is HC5_296366 [1,2].

Comparisons of the national sequences with the outbreak strains in the United Kingdom (UK) revealed cases with isolates genetically close to the UK strains. The increasing number of case reports from several EU/EEA countries and the UK triggered the investigations and initiation of a joint ECDC-EFSA Rapid Outbreak Assessment.

Resistance profile

According to the analyses in the UKHSA, the outbreak strain is **susceptible** to azithromycin (MIC = 4-8 mg/L), ciprofloxacin (MIC = <0.06 mg/L), meropenem (MIC = 0.03-0.06 mg/L), cephalosporins including cefotaxime (MIC = 0.25 mg/L) and ceftazidime (MIC = 0.25 mg/L).

The outbreak strain is **resistant** to six families of antibiotics:

- penicillins (*bla*_{TEM-1});
- aminoglycosides (streptomycin, spectinomycin, kanamycin, and gentamycin (gene combination varies); strA-strB, aac(6')-Ia, aac(3)-IIId, aph(6)-Id, aadA-2, aadA-8b, aadA-12, aadA-15 and aadA-17;
- phenicols (*cmlA1*, *floR*);
- sulfonamides (sul2 with some strains having an additional sul3 gene);
- trimethoprim (*dhfrA12*); and
- tetracyclines (*tetA* and *tetM*).

In addition, some strains contained the *lnu(F)* gene encoding resistance to **lincosamide**, but this could not be confirmed phenotypically.

The resistance to aminoglycosides, phenicols, and trimethoprim is rare in monophasic *S. Typhimurium* and could therefore be used for screening of probable cases. However, France has noted that a minor proportion of their isolates matching the outbreak sequence have lost a DNA block containing several genes, including those encoding for this rare resistance.

European outbreak case definition

The European outbreak case definition is as follows:

A confirmed outbreak case

- A laboratory-confirmed monophasic *Salmonella* Typhimurium case with symptom onset on or after 1 October 2021 (date of sampling or date of receipt by the reference laboratory if date of onset is not available).

AND

- Fulfilling the following laboratory criteria: a monophasic *S. Typhimurium* ST34 isolate clustering with any of the two representative outbreak strains by:
 - the national cgMLST pipeline within five allelic differences (AD); OR
 - clustering in a centralised whole genome sequencing (WGS) analysis within five ADs in a single linkage analysis; OR
 - belonging to the same cgMLST HC5_296366 cluster according to the Enterobase scheme; OR
 - falling into the 5-SNP (single nucleotide polymorphism) single linkage cluster 1.1.1.124.6096.7575.% (t5.7575) (eburst group 1), according to the UK Health Security Agency (UKHSA) pipeline; OR
 - the national SNP pipeline within five SNPs.

A probable outbreak case

- A laboratory-confirmed monophasic *S. Typhimurium* case with symptom onset on or after 1 October 2021 (date of sampling or date of receipt by the reference laboratory if date of onset is not available).

AND

- By phenotypical testing expressing resistance to ampicillin/amoxicillin, kanamycin/gentamicin, trimethoprim/co-trimoxazole (trimethoprim-sulfamethoxazole) and chloramphenicol.

OR

- MLVA (multilocus variable number tandem repeat analysis) profile 3-11-14-NA-0211 (determined by Belgium).

Epidemiological and microbiological investigations of human cases

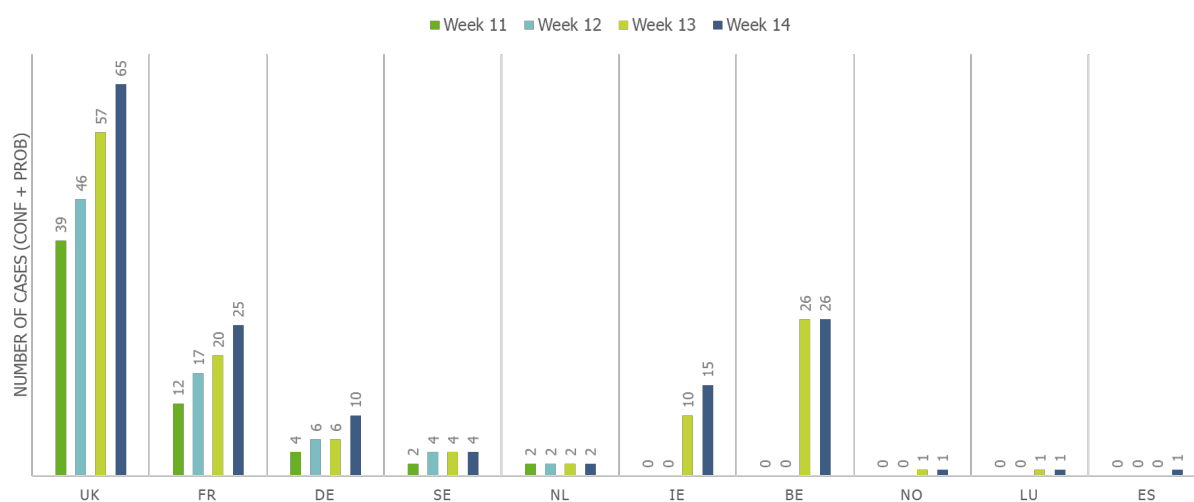
As of 8 April 2022, 150 confirmed or probable cases of monophasic *S. Typhimurium* have been reported in nine EU/EEA countries and the UK (Table 1). After the alert by the UK on 17 February 2022, the reported number of cases more than doubled within three weeks, from 57 cases in five countries on 18 March (week 11) to 150 cases in 10 countries on 8 April 2022 (week 14) (Figure 1). The increase is most notable in France, Ireland, and the UK (Figure 1).

The first case was reported in the UK on 7 January 2022 with a sampling date on 21 December 2021. The latest sampling date has been reported for two cases in the UK on 28 March 2022. The majority of infections are among children younger than 10 years, and many of them have been hospitalised (Table 1).

Table 1. Number of confirmed and probable cases of monophasic *S. Typhimurium* and proportion of hospitalisations by country, as of 8 April 2022

Country	Confirmed cases	Probable cases	Total number of cases	Hospitalised (among cases with available data)
Belgium	0	26	26	48%
France	25	0	25	50%
Germany	6	4	10	63%
Ireland	15	0	15	33%
Luxembourg	1	0	1	Case hospitalised
Netherlands	2	0	2	Unknown
Norway	1	0	1	No
Spain	0	1	1	No
Sweden	4	0	4	One of four cases
Total EU/EEA	54	31	85	
United Kingdom	65	0	65	43%
Total	119	31	150	

Figure 1. Cumulative number of confirmed and probable monophasic *S. Typhimurium* cases by week and country in nine EU/EEA countries and the UK, as of 8 April 2022



Information from patient interviews

The first interviews in the UK indicated that more cases than expected had consumed specific chocolate products of a common brand (Brand A) prior to illness. Subsequent interviews of cases in other countries strengthened the hypothesis of these chocolate products as likely vehicles of infections.

As of 8 April, 88 of 101 (87.1%) interviewed cases in 10 countries had reported consumption of various types of chocolate products of Brand A, mainly milk chocolate eggs with a small toy inside and/or small oval shaped, bite-sized chocolate pralines.

Microbiological and environmental investigations of food and control measures

This section summarises country-specific information on microbiological investigations and traceability analyses of the chocolate products, and control measures implemented by the involved countries as reported through the Rapid Alert System for Food and Feed (RASFF) alert notification 2022.1799 as of 8 April 2022 14:30 (72 follow-ups - *fup72*). A visual representation describing the traceability and control measures for chocolate products linked to food exposure information, and testing information linked to the Company A is provided in Figure A1 (Annex 1).

On 25 March 2022 the European Commission sent an alert through RASFF (RASFF alert notification 2022.1799) of an ongoing foodborne outbreak of infections caused by monophasic *Salmonella* Typhimurium. According to the food exposure information reported by the public health authorities in the United Kingdom (UK), Germany, France, and Sweden, different types of chocolate products from Brand A produced by Company A were suspected to be the vehicle of the infection. Company A has plants in Belgium (Belgian Processing Plant B), France, Germany, Ireland, Italy and Poland that produce different products, including chocolate products of Brand A (*fup23*).

On 8 April 2022, the food safety authority in Belgium informed through RASFF that the investigation in the Belgian Processing Plant B had shown that the plant had not been able to provide the necessary guarantees concerning its management of the contamination and was therefore not able to guarantee the safety of its products. The food safety authority decided to withdraw the authorisation for production of the Belgian Processing Plant B. Company A therefore decided to extend the recall to all batches of Brand A products manufactured in this facility, regardless of lot number or expiration date. Company A will inform all its business units in the different countries. They will in turn inform the local authorities. The food safety authority in Belgium has taken all the necessary measures concerning the Belgian Processing Plant B (*fup71*).

A summary of the investigations and control measures taken in each country as of 8 April 2022 is described below.

The United Kingdom

The epidemiological investigation performed by the public health authority in the UK pointed to chocolate products of Brand A from Company A as a possible vehicle of the infection. The UK's food safety authority and competent authorities had discussed the issue with Company A and provided additional information (*fup42*).

On 2 April 2022, the food safety authority in the UK issued a public warning to recall Product A (different sizes) with expiring dates up to October 2022 and a product withdrawal of Product B and other chocolate products with expiry dates between July and August. On 6 April 2022, the recall was extended to Product B of Brand A with expiring dates between April 2022 and August 2022, and to other chocolate products from the same brand that had been manufactured at the Belgian Processing Plant B too (*fup42*). Additional publications on the Food Safety Authority's website were also made on each date of the recall and public warnings to inform consumers the product recall was linked to a foodborne outbreak (2 April and 6 April).

Belgium

In Belgium, Company A produces products of Brand A (Product A, Product B, Product D, Product E) and other chocolate products of a different brand (Product F) in a single plant (Belgian Processing Plant B) (*fup23*).

On 5 April 2022, the food safety authority in Belgium reported in RASFF that official controls were ongoing at the Belgian Processing Plant B and official samples were collected from raw materials, finished products, from the external deposit of the plant, and from various retailers. Microbiological analyses are ongoing (*fup20*).

The Belgian Processing Plant B's own-check plan consists of microbiological analysis on finished products, raw materials, and surfaces. In particular, the Belgian Processing Plant B performs daily *Salmonella* testing of semi-finished and finished products on sampling equal to 250g for each analysis (*fup23*). The Belgian Processing Plant B only releases compliant final products onto the market. The leading time from manufacture to shelf is between 55 and 60 days (*fup42*). Company A communicated that some of the raw materials used are similar across various products. The supplier of the raw materials for products of Brand A is batch-dependent (two or three suppliers for

raw materials), but there have been no changes in suppliers, recipes or manufacturing process in the past year (*fup42*). In addition, Company A communicated that the shelf-life of Product A and of other products of Brand A is 270 days for the UK, while in Europe this is 225 days (*fup42*).

The food safety authority in Belgium informed that within the framework of the own-check analyses, *Salmonella* was recorded on 15 December 2021 from a semi-finished product produced on 12 December 2021 (*fup23*, *fup42*), specifically on the surface and in residual raw materials samples taken from buttermilk tanks (*fup42*). The food safety authority in Belgium was informed about this *Salmonella* finding at the beginning of April 2022 (*fup20*). In January, other samples on semi-finished and finished products and surface analyses were also positive for *Salmonella*. The last *Salmonella*-positive results were recorded by the Belgian Processing Plant B on 11 January 2022 (*fup42*), from two buttermilk tanks.

A total of nine isolates from this finding (*fup10*, *fup13*), all referring to samples of semi-finished products made at the Belgian Processing Plant B, were submitted between 5 January 2022 and 8 February 2022 by Company A to an Italian laboratory for serological and molecular typing. The exact dates of sampling and the sample matrixes linked to these isolates were not reported to RASFF. All isolates were typed as monophasic *Salmonella* Typhimurium ST34. WGS analysis of four out of nine isolates based on cgMLST V2 as implemented in EnteroBase [1] showed identical profiles as of the outbreak strain and revealed the presence of the following antimicrobial resistance genes: *aac(3)-IIId*, *strB*, *aadA1*, *aph(3')-Ia*, *aadA2*, *strA*, *sul2*, *sul3*, *dfxA12*, *tet(M)*, *tet(B)*, *cmiA1*, *floR*, *bla_{TEM-1B}*, and *lnu(F)* (*fup17*). Five out of nine isolates do not match the outbreak strain. However, the WGS analysis based on cgMLST V2 as implemented in EnteroBase [1] revealed that they form a different cluster at 0-1 allelic distance from each other (*fup17*).

Following an internal procedure of the Belgian Processing Plant B, the root cause analysis of the positivity findings in the Belgian Processing Plant B identified the butter circuit as the point of origin of contamination (*fup42*). After the positive finding of 15 December 2021, the production was stopped (except for the production line of Product F which was physically separated), the affected semi-finished product was destroyed (*fup23*), and deep cleaning of whole lines was carried out (*fup42*). Production was restored after microbiological negative results. The plant activated emergency protocol affecting all production, and released final products after negative test results (*fup42*). In addition, the concerned finished products, *i.e.*, Product A and Product B, that were produced from 10 December 2021 until 15 December 2021 were blocked by the Belgian Processing Plant B and stored in an external storage deposit (*fup20*). The products were released to the market after an internal investigation of the traceability of the semi-finished products used for the production of final products (*fup20*, *fup42*). After the positive finding on 11 January 2022, the production was stopped, the butter circuit was bypassed, and the entire line was deep cleaned. Production was progressively restored (*fup42*). The butter circuit was further dismantled and cleaned by an external company, and was reconnected to the production after negative results were obtained. *Salmonella* was not detected since the restore of the production (*fup42*).

As a result of the *Salmonella* detection on 15 December 2021, the Belgian Processing Plant B of Company A increased the amount of samples taken and the frequency of the sampling on the semi-finished and finished products, and on the production environment starting from the communication of the *Salmonella* detection on 15 December 2021 until March 2022, and released the product onto the market after testing *Salmonella* negative (*fup20*). The Belgian Processing Plant B tests the samples using validated PCR methodology after enrichment (*fup42*).

As of 7 April 2022, the food safety authority in Belgium reported in RASFF that the Belgian Processing Plant B of Company A has been conducting a recall in the concerned countries. Specifically, recall includes Product A, Product B (sold alone and as component of the mix packages), Product E and Product D with different batch numbers (batches concerned with expiry dates between April 2022 and November 2022) produced at the Belgian Processing Plant B (*fup20*, *fup23*). In addition, the recall also includes mix packages of chocolate products assembled in other processing plants of Company A but containing products produced at the Belgian Processing Plant B. These products had been distributed widely including EU/EEA and several third countries across the globe (*fup20*, *fup28*, *fup38*, *fup39*). This voluntary and precautionary recall was performed by Company A based on the *Salmonella* detection on 15 December 2021 in the Belgian Processing Plant B and on the epidemiological studies performed by the public health authorities in different countries, including the first case detection in the UK on 21 December 2021 (*fup20*).

From 8 April 2022, based on the outcome of investigations performed by the food safety authority in Belgium showing that the plant has not been able to provide the necessary guarantees concerning its management of the contamination and is therefore not able to guarantee the safety of its products, the food safety authority decided to withdraw the authorisation for production of the Belgian Processing Plant B. At the same time, Company A decided to extend the recall to all batches of all products of Brand A produced at the Belgian Processing Plant B (*fup71*).

Germany

In Germany, Company A produces different products of Brand A (including Product A) and other chocolate products of different brands in a single plant (German Processing Plant A) (*fup23*).

The food safety authority in Germany provided the traceability of the chocolate products that had been mentioned by the interviewed cases and that had a distribution link with the German Processing Plant A. The food safety authority clarified that Product B among those mentioned by the cases originated from the Belgian Processing Plant B.

The German Processing Plant A performs 150 microbiological self-checks daily and 35 000 per year (*fup1*). The German headquarters of Company A is exclusively responsible for the traceability within Germany (*fup29*). On 25 March 2022, the food safety authority in Germany reported in RASFF that the German Processing Plant A was inspected on 25 March 2022. Twenty-six official food samples were collected from different batches of chocolate products of Brand A (*fup1*).

An additional 17 samples of different products of Company A expiring in 2022 and 2023, including Product A, Product B and other products were collected in Hamburg on 28 and 29 March 2022 by the food safety authority in Germany (place of sampling was not available in RASFF). All samples tested negative for *Salmonella* (*fup24*).

In addition, samples of chocolate products were collected from retailers and from consumers. At consumer level, samples were collected from opened packages of Product C of Brand A, but also from other products of other brands of different companies (Product G of the Brand B and Product H belonging to Brand C). *Salmonella* was not detected in the collected samples (analysis performed by culture and/or PCR) (*fup4*).

Moreover, the food safety authority in Germany informed that 14 official samples from Product B of Brand A, originating from the Belgian Processing Plant B, were further collected on 30 March 2022 at retail level and at consumer level (one sample from an open package collected from a sick person). *Salmonella* was not detected (analysis performed by culture and/or PCR).

On 5 April 2022, a press release was issued by Company A in Germany to recall chocolate products of Brand A that had been produced at the Belgian Processing Plant B, sold alone or in a mix package, including Product A, Product B, Product C, Product D, Product E, and other chocolate products of Brand A with best before date between April and September 2022 (*fup28*).

On 8 April 2022, the existing recall was extended by Company A to all best-before dates.

Italy

In Italy, Company A produces products of Brand A in four processing plants: Italian Processing Plant C, Italian Processing Plant D, Italian Processing Plant E and Italian Processing Plant F. Company A informed that none of the semi-finished products produced at the Belgian Processing Plant B is used at the Italian Processing Plants (*fup23*).

On 6 April 2022, the food safety authority in Italy informed about precautionary measures taken by Company A. Concerning products produced at the Belgian Processing Plant B subjected to voluntary recall at European level, Company A informed, with regards to the Italian market, the following decisions:

- Product A: the product is not subject to recall in Italy since it is no longer present on the market; they were seasonal products for the Christmas time, and they are not available on the Italian market since January 2022 due to the seasonal withdrawal performed by Company A
- Product B: products with expiry dates between May 2022 and August 2022 are subject to precautional recall in Italy (*fup32*)
- Product E and Product D: products are not subject to recall in Italy since they are not currently present on the national territory.

In addition, the food safety authority in Italy reported that Product B had been distributed from Italy also to San Marino and Vatican City (*fup34*).

France

On 6 April 2022, the food safety authority in France reported that official controls were ongoing at the French Processing Plant G of Company A and that the cases' purchases were being investigated too (*fup6*, *fup44*). On 7 April 2022, the food safety authority in France reported that chocolate products manufactured at the Belgian Processing Plant B from Brand A were withdrawn: Product A with expiry dates between April 2022 and October 2022, Product B with expiry dates between April 2022 and August 2022, Product C with expiry date to August 2022, and Product E with expiry dates between April 2022 and August 2022 (*fup54*).

Ireland

On 6 April 2022, the food safety authority in Ireland informed that Company A recalled Product A with best before dates up to October 2022 (*fup47*). In addition, Product B, Product E, and other chocolate products of Brand A with best before dates between April and August 2022 were recalled. Point-of-sale recall notices had been displayed in stores supplied with the implicated batches. A food alert for action was published. (*fup14, fup30*).

The Netherlands

On 6 April 2022, the food safety authority in the Netherlands reported that Product A, Product B, Product C, Product D, and other chocolate products of Brand A expiring between March 2022 and October 2022 were recalled by Company A in the Netherlands and public warning was issued by the same Company A after which the food safety authority also published a public warning (*fup31*). The products had been further distributed by several Dutch distributors to recipients in Belgium, Germany, France, Luxembourg, Aruba and Canada (*fup36, fup37, fup40, fup41*).

Portugal

On 6 April 2022, the food safety authority in Portugal informed that control measures were implemented, and a public warning was issued. The following products produced at the Belgian Processing Plant B were recalled: Product A, Product B, expiring between May 2022 and August 2022, Product C with expiring dates in April and in August, Product D and other chocolate products of Brand A (*fup33, fup35, fup50, fup59*).

Sweden

On 6 April 2022, the food safety authority in Sweden reported that Product A, Product B, Product D, and Product E, expiring between April and October 2022 and manufactured at the Belgian Processing Plant B, were recalled and a public warning was issued (*fup43*).

Luxembourg

On 5 and 6 April 2022, the food safety authority in Luxembourg issued public warnings to recall chocolate products from Brand A: Product A, Product B, Product C and other chocolate products from Brand A (*fup44*).

The food safety authority in Luxembourg informed that following the implementation of the recalls by Company A, 23 official samples were collected and analysed by PCR on 7 April 2022. *Salmonella* was not detected. Further analyses by culture and by immunoassay method were both negative.

Spain

On 6 April 2022, the food safety authority in Spain informed that chocolate products from Brand A distributed in Spain were recalled as precautionary measures. Specifically, Product B with expiry dates between May and August, and other chocolate products, with expiry dates between May and August (*fup62*).

Hungary

On 6 April 2022, the food safety authority in Hungary published a public warning to recall chocolate products from Brand A as precautionary measures: Product B, Product D, Product C, Product E and other chocolate products from Brand A with expiry dates between May and August 2022 (*fup52*).

Finland

On 7 April 2022, the food authority in Finland issued a public warning to recall chocolate products manufactured at the Belgian Processing Plant B from Brand A as a precautionary measure: Product A, Product B and Product E with best before dates between May and October 2022 (*fup56*).

Norway

On 7 April 2022, the food safety authority in Norway informed that chocolate products manufactured at the Belgian Processing Plant B from Brand A were withdrawn: Product A, Product B, Product D and Product E (*fup57*).

Iceland

On 7 April 2022, the food safety authority in Iceland issued a public warning to recall chocolate products from Brand A: Product A (*fup58*).

Czechia

On 8 April 2022, the food safety authority in Czechia reported that the Czech operator of Company A had a videoconference on 3 April 2022 with Company A headquarters, and over the following days, specific products and batches were gradually specified by Company A. On 6 April 2022, the Czech operator of Company A provided to the food safety authority in Czechia the list of implicated products, which were distributed to the Czech and Slovak market. In addition, the Czech operator of Company A informed via social media and a press release the recall of chocolate products manufactured at the Belgian Processing Plant B from Brand A as a precautionary measure: Product B, Product D, Product C, Product E and other chocolate products from Brand A with expiry dates between April and September 2022 (*fup61*). The Czech operator of Company A only supplies the products from Company A to Czechia and Slovakia. The Czech operator of Company A asked its recipients in Czechia and Slovakia to withdraw the products from the market and return them to its warehouse in Czechia, after which they would be disposed of. On 7 April 2022, the food safety authority in Czechia carried out an inspection at the Czech operator of Company A. During the inspection, official samples from 10 randomly selected products (chocolate, confectionery expiring in 2022 and 2023) including Product B and other products, were taken to determine the presence of *Salmonella* (*fup61*). All tested samples were negative for *Salmonella*. Further 14 samples were collected on the market (results pending).

Denmark

On 8 April 2022, the food safety authority in Denmark reported that chocolate products manufactured at the Belgian Processing Plant B from Brand A were withdrawn: Product A with expiry dates between June 2022 and October 2022, Product B with expiry dates between May 2022 and August 2022, Product D with expiry dates between April 2022 and August 2022, and Product E with an expiry date of August 2022 (*fup67*).

Croatia

On 8 April 2022, the food safety authority in Croatia issued a public warning to alert on the recalls implemented by Company A regarding Product B, Product C and other chocolate products from Brand A with expiry dates between May 2022 and October 2022 (*fup75*).

Romania

On 8 April 2022, the food safety authority in Romania issued a public warning to recall chocolate products as a precautionary measure from Brand A: Product B, Product D, Product A, Product C and other chocolate products from Brand A with expiry dates between April and October 2022 (*fup72*).

Slovakia

On 7 April 2022, the food safety authority in Slovakia reported that chocolate products manufactured at the Belgian Processing Plant B from Brand A were recalled: Product B with expiry dates between May 2022 and August 2022, Product C with expiry dates between February 2022 and September 2022, Product D with expiry dates between April 2022 and July 2022, Product E with expiry dates between July 2022 and August 2022, and other chocolate products from Brand A with expiry dates between April and August 2022 (*fup53*). In addition, the food safety authority informed that Company A withdrew from the market in Slovakia all batches from Brand A: Product B, Product C, Product D, Product E, and other chocolate products.

Greece

On 8 April 2022, Company A informed the food safety authority in Greece that, as a precaution, they have taken the decision to voluntarily recall certain lots of chocolate products in Greece manufactured at the Belgian Processing Plant B: Product B and Product D. On 6 and 8 April 2022, the food safety authority in Greece also issued a public warning to inform consumers and it is monitoring the recall of the involved products.

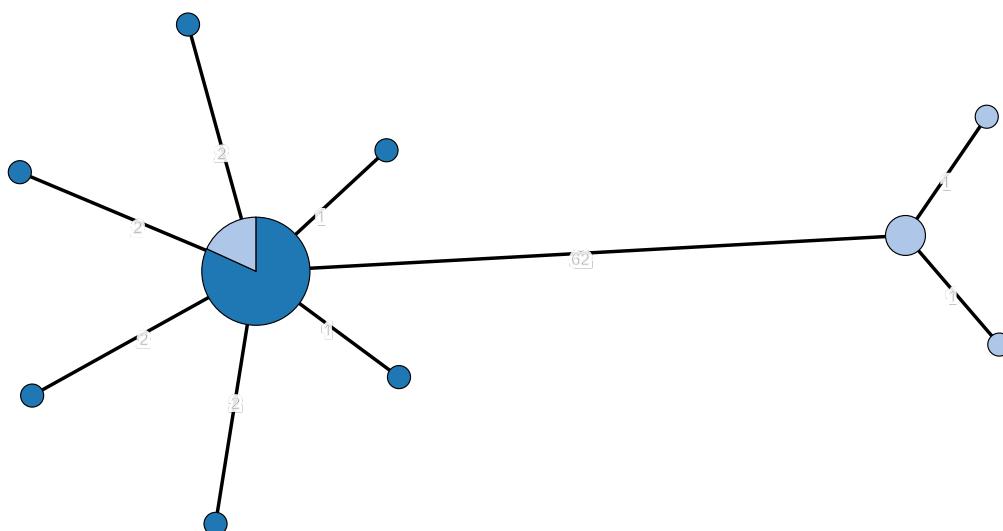
European whole genome sequencing analysis of human and non-human isolates

The EURL-*Salmonella* launched a consultation for submitting sequences of monophasic *S. Typhimurium* isolated from food between January 2021 and June 2022. As of 8 April 2022, National Reference Laboratories (NRL) in 10 countries had replied: Czechia, Cyprus, Germany, Ireland, Latvia, Malta, Slovenia, Spain, Switzerland, and the Netherlands. None of the identified sequenced isolates either matched the outbreak strain or were epidemiologically linked to the outbreak.

The Italian laboratory that typed the isolates from the Belgian Processing Plant B submitted to EFSA the genome sequences of nine monophasic *S. Typhimurium* isolates from samples of semi-finished products. The nine non-human isolates were analysed together with 24 human isolates of HC5_296366, including the two representative isolates of the outbreak strain, shared publicly by UKHSA and available in European Nucleotide Archive (ENA). CgMLST analysis was performed in EFSA using chewBBACA version 2.8.5 (<https://github.com/B-UJMMI/chewBBACA>) using the schema as described by Rossi et al. 2018 [3] for *Salmonella enterica* made available by chewie Nomenclature Server [4] at <https://chewbbaca.online/species/4>. Isolates with more than 1% of missing loci (32 over a total of 3 225 loci) were excluded from the analysis. The minimum spanning tree was constructed using MSTree V2 algorithm as implemented in GrapeTree v1.5.0 [5] and shown in figure 2.

The analysis shows the presence of two distinct clusters at 62 allelic differences from each other. One cluster includes the representative isolates of the outbreak strain (SRR17830210 and SRR18021617), all human isolates from HC5_296366 and four non-human isolates from the Belgian Processing Plant B. The second cluster includes only the non-human isolates from the Belgian Processing Plant B that belong to a different Enterobase cgMLST hierarchical cluster designation HC5_298160.

Figure 2. Minimum spanning tree of 24 human (dark blue) and nine non-human (light blue) monophasic *Salmonella Typhimurium* isolates



ECDC and EFSA risk assessment for the EU/EEA

As of 8 April 2022, 150 cases of monophasic *S. Typhimurium* ST34 have been identified in nine EU/EEA countries and the UK since 21 December 2021 (sampling date for a first identified case in the UK). The two most recent cases have sampling dates of 28 March 2022 in the UK. Most cases are in children younger than 10 years, and an exceptionally high proportion of cases have been hospitalised. Case interviews (88/101 in 10 countries) suggest chocolate eggs with a surprise toy inside (Product A) and small oval shaped, bite-sized chocolate pralines (Product B) of Brand A as likely vehicles of infection, both produced by Company A in Belgium.

At the Belgian Processing Plant B of Company A, monophasic *S. Typhimurium* matching the representative outbreak strain was identified on 15 December 2021 in own-check samples collected from residual raw materials from buttermilk tanks. The processing step involving buttermilk was identified by the Belgian Processing Plant B as the point of the contamination involving the production of both Products A and B. It is worth noting that Product A was identified in several countries, including the UK, as the most frequently reported product consumed by cases and that for the UK market it is only produced at the Belgian Processing Plant B. Moreover, Product B was one among those products mentioned by the cases and also originated from the Belgian Processing Plant B.

Considering that the average time from production to retail is approximately 60 days, the first identified case in the UK on 21 December 2021 cannot be explained by the contamination detected in the Belgian Processing Plant B in December. This suggests that if the Belgian Processing Plant B was the sole source of the infection, the contamination in the production line occurred earlier. Based on this information, public warnings were issued by the national competent authorities in different countries. Then, initially Company A implemented voluntary and precautionary recalls of Product A, Product B and of other products of Brand A produced at the Belgian Processing Plant B with expiry dates from April to October 2022, based on the *Salmonella* detection on 15 December 2021 in the Belgian Processing Plant B and on the epidemiological studies in different countries, including the first case detection in the UK on 21 December 2021. On 8 April 2022, the official controls performed by the food safety authority in Belgium showed that the plant was not able to guarantee the safety of its products. Therefore, the food safety authority decided to withdraw the authorisation for production of the Belgian Processing Plant B. At the same time, Company A decided to extend the recall to all batches of all products of Brand A produced at the Belgian Processing Plant B.

This is a rapidly evolving outbreak of monophasic *S. Typhimurium* with children at most risk for severe infection. The high hospitalisation rate warrants specific attention and based on antimicrobial susceptibility testing, the outbreak strain seems to be susceptible to azithromycin, ciprofloxacin, meropenem and cephalosporins including cefotaxime and ceftazidime. Considering the type of the implicated chocolate products, which are widely consumed by children, and Easter approaching, the initiation of recalls and withdrawals of the suspected chocolate products in several countries is well justified as immediate control measures. It is likely that cases in other countries may have remained undetected due to limited capability for sequencing.

The recalls and withdrawals launched worldwide will reduce the risk of further infections. However, there are several information gaps that need to be investigated further to understand the root cause, timing and possible factors behind the contamination, including the evaluation of the possibility of the wider use of contaminated raw material in other processing plants.

Options for response

ECDC continues the prospective monitoring of reported cases on its website and encourages Member States to be alert for, and investigate, human infections with monophasic *S. Typhimurium* strains that have multi-drug resistance profiles, particularly showing resistance or having resistance markers to kanamycin/gentamicin, trimethoprim or co-trimoxazole (trimethoprim-sulfamethoxazole), and chloramphenicol. Further sequencing of such isolates is recommended. ECDC encourages countries to interview those cases for possible exposure to chocolate products described in this ROA. Any new information on human cases linked to this event should be reported in EpiPulse under the event 2022-FWD-00014. ECDC can offer sequencing support for countries with limited or no WGS capacity. Notifications in the Early Warning and Response System (EWRS) should be issued if the appropriate criteria are fulfilled. ECDC further encourages public health authorities to cooperate closely with food safety authorities.

EFSA encourages Member States to perform sequencing of monophasic *S. Typhimurium* food isolates related to the RASFF notification 2022.1799 and/or linked to the present cluster either microbiologically (serogroup or ST) or epidemiologically (e.g. consumption of chocolate products by human cases or isolates linked to the company involved as in RASFF 2022.1799), and to share these sequences with EFSA and the EURL for *Salmonella*. Further information about food traceability investigation can be requested from the RASFF contact point for the relevant countries. EFSA can offer sequencing support to those countries that have no capacity (on request via roa-efsa@efsa.europa.eu).

Source and date of request

DG SANTE, EFSA, and ECDC agreed on 4 April 2022 to produce a Rapid Outbreak Assessment. ECDC sent an official request to EFSA on 4 April 2022 and EFSA accepted it on 5 April 2022.

Consulted experts and national contact points

ECDC experts (in alphabetical order): Áine Collins, Johanna Takkinen, Therese Westrell

Public health experts:

Belgium: Dieter Van Cauteren, Valeska Laisnez, Wesley Mattheus (Sciensano), Inne Nauwelaers;

Czechia: Ondřej Daniel (National Reference Laboratory for Salmonella, National Institute of Public Health), Michaela Špačková (Department of Infectious Diseases Epidemiology, National Institute of Public Health);

France: Maria Pardos de la Gandara and François-Xavier Weill (Institut Pasteur, Centre National de Référence des *E. coli*, *Shigella* et *Salmonella*); Nathalie Jourdan-da Silva and Henriette de Valk (Santé publique France);

Germany: Sandra Simon (National Reference Centre for Salmonella and other bacterial enteric pathogens, Robert Koch Institute); Gerhard Falkenhorst and Raskit Lachmann (Department of Infectious Disease Epidemiology, Robert Koch Institute);

Ireland: Patricia Garvey, Sarah Gee, and Paul McKeown (Health Protection Surveillance Centre); Martin Cormican and Niall De Lappe (National *Salmonella*, *Shigella* and *Listeria* Reference Laboratory, University Hospital Galway); Charlotte Salgaard Nielsen, ECDC Fellowship Programme, Field Epidemiology path (EPIET) (European Centre for Disease Prevention and Control and Health Protection Surveillance Centre);

Luxembourg: Joël Mossong and Anne Vergison (Health Directorate); Catherine Ragimbeau (National Health Laboratory);

The Netherlands: Maaike van den Beld and Roan Pijnacker (National Institute for Public Health and the Environment);

Norway: Lin T. Brandal and Heidi Lange (Institute of Public Health);

Spain: Silvia Herrera León (National Centre of Microbiology, Instituto de Salud Carlos III), Carmen Varela Martinez (National Centre of Epidemiology, Instituto de Salud Carlos III);

Sweden: Rikard Dryselius and Nadja Karamehmedovic (Public Health Agency);

The United Kingdom: Marie Chattaway, Suzanne Gokool, Ann Hoban, Lesley Larkin, Jacquelyn McCormick, and Anaïs Painset (United Kingdom Health Security Agency), Derek Brown, Lynda Browning, and John Cowden (Public Health Scotland)

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

EFSA staff (in alphabetical order): Lorena Corredor Barrera, Ernesto Liebana, Denise Pezzutto, Valentina Rizzi, Mirko Rossi, Eleonora Sarno.

RASFF contact points: Austria, Belgium, Bulgaria, Cyprus, Czechia, Switzerland, Germany, Denmark, Estonia, Spain, Finland, France, Greece, Hungary, Croatia, Iceland, Ireland, Italy, Lithuania, Luxembourg, Latvia, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Sweden.

National experts consulted by the RASFF contact points:

Cyprus: Herodotos Herodotou (Public Health Services)

Czechia: Lenka Bartošová (Agriculture and Food Inspection Authority)

Estonia: Jelena Sögel (Food Department Agriculture and Food Board)

Finland: Miika Varjonen (Food Authority), Paula Hietanen (Food Authority)

Germany: Beatrice Ladewig (Food Safety Task-Force, Darmstadt Regional Council)

Greece: Aikaterini Choupa, Zinovia Fakiridou, Evangelia Foukaraki (Hellenic Food Authority)

Hungary: Mária Belláné Apostol (National Centre for Public Health), György Pleva Dr. (Directorate for Food and Feed Safety, National Food Chain Safety Office)

Ireland: Martine Brennan (Food Safety Authority)

Italy: Giovanni Mattalia, Raffaello Lena, Loredana Iuliano, Valentina Cambiotti (Office 8 DGISAN Ministry of Health), Lucia Decastelli (IZSPLV)

Luxembourg: Claude Scholtes (Commissariat alimentaire), Josiane Dahm (Division de la Sécurité alimentaire), François Zimer (Division de la Sécurité alimentaire), Patrick Hau (Commissariat alimentaire).

The Netherlands: Coen van der Weijden (Food and Consumer Products Authority)

Sweden: Mats Lindblad (Food Agency)

Other experts exceptionally consulted for the provision of technical data:

The United Kingdom: Tracy Bishop, Christine Gathumbi, Caroline Handford, Daniel Lloyd, Glynne Parmenter, Tina Potter (Food Standards Agency)

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 12 April 2022. 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.

Annex 1. Food traceability and analyses

Figure A1. Graphical representation of the traceability, testing information and control measures for chocolate products linked to food exposure and to Belgian Processing Plant B, as reported by the countries involved under RASFF notification 2022.1799



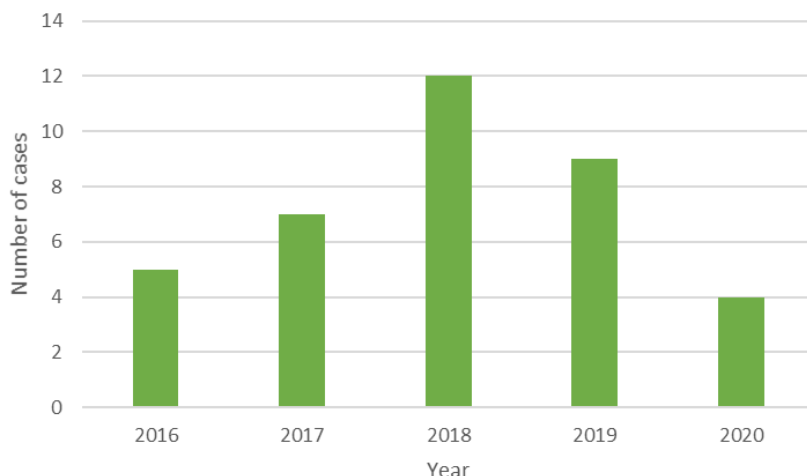
Annex 2. Disease background

Epidemiology of MDR monophasic *S. Typhimurium* in the EU

Monophasic *Salmonella* Typhimurium $\underline{1,4,[5],12:i:-}$ is the third most common serovar (or rather variant of Typhimurium) among human *Salmonella* infections in the EU/EEA [6]. Between 2016 and 2020, it accounted for 8.9% of reported salmonellosis cases. The serovar is known for expressing resistance to ampicillin, streptomycin, sulfonamides and tetracycline (resistance pattern ASSuT). However, the strain in the current outbreak is also expressing resistance to aminoglycosides (such as gentamicin and kanamycin), phenicols (such as chloramphenicol), and trimethoprim. Genes conferring resistance to lincosamides have also been identified but are not expressed in most tested isolates. The isolates are susceptible to macrolides, fluoroquinolones and third-generation cephalosporins.

Between 2016 and 2020, 14 EU countries reported antimicrobial susceptibility results for monophasic *S. Typhimurium* $\underline{1,4,[5],12:i:-}$ on the antimicrobial classes mentioned above to TESSy. Of 7 157 tested isolates, only 37 (0.5%) expressed this resistance, with the highest number of cases in 2018 (Figure A2). (Resistance here is considered as either non-wild type, according to EUCAST epidemiological cut-off values, or as decreased susceptibility, according to EUCAST clinical breakpoints). The 37 isolates were reported by 10 of the 14 countries and the cases were either domestically acquired (20 cases) or without information on travel status. Spain accounted for one third of the cases (n=12) but Luxembourg and Ireland reported the highest proportion of monophasic *S. Typhimurium* with this resistance pattern (3.6% and 2.9% of tested isolates, respectively). Children aged 0-4 years accounted for 30.0% of the cases, and the male-female ratio was 1:1.8.

Figure A2. Number of cases with resistance to the seven antimicrobial classes reported to TESSy, 2016-2020 (N=37)



Food-borne outbreaks caused by monophasic *S. Typhimurium* linked to chocolate products

This section summarises country-specific data on foodborne outbreaks associated with monophasic *S. Typhimurium* in the food categories 'Sweets and chocolate', 'Chocolate', and 'Confectionery products and pastes - chocolate-based product' reported from 2015 to 2020 to EFSA by EU Member States in accordance with the Zoonoses Directive 2003/99/EC. During the years 2015–2019 the United Kingdom was an EU Member State.

For the years 2015–2020, no monophasic *S. Typhimurium* food-borne outbreaks were reported linked to the food categories 'Sweets and chocolate', 'Chocolate', and 'Confectionery products and pastes - chocolate-based product'.

Occurrence of monophasic *S. Typhimurium* in chocolate products

This section summarises country-specific data on the occurrence of monophasic *S. Typhimurium* in the food categories 'Chocolate' and 'Confectionery products and pastes - chocolate-based product' from 2015 to 2020, as reported to EFSA by the EU Member States in accordance with the Zoonoses Directive 2003/99/EC. During the years 2015–2019 the United Kingdom was an EU Member State.

For the years 2015–2020, no units were reported to be positive for monophasic *S. Typhimurium*.

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