

JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of *Salmonella* Typhimurium and *S. Anatum* infections linked to Brazil nuts

21 October 2020

Since 1 August 2019, a multi-country outbreak, caused by *Salmonella* Typhimurium ST19 and *S. Anatum* ST64, has affected three European Union (EU) countries, the United Kingdom and Canada. As of 20 October 2020, 123 cases of *S. Typhimurium* ST19 and one case of *S. Anatum* have been reported, of which 105 were in the UK (including the *S. Anatum* case), 14 in France, three in Luxembourg, one each in the Netherlands and Canada. A case-control study in the UK and patient interviews in the UK, France and Luxembourg indicated Brazil nuts and nut bars as likely vehicles of infections.

Two batches of Brazil nuts from Bolivia, sampled at the British Processing Company B, tested positive for *S. Typhimurium* ST19 (Batch A) and *S. Anatum* ST64 (Batch B) matching the outbreak strains. These Brazil nuts were used for the production of certain batches of Nut Products A and Nut Product L. Brazil nuts, Nut Products A, and Nut Product L were identified as risk factors for illness in patients with *S. Typhimurium* ST19 infection in the UK. Brazil nuts were also used in other nut products manufactured by different companies in the UK and one in Austria. It is likely that the origin of infections is contaminated Brazil nuts, but with the available data the exact point of contamination cannot be established. Extensive recalls and withdrawals of nut products have been implemented since August 2020.

In conclusion, the outbreak appears to be controlled and the likelihood of the occurrence of new cases that are linked to this event is low but possible, as nut products have a long shelf-life and people may have bought the products before control measures were implemented.

ECDC and EFSA monitor the public health impact and the success of control measures with EU/EEA countries and the UK.

Event background

On 24 April 2020, the United Kingdom reported a 5-SNP (single nucleotide polymorphism) cluster of 38 *Salmonella* Typhimurium sequence type (ST) 19 infections in the Epidemic Intelligence Information System (EPIS), with sampling dates between 2 August 2019 and 4 April 2020. Over 60% of cases were reported in March–April 2020. The cases were widely distributed within the United Kingdom and they reported no travel history. Of the cases, 53% were male and the median age was 40 years (range 3–89 years). Phylogenetic analysis of sequenced isolates indicated that the majority of the cases (36/38) within this 5-SNP cluster were from a single clonal population, which was genetically distinct from the majority of the *S. Typhimurium* isolates originating from humans and

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animals in the UK. In the following weeks, human cases with genetically closely related *S. Typhimurium* isolates were reported in Canada (one), France (five), the Netherlands (one), and Luxembourg (three).

Public Health England (PHE) in the UK initiated a case-control study, the results of which pointed to nut products and Brazil nuts as suspected vehicles of infection. Microbiological sampling of Brazil nuts resulted in the isolation of *S. Typhimurium* ST19 and *S. Anatum*.

This Rapid Outbreak Assessment (ROA) covers the public health risk assessment for the contaminated food products related to this event.

Multi-country investigations

EU/EEA outbreak case definition

The European outbreak case definition is as follows:

A confirmed outbreak case

- A laboratory-confirmed *Salmonella* Typhimurium case with symptom onset on or after 1 August 2019 (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 strain sharing the same t5-level SNP address as one of the outbreak clusters defined by the PHE SNP pipeline [1]: 1.222.503.919.5052.6145.% (t5.6145 –accession numbers SRR11435802 and SRR10810751) OR clustering within 3 cg-allelic differences from at least one of the two UK representative sequences in cgMLST-based single linkage analysis (Enterobase scheme) [2]
OR
- A laboratory-confirmed *Salmonella* Anatum case with symptom onset on or after 1 August 2019 (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 strain sharing the same t5-level SNP address as one of the outbreak strains defined by the PHE SNP pipeline [1]: 4.123.150.180.205.214.% (t5.214 –accession number SRR12251290) OR clustering within 3 cg-allelic differences from the UK representative isolate in cgMLST-based single linkage analysis (Enterobase scheme) [2]

Screening suggestion for *Salmonella* Typhimurium

- HC10:138472 in Enterobase [2]

Screening suggestion for *Salmonella* Anatum

- HC20 236760 in Enterobase [2]

Exclusion criteria

- Secondary cases defined as those confirmed cases that have had person-to-person contact with a confirmed case and no exposure to a common source.

Epidemiological and microbiological investigations of human cases

Case-control study in the United Kingdom

Public Health England (UK) performed 13 interviews, starting in April 2020, to generate hypotheses for a suspected vehicle of infection. These interviews identified primary hypotheses of nuts/nut bars, chicken and salad consumption. A case-control study was initiated in June 2020 to test the case-consumption association. Cases were selected among patients with *S. Typhimurium* ST19 infection with the outbreak strain and controls were selected among market research panel respondents. Univariate analysis revealed nut and seed products as a risk factor with odds ratio (OR) 7.8, 95% confidence interval (CI) 2.5–34.2. Multivariate logistic regression was performed to adjust for confounders and it identified three types of food products as independent risk factors for infection: Brazil nuts (aOR 6.7, 95% CI 1.1–48.7), nut bar brand 1 (aOR 23.3, 95% CI 2.4–386), nut bar brand 2 (aOR 54.6, 95% CI 3.3–1810), and cabbage (aOR 15.1 (95% CI 1.8–193). Cases reported consumption of several types of nut bars under two different brand names, both produced by the British Company B (see the section for food traceability).

Epidemiological overview

As of 20 October 2020, according to the case definitions, one *S. Anatum* ST64 human case and 123 confirmed human cases of *S. Typhimurium* ST19 infection have been reported by three European Union (EU) countries (France, the Netherlands, and Luxembourg), the United Kingdom, and Canada since 1 August 2019 (Table 1). The first human case was identified in the UK with a sampling date of 2 August 2019. The highest burden in terms of the number of *S. Typhimurium* ST19 cases is in the UK, which account for 84.6% of all confirmed cases. Information about hospitalisation was available for 72 cases (58.1%), including 71 *S. Typhimurium* ST19 cases and one *S. Anatum* case. Of these, 13 *S. Typhimurium* ST19 cases (18.1%) were hospitalised, among them two children below five years of age. One case was hospitalised during the incubation period and possibly acquired the infection in the hospital. One death has been reported in the United Kingdom, but the role of *Salmonella* infection in the cause of death is not known (Table 1).

The first case of *S. Typhimurium* ST19 infection was identified in the United Kingdom in August 2019, followed by a second case in October 2019. A rise in outbreak cases started to develop in December 2019, reaching the most number of cases between March and May 2020 (Figure 1). After a duration of 14 months, the outbreak appears to be subsiding, with the latest case reported from the UK in September 2020. The human case of *S. Anatum* ST64 was reported by the UK in June 2020.

The French National Reference Centre for *E. coli*, *Shigella* and *Salmonella* analysed the *S. Typhimurium* ST19 strain for the presence of resistance genes. The strain showed the presence of genes that are associated with resistance to aminoglycosides (*aac(6)_Iaa*).

Table 1. Number of confirmed *S. Typhimurium* ST19 cases, *S. Anatum* ST64 case, hospitalisations, and reported deaths by country, 1 August 2019–20 October 2020

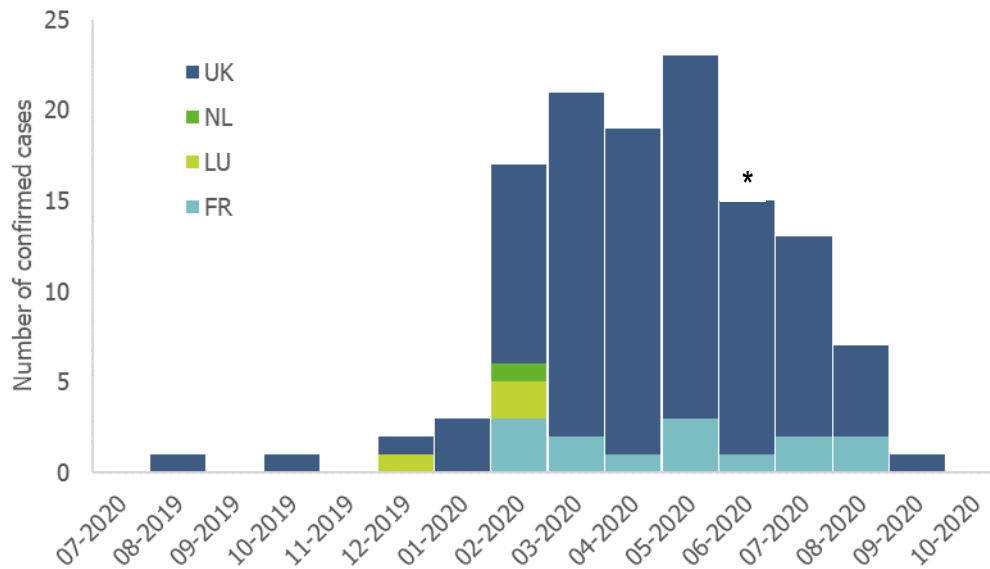
Country	Number of confirmed cases		Hospitalised			Deaths
	<i>S. Typhimurium</i>	<i>S. Anatum</i>	Yes	No	Unknown	
Canada*	1	0	0	0	1	0
France	14	0	4	3	7	0
Luxembourg	3	0	0	3	0	0
The Netherlands	1	0	0	0	1	0
United Kingdom	104	1	9**	52	43	1***
Total	123	1	13	58	52	1

*Canadian case was not included in further analyses

**One case already in hospital during incubation period

***Unknown if *Salmonella* contributed to death; cause of death data not available

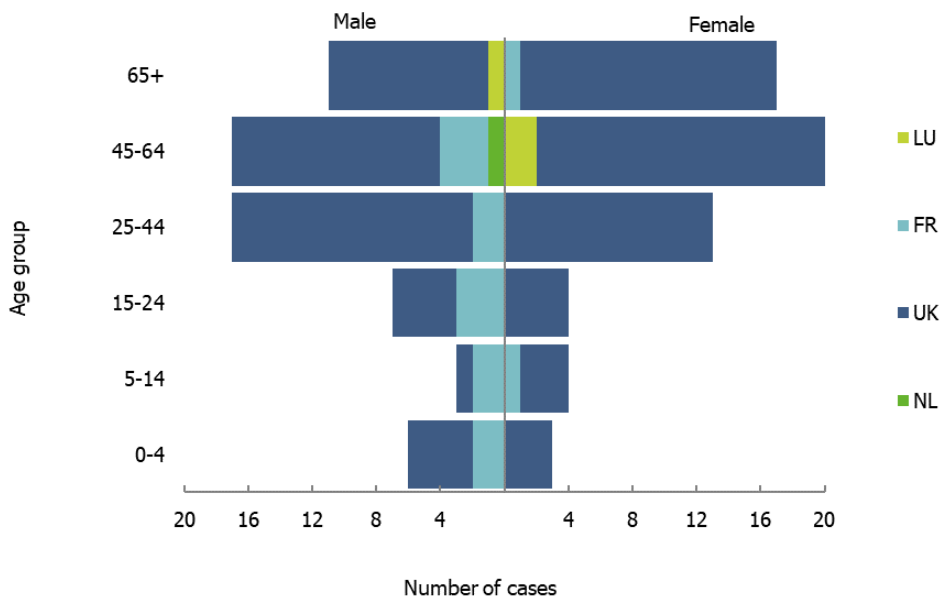
Figure 1. Distribution of confirmed outbreak *S. Typhimurium* ST19 cases and one *S. Anatum* ST64 case by month-year and country, EU/EEA and the United Kingdom, 1 August 2019–20 October 2020



*Includes one *S. Anatum* ST64 case from the UK.

The highest proportion of *S. Typhimurium* ST19 cases in the EU/EEA (30.3%) were in the age group 45–64 years of age while 77.9% of cases were above 25 years. Cases in France were distributed quite evenly across all age groups whereas most cases in the United Kingdom were among adults over 25 years (Figure 2). Median age was 48 years (range 0–89 years). There were no significant differences by gender across age groups and the male-to-female ratio was 1:1.

Figure 2. Distribution of confirmed *S. Typhimurium* ST19 cases by gender and age groups, 1 August 2019–20 October 2020



Prepared by Public Health England

Information from patient interviews

Based on the case control study in the UK, Brazil nuts were considered as likely common vehicles in human infections. The countries had collected information from national patient interviews covering not only nuts but also products that may contain nuts. As countries use questionnaires adapted to their country, the question related to nuts and nut containing food products may be formulated differently by countries. Also, consumers are not always fully aware which type of nuts they have eaten and/or which types of nuts have been included in a food product, like cereals, although nuts may be listed as ingredients.

Of the 122 cases with *S. Typhimurium* ST19 infection in the EU/EEA, interviews were performed with 49 persons. In addition, the single case of *S. Anatum* ST64 was also interviewed. The majority of the interviews were performed in the UK (41), followed by France (six) and Luxembourg (three). For each interviewed case, consumption information was collected by the following categories: 1) Brazil nuts; 2) mixed nuts; 3) nut bars/cereal bars; 4) cereals (e.g. granola/muesli); 5) any other product containing nuts. Of the 50 interviewed cases, two replied 'no' consumption of nuts or nut products. Thus, nut consumption in some form was reported by 96% of interviewed cases. Consumption of Brazil nuts was reported by 61.9% of cases while consumption of cereals was the most commonly reported food product containing nuts (71.0%) (Table 2). It should be noted that a person may have consumed several types of nut-containing products. In the category of 'other types of food products containing nuts', the following food products were mentioned: granola squares/flapjacks from supermarket bakery, ice cream stick noss, nuts in bags (loose), oatmeal (loose), organic cereals, chocolate squares (loose), and hazelnut cocoa cream.

Table 2. Consumption information of 49 interviewed *S. Typhimurium* ST19 cases and one *S. Anatum* case from the United Kingdom (n=41, includes *S. Anatum* case), France (n=6) and Luxembourg (n=3) by food products, 1 August 2019–20 October 2020

Exposures		Total (%)
Consumption of Brazil nuts (n=42)	No	38.1
	Yes	61.9
Consumption of mixed nuts (n=45)	No	57.8
	Yes	42.2
Consumption of nut bars/cereal bars (n=48)	No	37.5
	Yes	62.5
Consumption of cereals (n=45)	No	29.0
	Yes	71.0
Consumption of any other product containing nuts (n=44)	No	86.4
	Yes	13.6

Prepared by Public Health England

Microbiological investigations of food and control measures

This section summarises country-specific information on microbiological investigations and traceability analyses of products, and control measures implemented by the involved countries as reported through the RASFF notification 2020.3287 (58 follow ups - *fup*, as of 15 October 2020). A visual representation is provided in Figure 2 (Annex 2).

Traceability and microbiological investigations of Brazil nuts (Batch A and Batch B) and of nut products positive for *Salmonella*

On 14 August 2020, the Food Competent Authority (Food Standards Agency) in the United Kingdom, in the context of a national outbreak investigation, launched an alert notification in RASFF (2020.3287) on the detection of *Salmonella* in two batches (Batch A and Batch B) of organic Brazil nuts imported from Bolivia.

In summary, following whole genome sequencing (WGS) analysis, some samples from Batch A showed the presence of seven *Salmonella* Typhimurium isolates with SNP address 1.222.503.919.5052.6145.% (t5:6145) matching the representative outbreak strain (*fup51*). Some samples from Batch B revealed the presence of eleven *Salmonella* Anatum isolates with SNP address 4.123.150.180.205.214.% (t5:214) (*fup1*).

Batch A was manufactured by the Bolivian Processing Company A and imported in the United Kingdom entirely by the British Wholesaler A in August 2019 in two aliquots of 8 000 kilograms each (vacuum sealed bags) (*fup37*). The British Wholesaler A delivered Brazil nuts from Batch A to the British Wholesaler B that distributed them to the British Processing Company B only (*fup51*).

The Food Competent Authority in the United Kingdom reported that samples from Batch A were collected in the frame of an official control performed on 6 August 2020 at the British Processing Company B. Microbiological analysis showed the presence of five *S. Typhimurium* ST19 (t5:6145) isolates matching the representative outbreak strain (*fup51*).

An additional sample of Brazil nuts from Batch A was collected at the same British Processing Company B during an own-check control (sampling date not available) and tested on 14 August 2020. The original sample was further re-analysed by Public Health England (PHE) (*fup52*), and microbiological analysis revealed the presence of one isolate of *S. Typhimurium* ST19 (t5:6145) (*fup51*). Samples of Brazil nuts from Batch A were also collected at the British Wholesaler A during an official control performed on 25 August 2020. Microbiological analysis showed the presence of one isolate of *S. Typhimurium* ST19 (t5:6145) (*fup51*).

The Food Competent Authority in Bolivia (National Animal Health and Food Safety Service, SENASAG) stated that Batch A had been microbiologically tested in the context of own-check controls (sampling date not available) within the Bolivian Processing Company A and that *Salmonella* had not been found (*fup37*).

Batch B was manufactured by the Bolivian Processing Company A and imported in the United Kingdom entirely by the British Wholesaler A (*fup1*) in January 2020 (one aliquot of 16 000 kilograms). Brazil nuts of Batch B were further delivered by the British Wholesaler A to the British Wholesaler B who further distributed them to the British Processing Company B. In addition, the British Wholesaler A distributed the Brazil nuts to food business operators within the United Kingdom (e.g. British Retailer A, British Processing Company C, British Processing Company D, British Processing Company F, and the British Wholesaler E) and to one wholesaler located in Austria (Austrian Wholesaler D) (*fup51*). The British Wholesaler E further distributed the Brazil nuts belonging to Batch B to the British Wholesaler C and they further distributed some Brazil nuts to the British Processing Company E.

The Food Competent Authority in the United Kingdom reported that samples from Batch B were collected in the context of an official control performed on 6 August 2020 at the British Processing Company B. Microbiological analysis showed the presence of one isolate of *S. Anatum* ST64 (t5:214) (*fup51*) matching the representative outbreak strain as defined by the European case definition.

Additional samples of Brazil nuts from a remaining stock of Batch B (on hold) were collected at the British Wholesaler A by the British Food Competent Authority on 25 August 2020, during an official control. Microbiological analysis showed the presence of seven *S. Anatum* ST64 (t5:214) isolates (*fup51*).

Samples of Brazil nuts from Batch B were also collected during an own-check control at the British Wholesaler C (sampling date not available in RASFF). Microbiological analysis resulted in the detection of three isolates of *S. Anatum* ST64 (t5:214) (*fup51*). The Brazil nuts did not undergo a heat treatment before being used by the British Wholesaler C. The information on the types of nut products produced by the British Wholesaler C was not available in RASFF, nor the information on the implementation of control measures. Most of the Brazil nuts from Batch B were still on site apart from those that were further distributed to the British Wholesaler E.

The Food Competent Authority in Bolivia informed that Batch B was microbiologically tested during own-check controls (sampling date unknown), performed at the Bolivian Processing Company A, and that *Salmonella* was not found (*fup37*).

On 18 August 2020, the Food Competent Authority in the United Kingdom reported that samples of the Nut Products A (batch unknown) collected at the British Processing Company B, in the frame of an own-check control, tested *Salmonella* positive (sampling date and serovar not available). The Food Competent Authority informed that Nut Products A contained the Brazil nuts from Bolivia (Processing Company A) belonging to Batch A and Batch B (*fup51*). The Processing Company B stated that the manufacturing process of nut products includes a heat treatment that is intended only for organoleptic purposes.

Precautionary and control measures on nut products linked to traceability

Overall, control measures for products deemed to contain nuts of Batch A and Batch B were implemented as follows:

- Nut Products A (heat treated for organoleptic purposes) with expiry dates up to 2021 were withdrawn and recalled on 22 August 2020 by the British Processing Company B that had produced them. These nut products were recalled from recipients in Europe i.e. Belgium, Cyprus, France, Germany, Gibraltar, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, and Spain and outside Europe. Nut Products A is the same as the 'nut bar brand 1' that was mentioned to having been consumed by the British cases in the section 'Case-control study in the United Kingdom'
- Nut Products B (heat treated for organoleptic purposes) with expiry dates up to 2021 were withdrawn and recalled on 22 August by the British Processing Company B that had produced them. These nut products were recalled from recipients in Europe (Austria, Belgium, France, Germany, Luxembourg, the Netherlands, Spain, and the United Kingdom).

Further control measures for products deemed to contain nuts from Batch B were implemented as follows:

- Nut Product C (organic granola) (Batch C, not heat-treated), produced by the British Processing Company D and intended to be distributed to Canada, was quarantined at the Canadian border control point.
- Nut Product D (Muesli) (not heat-treated) produced by the British Processing Company E with expiry dates June–July 2021, was recalled on 24 August 2020 from recipients in Europe (France, Gibraltar, Greece, Hungary, Ireland, the Netherlands, Norway, and Switzerland) and outside Europe.
- Nut Products E-J (not heat-treated) with the expiry dates ranging between October 2020 and March 2021, that had been produced by British Retailer A, were withdrawn and recalled on 27 August 2020 by the British Retailer A. These nut products were recalled from recipients in Belgium, Ireland, the Netherlands, and the United Kingdom.
- Nut Product K (granola) produced by the British Processing Company B and distributed only in the United Kingdom was recalled.
- Nut Product L (muesli bar) produced by the British Processing Company B and distributed only in the United Kingdom was recalled. Nut Product L (muesli bar) is the 'nut bar brand 2', which was referred to having been consumed by the British cases in the section 'Case-control study in the United Kingdom'.
- Nut Products M (bio Brazil nuts in pieces - expiry date December 2021; not heat-treated), that had been produced by the Austrian Wholesaler D were recalled on 19 August 2020 and blocked at the warehouse by the same producing company. These nut products were recalled from recipients in Austria, Belgium, Germany, Denmark, Finland, France, Italy, Luxembourg, Spain and the United Kingdom.

The detailed description on nuts and nut products linked to the traceability described above and the implementation of control measures by the involved countries (as shared in RASFF 2020.3287) is provided in Annex 2.

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

Initial WGS-based searches for identifying possible outbreak-related *S. Typhimurium* ST19 and *S. Anatum* isolates were performed in the Member States' public health institutes and national reference centres using sequences of the three UK representative strains, shared through EPIS FWD and identified by national WGS pipelines. Sequence read data were collected for centralised analyses at ECDC. In total, sequences were shared for 92 closely related (as reported through EPIS) *S. Typhimurium* human isolates by public health institutes and national reference centres in France (four), Luxembourg (three), the Netherlands (one) and the UK (84). In addition, publicly available sequences from seven food isolates from the UK were shared with ECDC by EFSA. Sequences from *S. Anatum* isolates were shared by the UK from one human isolate and 11 food isolates. The EURL-*Salmonella*

launched a consultation to Member States for submitting sequences of *S. Typhimurium* ST19 and *S. Anatum* ST64 possibly isolated from nuts and nut products. No isolates matching the representative outbreak strains were reported.

Sequences were analysed by ECDC with BioNumerics version 7.6.3 (Applied-Maths, Sint-Martens-Latem, Belgium), which 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 Enterobase core genome scheme [2] as implemented in BioNumerics, resulting in a cgMLST allelic profile per isolate. Isolates were excluded from further analysis if less than 2 702 (90%) of the 3 002 core loci were detected.

All 99 *S. Typhimurium* ST19 isolates clustered within 3 cg-allelic differences in single linkage analysis (i.e. each isolate differed by maximum 3 cg-alleles from at least one other isolate, Figure 3), and all *S. Anatum* isolates within one cg-allelic difference (Figure 4), indicating close genetic proximity and possible common origin within the two clusters.

Figure 3. Minimum spanning tree (cgMLST, Enterobase scheme) including sequences from 92 human *S. Typhimurium* ST19 isolates from four countries, EU/EEA, 2019 to 2020, and seven non-human isolates collected in the UK in 2020

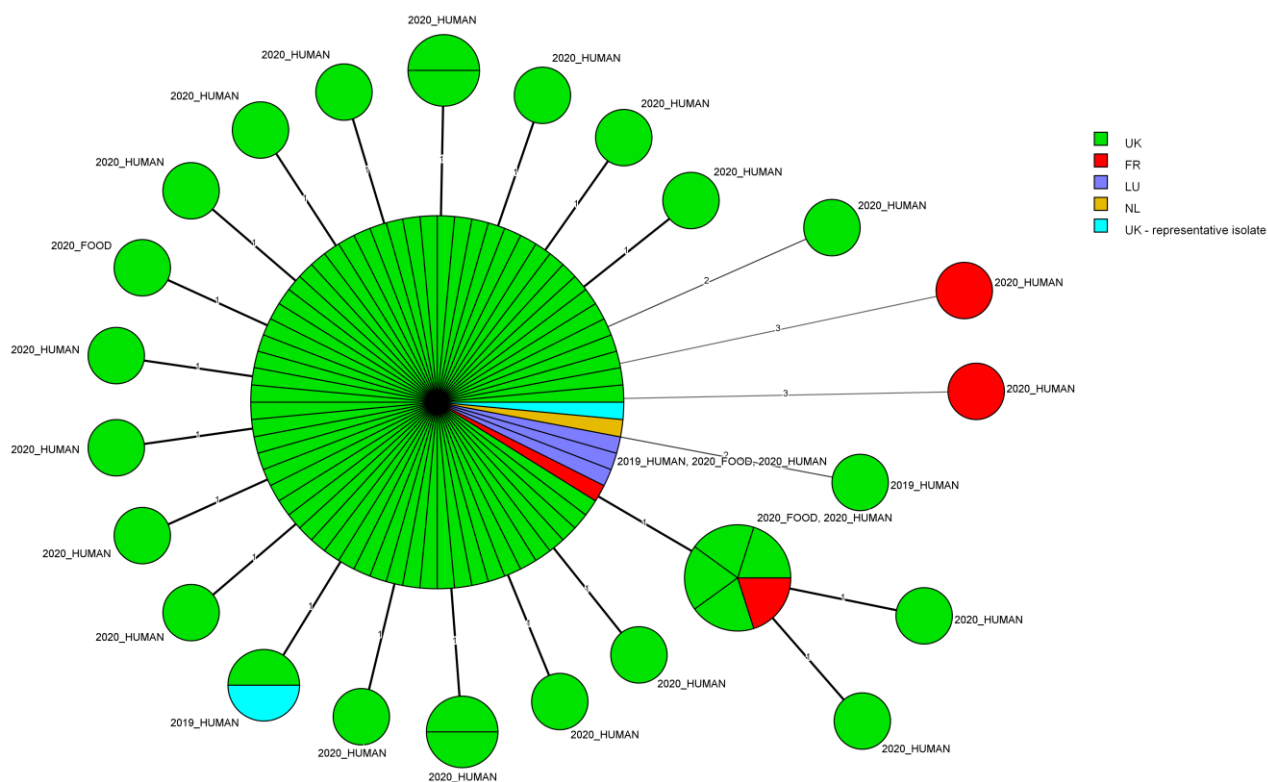
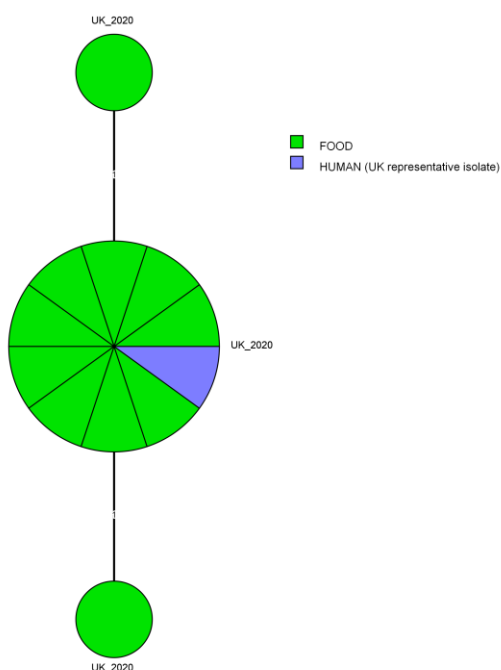


Figure 4. Minimum spanning tree (cgMLST, Enterobase scheme) including sequences from one human *S. Anatum* isolate and 11 non-human isolates from the UK, 2020



ECDC and EFSA risk assessment for the EU/EEA

Risk assessment questions

What is the magnitude and severity of the multi-country outbreak caused by the outbreak strain *S. Typhimurium* ST19 and *S. Anatum* ST64 and is it linked to Brazil nuts and nut products?

A multi-country outbreak, caused by distinct strains of *Salmonella* Typhimurium ST19 and *Salmonella* Anatum ST64, has affected at least three EU countries, the United Kingdom, and Canada since 1 August 2019. As of 20 October 2020, 123 cases of *S. Typhimurium* ST19 and one case of *S. Anatum* have been identified, of which 105 were in the United Kingdom (including one *S. Anatum* case), 14 in France, three in Luxembourg, one in the Netherlands, and one in Canada. Thirteen cases (18.1%) were hospitalised and one death was reported in the UK, where the role of *Salmonella* infection with respect to the cause of death was not known. As *S. Typhimurium* is the second most commonly reported serovar in the EU/EEA, the magnitude of this event is likely under-estimated as many countries do not have sequencing capacity or they do not routinely sequence *S. Typhimurium* isolates. The highest proportion of *S. Typhimurium* ST19 infections in the EU/EEA (30.3%) were detected in the 45–64 years age group and most cases (77.9%) were among adults over 24 years of age. A case-control study in the UK revealed consumption of Brazil nuts and nut bars as significant independent risk factors for infection. These consumed nut bars were produced by the British Processing Company B (see below). Patient interviews confirmed consumption of Brazil nuts in 61.9% and nut bars/cereal bars in 62.5% of all interviewed cases in three countries (France, Luxembourg and United Kingdom). Consumption of any type of nut products was reported by 96% of 50 interviewed cases, including the case with *S. Anatum* infection. The strain of *S. Typhimurium* ST19 showed presence of genes that are associated with resistance to aminoglycosides. Despite potential resistance to aminoglycosides, there are still good treatment options for severely ill patients.

In the context of the national outbreak investigation in the United Kingdom, seven food isolates of *S. Typhimurium* ST19 (SNP address 1.222.503.919.5052.6145.%) and 11 food isolates of *S. Anatum* ST64 (SNP address 4.123.150.180.205.214.%) were found to be closely related (t5-level SNP address) to the representative outbreak strains. The isolates of the two serotypes were detected in Brazil nuts of Batch A (*S. Typhimurium* ST19) and of Batch B (*S. Anatum* ST64), both imported in the United Kingdom by the British Wholesaler A and distributed to several food business operators in the United Kingdom and one in Austria.

Based on the case control study in the UK, the Nut Products A, manufactured by the British Processing Company B, were reported as a risk factor for illness by patients with *S. Typhimurium* ST19 infection in the United Kingdom, indicating that these products were likely one of the possible vehicles of the human infections. However, traceability data did not allow to establish exactly which batches of Nut Products A contained contaminated Brazil nuts of Batch A and Batch B. Further, sampling of Nut Products A gave positive results for *Salmonella* although serotyping was not further specified, neither confirming nor excluding that Nut Products A were contaminated with the outbreak strains. The first human case was sampled on 2 August 2019 and the importation date of the contaminated Batch A of Brazil nuts was August 2019, which makes it difficult to assess the temporal link between the first case and the Batch A of Brazil nuts.

Based on the case control study in the UK, Nut Product L (muesli bar), manufactured by the British Processing Company B, was identified as another risk food consumed by the British patients with *S. Typhimurium* ST19 infections. However, *S. Typhimurium* ST19 was not isolated in Batch B, which was contaminated with *S. Anatum*. The available traceability data did not allow to establish which batches of Nut Product L contained Brazil nuts from Batch B and which batches of Nut Product L were consumed by the human cases. This product was nationally distributed and, based on the available microbiological data, could be only implicated as a likely source of *S. Anatum* infection in the British case.

The contaminated Brazil nuts of Batch A and/or Batch B were also used by different processing companies in the United Kingdom and in Austria for the production of other nut products, even though no specific information on the batches of those nut products was provided. Moreover, no microbiological results were available for those products.

As the official samplings in the UK revealed the contamination in specific batches of Brazil nuts, it is likely that the origin of infections is the contamination of Brazil nuts imported from Bolivia, but with the data available the exact point of contamination cannot be established. There were several *S. Anatum* isolations from one batch of Brazil nuts while only one human case was confirmed with an infection with a closely related strain. This serotype is relatively rarely reported in EU/EEA (around 120 cases reported annually) [3] and not all *S. Anatum* isolates from human infections are further sequenced.

In this outbreak, the patient interviews in the affected countries, the case-control study in the UK, and food investigations in the UK pointed to consumption of Brazil nuts and products containing Brazil nuts as vehicles of human infection. These can be ingredients in multiple types of food products and also sold loose or in packages of mixed nuts. This highlights the challenges related to outbreaks caused by a contaminated ingredient in multiple types of food products, as these may be very difficult to identify in patient interviews or in analytical epidemiological studies.

What control measures have been implemented?

Starting in August 2020, an extensive effort at the EU level to withdraw and recall nut products (see Annex 2), deemed to contain the contaminated Brazil nuts of Batch A and/or Batch B, has been carried out by many food business operators as a precautionary measure.

What is the remaining risk for human infections of outbreak strain *S. Typhimurium* ST19 and *S. Anatum* ST64 after implementation of control measures?

While the measures taken appear to have had a positive public health impact as case numbers have dropped notably since September 2020, new cases may still be reported due to a delay in detection and reporting of cases. Considering the comprehensiveness and speed of the immediate control measures, the likelihood of new infections occurring, linked to this event, is low but not negligible, due to long shelf-life and possible shopping of implicated products by consumers before implementation of control measures.

Options for response

New human cases that fulfil the EU case definition and other developments on public health investigations related to this event should be reported in EPIS-FWD UI-636. Notifications in the Early Warning and Response System (EWRS) should be issued in case the criteria for these are fulfilled.

ECDC encourages public health authorities to interview new cases that fulfil the EU case definition to assess possible exposures, including possible exposure to Brazil nuts and nut products, and where possible, to store related information on brands and lots of suspected food products.

Food safety authorities in the involved EU countries should share further/additional information at the European level on microbiological investigations (including analysis of raw materials at entrance and environmental investigation) and tracing information by issuing relevant notifications through the Rapid Alert System for Food and Feed (RASFF). To fill the highlighted gaps, microbiological information of other batches of Brazil nuts (raw

materials) and of nut products containing Brazil nuts should be shared in RASFF as well as their trace back and forward information.

Source and date of request

On 4 September 2020, ECDC sent a request for a Rapid Outbreak Assessment to EFSA and EFSA accepted the request on the same day.

Consulted experts and national contact points

ECDC experts (in alphabetical order): Saara Kotila, Taina Niskanen, Ettore Severi, Johanna Takkinen, Therese Westrell

Public health experts:

Canada: Ashley Kerr, Public Health Agency of Canada

France: Nathalie Jourdan Da Silva, Santé publique France

France: Maria Pardos De La Gandara, National Reference Centre for *E. coli*, *Shigella* and *Salmonella*, Institut Pasteur

Luxembourg: Joël Mossong, Laboratoire National de Sante

The Netherlands: Roan Pijnaker, National Institute for Public Health and the Environment

The United Kingdom: Jacquelyn McCormick, Public Health England

The United Kingdom: Lesley Larkin, Public Health England

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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 20 October 2020. 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 1. Disease background

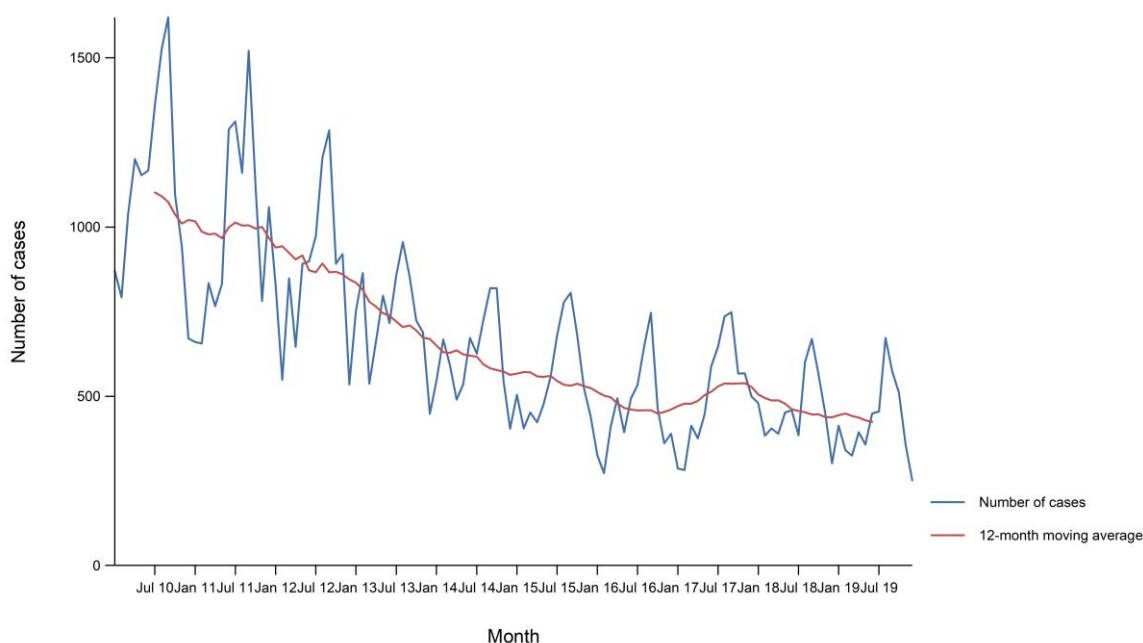
Disease characteristics

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

Disease surveillance for *S. Typhimurium* and *S. Anatum* infections in the EU/EEA

Salmonella Typhimurium is the second most commonly detected serovar in cases of human non-typhoidal salmonellosis in Europe. It has declined substantially in the last ten years (Figure 1), most likely as a result of successful control measures implemented under Regulation (EC) No. 2160/2003, aimed at food business operators to improve hygiene implemented under the EU Food Law, including the introduction of microbiological criteria for *Salmonella* [7].

Figure 1. Trend of reported confirmed cases of *Salmonella Typhimurium*, EU/EEA, 2010–2019



Source: ECDC [8]

From 2010 to 2019, 137 174 cases of *S. Typhimurium* were reported to The European Surveillance System (TESSy) (between 9 099 to 21 324 cases annually) by 29 EU/EEA countries. The majority of cases was reported by Germany (38%) which, together with France and the United Kingdom, accounted for 62% of reported cases. The trend significantly decreased in 2010–2019, but stabilised during the last five years. Cases were distributed over the year, with a peak from July to September.

The median age for all cases where information was available was 28 years (interquartile range IQR=4–51). Fifty-two percent of the cases were males (N=102 023). Cases were more common in males in all age groups except in the over 64 years age group. The majority (91%; N= 95 802) of the cases with available information were acquired domestically. To date, 327 *S. Typhimurium* cases have been reported by 10 countries to TESSy for 2020 (data not published).

Salmonella Anatum was the 47th most common *Salmonella* serotype in the EU/EEA in 2015–2019 and was reported by 23 EU/EEA countries with 111–135 cases per year in this period. The UK accounted for 31% of the cases, followed by France, Germany and Italy (18, 13 and 11%, respectively). Cases were most frequent among adults with the highest proportion among those 65 years and older (26%). Female cases were slightly more common than men (56% of cases), particularly in the age groups 5–14, 25–44, 45–64 and 65+ years. Travel information was available for 54% cases and of these, 44% were imported. Egypt, Turkey and Tunisia accounted for 13%, 13% and 7%, respectively of the travel-associated cases.

Food-borne outbreaks caused by *S. Typhimurium* and *S. Anatum*

In accordance with the Zoonoses Directive 2003/99/EC [9], for the years 2005–2018, no food-borne outbreaks caused by *S. Typhimurium* and *S. Anatum* associated to the category 'Cereal products including rice and seeds/pulses (nuts, almonds)', which represents the food category for the suspected food products of this investigation, were reported to EFSA by EU Member States and non-EU countries.

Occurrence of *S. Typhimurium* and *S. Anatum* in food

In accordance with the Zoonoses Directive 2003/99/EC [9], for the years 2005–2018, one unit positive for *S. Typhimurium* was reported to EFSA for the category 'RTE Cereals, legumes and nuts' out of 1 320 total units tested by EU Member States (Austria, Estonia, Hungary, Ireland, Slovakia, and Sweden) and the United Kingdom. The positive unit was reported by Ireland in 2005 and belonged to the food category 'Nuts and nut products'.

During the period 2005–2018, no units positive for *S. Anatum* were reported to EFSA for the category 'RTE Cereals, legumes and nuts' by the EU Member States and non-EU countries.

Annex 2

This section describes the details of the distribution of nut products that were identified in the context of the national outbreak investigation in the United Kingdom (RASFF 2020.3287) as well as the implementation of precautionary control measures on those products.

In the context of the national outbreak investigation, the Food Competent Authority in the United Kingdom, through RASFF 2020.3287 warned other competent authorities to implement control measures for certain food products (cereal nut bars) (Nut Products A and Nut Products B - expiry dates up to 2021) that had been exported to their countries and that had been recalled on 21 August (*fup2*) in the United Kingdom due to the possible manufacture with Brazil nuts likely contaminated by *Salmonella*. Nut Products A and Nut Products B were produced by the British Processing Company B that had received Brazil nuts of Batch A and Batch B. With the available information shared in RASFF, it cannot be established which batch of Nut Products A and Nut Products B contained the *Salmonella* contaminated Batch A and Batches B. In any case, the British Processing Company B took the precautionary approach of recalling all of their products with expiry dates up to 2021 containing Brazil nuts.

The Nut Products A were further distributed to food business operators located in Europe i.e. Belgium, Cyprus, France, Gibraltar, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Spain and outside Europe i.e. Egypt, Hong Kong, India, Philippines, and Qatar (*fup2*, *fup7*). The Dutch food business operators further distributed them to Belgium, Germany, and Luxembourg (*fup12*, *fup38*, *fup50*), to Iraq, Mali, and Somalia (*fup14*), and to the United States (*fup18*). Belgian food business operators further distributed them to Luxembourg (*fup31*) and the Netherlands (*fup22*, *fup31*). The Italian food business operator further distributed them within Italy and to France (*fup32*).

On 24 August 2020, the Food Competent Authority in Luxembourg (ComAlim) notified that the Luxembourg Retailer B (*fup3*) recalled the Nut Products A and that a public warning was issued on the Food Competent Authority website to recall the products due to a possible *Salmonella* contamination (*fup34*).

On 24 August 2020, the Food Competent Authority in Cyprus (Public Health Services) notified the withdrawal of Nut Products A by the Cypriot food business operator that received the consignment and the detention of those products still in its warehouse (*fup20*).

On 25 August 2020, the Food Competent Authority in Malta (Environmental Health Directorate) notified about the withdrawal of the consignments (Nut Products A) that had reached Malta and had further been traded by food business operators of Malta (*fup16*, *fup39*). On 28 August 2020, a press release was issued to inform the public about the possible presence of *Salmonella* (*fup30*). On 1 October 2020, part of the consignment was destroyed by incineration under the supervision of the Competent Authority (*fup56*).

On 25 August 2020, the Food Competent Authority in Belgium (Belgian Federal Agency for Safety of the Food Chain) notified that a public warning to recall the Nut Products A was also issued (*fup22*). On 28 August 2020, the Food Competent Authority of Belgium reported to have been informed that the consignment intended to be delivered by a Belgian trader to Egypt was blocked in Belgium at the seaport border inspection point (*fup2*, *fup31*).

On 25 August 2020, the Food Competent Authority in Italy (Ministry of Health) issued a public warning to recall all Nut Products A with expiry dates August 2020 and July 2021 (*fup#439186*).

On 26 August 2020, the Food Competent Authority in Hungary (National Food Chain Safety Office) notified that on 22 August 2020 the Hungarian Wholesaler F had issued a public warning and withdrawn the Nut Products A from the market (*fup25*).

On 8 September 2020, the Food Competent Authority in Gibraltar notified that the received Nut Products A were withdrawn from the point of sales (*fup45*).

On 14 September 2020, the Food Competent Authority in Ireland (Food Safety Authority of Ireland - FSAI) informed that on 26 August 2020, the Nut Products A that had been distributed to the Irish food business operators underwent a precautionary withdrawal and recall (*fup50*).

On 29 September 2020, the Food Competent Authority in Lithuania (State Food and Veterinary Service of the Republic of Lithuania - SFVS) notified on the outcome of the inspections performed at two Lithuanian food business operators that had received Nut Products A. The Competent Authority ordered the destruction or the return to the producer of the part of the consignments that was detained at their warehouses. The remaining part that had already been distributed to the market was withdrawn and recalled (*fup54*) by the Lithuanian food business operators and a press-release was issued to inform consumers (*fup54*, *fup55*).

On 6 October 2020, the Food Competent Authority in the Netherlands (Netherlands Food and Consumer Product Safety Authority - NVWA) informed that a public warning was issued on its website on 22 August 2020 in order to recall Nut Products A. The products were withdrawn from the market.

On 6 October 2020, the Food Competent Authority in France (Unité d'Alerte - DGCCRF) notified that on 24 August 2020 a public warning to inform consumers and to recall Nut Products A was published on its website (*fup58*).

The Nut Products B that underwent the recall had been further distributed to food business operators located in Europe, namely Austria, Belgium, France, Germany, Luxembourg, the Netherlands, Spain, and the United Kingdom (*fup11*).

On 25 August 2020, the Food Competent Authority in Luxembourg (ComAlim) notified that the public warning to recall Nut Products B was published on its website (*fup34*).

On 26 August 2020, the Food Competent Authority in Austria (Austrian Agency for Health and Food Safety) reported that the Nut Products B that were already commercialised were recalled and the products still in stock were destroyed (*fup26*).

On 8 September 2020, the Food Competent Authority in Belgium (Federal Agency for Safety of the Food Chain, FASFC) informed that the Dutch Retailer B had withdrawn the Nut Products B from its shops and had informed the consumers of the possible *Salmonella* contamination (*fup44*). A public warning was issued and published on the Competent Authority website on 25 August 2020.

On 2 October 2020, the Food Competent Authority in Spain (Agencia Española de Seguridad Alimentaria y Nutrición, AESAN) notified that the withdrawal and the recall of the Nut Products B that were already commercialized was implemented. The recalled products were destroyed (*fup57*).

On 6 October 2020, the Food Competent Authority in the Netherlands (Netherlands Food and Consumer Product Safety Authority - NVWA) informed that a public warning was issued on 22 August 2020 on its website to recall Nut Products B. The products were withdrawn from the market.

On 6 October 2020, the Food Competent Authority in France (Unité d'Alerte - DGCCRF) notified that on 28 August 2020 a public warning to inform consumers and to recall Nut Products B was published on its website (*fup58*).

The Food Competent Authority in the United Kingdom informed that the British Processing Company D manufactured the Nut Product C (organic granola) (Batch C) using Brazil nuts from Batch B (*fup40*). Nut Product C (Batch C) was intended to be distributed to the Canadian Retailer C but it was quarantined at the Canadian border control point awaiting destruction (*fup40*).

Furthermore, the Food Competent Authority in the United Kingdom reported that the British Processing Company E received the Brazil nuts from Batch B (*fup51*) and used them to manufacture the Nut Product D (Muesli). Nut Product D (Muesli) did not undergo a heat treatment during processing. Hence, on 24 August 2020, the British Processing Company E implemented the precautionary recall of Nut Product D (Muesli) with expiry dates June-July 2021, due to a possible *Salmonella* contamination (*fup10*). The recalled cereal products had been distributed to countries in Europe (France, Gibraltar, Greece, Hungary, Ireland, the Netherlands, Norway, and Switzerland) and outside Europe (Bahrain, Jordan, Philippines, South Africa and China-Hong Kong) (*fup10, fup13, fup24, fup25, fup27, fup45, fup58*).

On 24 August 2020, the Food Competent Authority in Hungary (National Food Chain Safety Office) notified about (*fup25*) the recall of Nut Product D (Muesli), with expiry dates June-July 2021, that had already been distributed, and about the blocking of the remaining products implemented at the Hungarian Wholesaler F.

On 25 August 2020, the Food Competent Authority in Norway (Norwegian Food Safety Authority) informed that the destruction of the consignment of Nut Product D (Muesli), with expiry dates June-July 2021, was planned (*fup21*) and therefore the consignment was not placed into the market.

On 27 August 2020, the Food Competent Authority in Switzerland (Federal Food Safety and Veterinary Office) informed that all the cardboard boxes of Nut Product D (Muesli) were blocked (*fup28*).

On 8 September 2020, the Food Competent Authority in Greece (Hellenic Food Authority - EFET) informed about the outcome of national inspections and reported that the whole consignment of Nut Product D (Muesli) was blocked at the warehouse of the Greek Wholesaler G (*fup43*).

On 8 September 2020, the Food Competent Authority in Gibraltar notified that the received Nut Product D (Muesli) were withdrawn and a public warning was displayed at the point of sales (*fup45*).

On 14 September 2020, the Food Competent Authority in Ireland (Food Safety Authority of Ireland) notified about the previous implementation on 25 August of the recall from the point of sales of Nut Product D (Muesli) with expiry dates June-July 2021 (*fup50*).

On 6 October 2020, the Food Competent Authority in the Netherlands (Netherlands Food and Consumer Product Safety Authority - NVWA) informed that on 27 August 2020, a public warning was displayed at the point of sales and on its website. Nut Product D (Muesli) was withdrawn from the market.

On 6 October 2020, the Food Competent Authority in France (Unité d'Alerte - DGCCRF) notified that Nut Product D (Muesli) was no longer in stock at the retailer in France and was not recalled as it was used in a hotel lunch basket (*fup58*).

The Food Competent Authority in the United Kingdom notified in RASFF that the British Retailer A, that had received Brazil nuts of Batch B, implemented the withdrawal and recall of some nut products, as a precautionary measure, on 27 August 2020. In particular, these measures regarded Nut Products E-J with the expiry dates ranging between October 2020 and March 2021 that did not receive any heat treatment while manufactured at the British Retailer A with Brazil nuts from Batch B, and that had already been distributed within the United Kingdom and outside, i.e. to Ireland, Belgium and the Netherlands (*fup35*). On 28 August 2020, the Food Competent Authority in Ireland issued a public warning to advise the food business operators of Ireland that had received these nut products to withdraw and recall them due to a possible *Salmonella* contamination in one of the ingredients, i.e. Brazil nuts (*fup50*). On 8 September 2020, the Food Competent Authority in Belgium (Belgian Federal Agency for Safety of the Food Chain - FASFC) informed in RASFF that they were aware of the recall done by the British Retailer A (*fup44*), and that a public warning had been issued on 28 August 2020 and published on their website. On 6 October 2020, the Food Competent Authority in the Netherlands (Netherlands Food and Consumer Product Safety Authority - NVWA) informed, that on 28 August 2020, a public warning had been issued and all concerned products had been withdrawn from the Dutch retail stores.

The British Competent Authority informed that further recalls were issued on nut products manufactured by the British Processing Company B (i.e. Nut Product K (granola) and Nut Product L (muesli bar)). These nut products were only nationally distributed (traceability details and implementation of control measures not available in RASFF).

On 24 August 2020, the Food Competent Authority in Austria (Austrian Agency for Health and Food Safety - AGES) notified that the Austrian Wholesaler D, that had received Brazil nuts of Batch B (*fup53*), issued on 19 August 2020 a public warning to recall Nut Products M (bio Brazil nuts in pieces - expiry date December 2021; not treated thermally) due to a possible *Salmonella* contamination and notified that the remaining stock was blocked (*fup6*). The recalled nut products had been delivered via an e-commerce platform to clients/recipients in Austria, Belgium, Germany, Denmark, Finland, France, Italy, Luxemburg, Spain and the United Kingdom (*fup6*). On 25 August 2020, the Food Competent Authority in Austria notified that all e-commerce customers were informed of the recall by the e-commerce platform (*fup23*). Wholesaler D did not use Brazil nuts from Batch B as ingredients for nut products other than Nut Products M (bio Brazil nuts in pieces) (*fup53*).

On 6 October 2020, the Food Competent Authority in the United Kingdom informed that the British Processing Company C used the Brazil nuts from Batch B to manufacture the Nut Products N (flapjacks) (batch numbers not available in RASFF) while the British Processing Company F used the Brazil nuts from Batch B to manufacture the Nut Products O (nut bars). The nut products from both companies received heat treatment during their manufacturing process that was considered sufficient to eliminate *Salmonella*. Therefore, the two companies did not implement the withdrawal and recall of their nut products.

Figure 2. Graphical representation of traceability, testing information and control measures as reported by the involved countries under the RASFF notification 2020.3287 with last access 15 October 2020

