



JOINT ECDC-EFSA RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of Salmonella Poona infections linked to consumption of infant formula 12 March 2019

Conclusions

An outbreak of 32 *Salmonella enterica* serotype Poona cases in infants and young children has recently been identified in France (30 outbreak-confirmed case), Belgium (one outbreak-confirmed case) and Luxembourg (one outbreak-confirmed case). All 32 patients were infected with the same bacterial strain based on core genome multilocus sequence typing (cgMLST) analysis. All patients had onset of symptoms between August 2018 and February 2019. Information from interviews was available for 30 of the 32 patients, indicating that all had consumed one of three infant formula products based on rice proteins (A, B or C) from the same brand before onset of symptoms.

The suspected infant formula products were manufactured between August and October 2018 by the Spanish processing company B and marketed by the French company A. The products were distributed to French wholesalers, retailers and pharmacies who sold them to several EU, EFTA and other countries through wholesalers, online shops or the e-commerce operator A. In addition, the French company A distributed the products to four countries outside of Europe.

So far, *S*. Poona has not been detected in any sample of the implicated batches of infant formula tested either at the Spanish processing company B or at the French company A. Moreover, no positive samples for *S*. Poona have been reported in the production environment of the Spanish processing company B or in any other product dehydrated in the same drying tower since 2017.

According to the French competent authorities a recall and a withdrawal of infant formula products and baby food of the same brand were initiated on 24 January 2019 by the French company A in France and this was followed by a recall in Luxembourg. Moreover, public warnings were released in France, Belgium and Spain, and the e-commerce operator A informed all customers. In addition, recalls and public messaging were initiated in response to an INFOSAN alert in several non-European countries where the products had been distributed. Such measures should decrease the risk of new infections. However, additional outbreak cases may be reported, particularly among those having consumed the implicated products already sold and not recalled.

Suggested citation: European Centre for Disease Prevention and Control and European Food Safety Authority. Multi-country outbreak *S.* Poona infections linked to consumption of infant formula, 12 March 2019

Options for response

In order to prevent infections when using infant formula, Member States should consider providing advice to the public on basic hygiene rules for the preparation of food for infants, including information on the safe preparation, handling and storage of powdered infant formula products [1,2].

Caregivers of children who have consumed infant formula and develop diarrhoea should be advised to contact their healthcare provider. Cases of salmonellosis in infants should be notified to the national health authorities for serotyping. *S.* Poona isolates should be sequenced to explore whether they are associated with this outbreak.

Given that the detection of *Salmonella* in dry products may be difficult due to low and non-homogenous contamination, the sensitivity of the sampling procedures and the analytical method for this food matrix warrants further evaluation.

Competent authorities are encouraged to report new human cases associated with this event and the findings of public health investigations to the ECDC Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD). They are also encouraged to consider interviewing the parents of new and recent patients infected by *S*. Poona about consumption of infant formula in order to identify potential gaps/faults in the withdrawal and recall process.

ECDC is funding whole genome sequencing (WGS) analysis of human *S*. Poona isolates from cases possibly related to this outbreak and reported in countries that do not routinely perform WGS. Since the microbiological confirmation in the European case definition of this outbreak also includes the ECDC cgMLST pipeline, ECDC suggests that countries with sequenced isolates share with ECDC any *S*. Poona sequences that are closely related with the representative outbreak strains (EBI-ENA project PRJEB31267) so that they can be included in the multi-country WGS analysis.

The European Union Reference Laboratory for *Salmonella* is providing support to Member States that do not have WGS capacity to perform WGS analysis of non-human isolates possibly related to this outbreak strain. In order to identify the source of contamination, those Member States concerned are advised to carry out environmental and food sampling and testing at critical sites along the production lines and distribution of the suspected food item.

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

Source and date of request

ECDC proposed the production of this Rapid Outbreak Assessment (ROA) to EFSA on 7 February 2019 and the proposal was accepted by EFSA on 12 February 2019.

Public health issue

This document provides an assessment of the cross-border public health risk related to the outbreak of *S*. Poona infections in infants and young children linked to consumption of infant formula described in the EPIS FWD urgent inquiry UI-537 and the RASFF notification 2019.0224.

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

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

Consulted experts

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- EFSA experts (in alphabetical order): Ernesto Liebana, Valentina Rizzi, Mirko Rossi, Eleonora Sarno.
- European Union Reference Laboratory for Salmonella (EURL-Salmonella): Kirsten Mooijman
- World Health Organization (WHO): Peter Ben Embarek, Adam Bradshaw, Carmen Savelli, Raul Garcia Acevedo (INFOSAN Secretariat). The views expressed by the WHO experts in this document do not necessarily represent the views of WHO.
- External public health experts representing national authorities (in alphabetical order of countries): Belgium: Wesley Mattheus and Dieter Van Cauteren (Sciensano - Belgian Institute for Health); France: Nathalie Jourdan-da Silva, Gabrielle Jones (Santé publique France), Maria Pardos de la Gandara, François-Xavier Weill (French National Reference Center for *E. coli, Shigella* and *Salmonella*, Institut Pasteur);

Luxembourg: Joël Mossong, Catherine Ragimbeau, Patrick Hau, Pierre Weicherding (Health Directorate); External experts representing food and veterinary national authorities (in alphabetical order of countries):

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• RASFF contact points in Germany and Austria were consulted by EFSA to clarify and validate their national data on food and environmental investigations.

Disclaimer

ECDC issued this outbreak assessment document in accordance with Article 10 of Decision No 1082/13/EC and Article 7(1) of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC), and with the contribution of EFSA in accordance with Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety.

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

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

All data published in this rapid outbreak assessment are correct to the best of ECDC's and EFSA's knowledge on 6 March 2019. Maps and figures published do not represent a statement on the part of ECDC, EFSA or its partners on the legal or border status of the countries and territories shown.

Disease background information

Salmonella Poona infections in humans

Salmonella Poona is the 36th most common *Salmonella* serotype causing human infection reported in the European Surveillance System (TESSy). During the period 2013–2017 it was reported by 23 EU/EEA countries with 147–206 cases per year. In the five-year period, France accounted for 34% of the cases, followed by the United Kingdom with 26%. Cases were most common in children 0–4 years old (37% of cases), where cases in males were more common (58%) than in females. Travel information was available for 55% cases and of these, 45% were imported. Thailand was the most common destination, accounting for 21% of the travel-associated cases.

Foodborne outbreaks caused by Salmonella Poona

This section summarises country-specific data on foodborne outbreaks associated with *S*. Poona reported to EFSA by the Member States during the period 2009–2017 in accordance with the Zoonoses Directive 2003/99/EC and published annually in the EU summary report on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks [3]. During the period 2009–2017, three foodborne outbreaks due to *S*. Poona were reported to EFSA by three EU countries (Austria, Hungary and Sweden). In the outbreak reported by Hungary in 2009, strong evidence supported an association between the human cases and the suspected food vehicle (i.e. pig meat and products thereof). In this outbreak a total of 26 cases were reported to be associated with the consumption of the suspected food product purchased from a mobile retailer or market/street vendor. For the other two outbreaks (in Austria and Sweden) the association between the cases and the suspected food was based on weak evidence and the places of exposure were unknown; the suspected food vehicle was identified only in the outbreak in Sweden (i.e. cereal products).

In 2011, a large national outbreak due to *S*. Poona was investigated in Spain. Human cases occurred from 8 January 2010 to 12 July 2011 and were associated with the consumption of infant formula. A total of 285 confirmed cases were reported and *S*. Poona was isolated in samples of infant formula from both open and sealed packages of a single batch of a brand consumed by 88 cases [4].

Outbreaks of *S.* Poona have been reported in the USA over the last two decades associated with exposure to pet turtles and consumption of contaminated cantaloupe and cucumbers [5-7]. The pet turtle outbreak also involved several cases in Luxembourg and Chile [6]. The 2016 outbreak related to the consumption of cucumbers involved a total of 907 people from 40 different US States [7].

Salmonella Poona isolation in food

This section summarises country-specific data on the occurrence of S. *Poona* in food, animal and feed reported to EFSA by the Member States during the period 2004–2017 in accordance with the Zoonoses Directive 2003/99/EC and published annually in the EU summary report on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks [8].

During the period 2004–2016, a total of 69 units positive for *S*. Poona were reported from food (n=10) animals (n=22), and feed (n=37). The reported positive food units included meat or meat products from broilers (*Gallus gallus*) (n=1), cattle (n=1), pigs (n=2) and other animal species (not specified, n=2). Additional positive samples were reported from 'dried seed' (n=2), molluscan shellfish (n=1) and other food of non-animal origin (n=1). During the period 2005–2018, no positive results for *S*. Poona were reported in the food categories 'foodstuffs intended for special nutritional uses' (7 249 units tested) and 'infant formula' (22 416 units tested).

For 2017 data, no positive samples were reported from the 986 and 1 305 units tested for the food categories 'foodstuffs intended for special nutritional uses' and 'infant formula', respectively. No positive samples were reported for other foodstuffs in 2017.

From 2004 to 2016, *S*. Poona was detected in 22 samples from different animal species, mainly from chickens (*Gallus gallus*) (n=11) but also from turkeys (n=2), cattle (n=1) and reptiles and zoo animals (n=8). No positive samples were reported in 2017.

During the period 2004–2016, 37 samples of feed were reported positive for *S*. Poona: compound feeding stuffs for fur animals (n=12), feed material of land animal origin (n=17), feed material of marine animal origin (n=3), feed material of oil seed or fruit origin (n=3) and other feed material (n=2). In 2017 a single sample of generic feed was reported to be positive.

Event background information

On 21 January 2019, Santé publique France and the Institut Pasteur in Paris reported in EPIS FWD a small cluster of *S*. Poona infections in infants and young children. National WGS analysis of the clinical isolates from these French cases concluded that the isolates belonged to the same cgMLST cluster. France and other EU countries subsequently reported additional *S*. Poona cases in infants and young children. ECDC convened a multi-country outbreak investigation team that prepared an EU outbreak case definition and collected information on the investigations performed in the different countries.

Multi-country investigations

EU outbreak case definition

Outbreak-confirmed case:

 An EU/EEA resident with laboratory-confirmed Salmonella Poona infection with symptom onset on or after 1 January 2018 (date of sampling or date of receipt by the reference laboratory if date of onset is not available)

AND

with a clinical S. Poona isolate within five allelic differences by cgMLST to at least one of the representative sequences (EBI-ENA project PRJEB31267) based on the ECDC pipeline (EnteroBase scheme with 3002 loci – Annex 1) or to EnteroBase cgMLST [9] profile HC5-164707 when analysed by the Institut Pasteur.

Exclusion criterion:

Secondary cases defined as those confirmed cases that have had person-to-person contact with an
outbreak-confirmed case in the seven days prior to disease onset and no known exposure to a common
source.

Epidemiological and microbiological investigations of humans

As of 6 March 2019, three EU countries have identified 32 outbreak-confirmed cases with onset of symptoms reported from August 2018 to February 2019 (Figure 1). France reported 30 of these cases, while Belgium and Luxembourg reported one case each. The patients' mean age is 11 months, ranging from 3 to 28 months. Nineteen patients are male. None of the patients are known to have travelled outside their country of residency within the incubation period. Information on hospitalisation is available for 30 cases, 14 of which were hospitalised. All children have improved or fully recovered from their illness. The French patients live in at least 11 different regions of mainland France and no geographical clustering was identified.

The cgMLST analysis performed by Pasteur Institute concluded that all 30 French isolates are within five allelic differences and belong to EnteroBase [9] cgMLST profile HC5-164707, and that a subcluster of 25 isolates are within two allelic differences (HC2-167014), and, between them, five isolates are undistinguishable. The isolates from Belgium and Luxembourg are within 0–1 allelic differences from the two French representative sequences based on the ECDC cgMLST pipeline (Annex 1) and are part of the EnteroBase cgMLST profile HC5-164707 when analysed by the Institut Pasteur.

In addition, one suspected case has been identified in Belgium. This is a young child infected with *S*. Poona and with known exposure to the same brand of infant formula as the outbreak-confirmed cases prior to disease onset. However, no specimen was available for this patient and it has not been possible to confirm through sequencing that the case was a part of the same outbreak.

Other EU countries have also reported *S*. Poona in infants and young children in 2018 and 2019. However, most of these cases were either not known to have consumed the implicated infant formula products or were ruled out following WGS analysis. Sequencing results are currently being awaited from the Czech Republic, but the infants and young children from this country are not known to have consumed the implicated infant formula.

According to the French and Spanish National Reference Laboratories, the sequences of the French human isolates from the current outbreak and the sequences from the Spanish human isolates from the outbreak in 2011 are genetically-related based on cgMLST analysis (same EnteroBase cgMLST profile HC20-44730; i.e. within 20 allelic differences).

Figure 1. *S.* Poona outbreak-confirmed cases by country and week of onset*, EU, 2018 and 2019, as of 6 March 2019 (n=32)



* Week of sampling or week of receipt by the reference laboratory if week of onset unavailable.

Information from patient parent interviews

For 30 of the 32 outbreak-confirmed cases, it was possible to obtain information from parents on consumption of infant formula prior to disease onset. All 30 children's parents mentioned that their children had consumed one of the three infant formula products based on rice proteins from the same brand in the days preceding the symptoms. The children had not consumed any other common food or drink. The bottles for the 28 French infants and young children with available information were prepared with bottled water from at least seven different brands.

Microbiological and environmental investigations of food

This section summarises country-specific information on food and environmental investigations and traceability of the products associated with this outbreak that were reported through RASFF (notification 2019.0224). It also summarises information reported directly to EFSA from INFOSAN and by national competent authorities between 21 January 2019 and 5 March 2019 (see Figure 2 below for details on traceability and testing).

France

On 21 January 2019, the French competent authority released the RASFF news (2019.0224) of two cases of *S*. Poona involving infants and young children, the first one with the isolation date of 20 December 2018. The two children consumed the same infant formula product (product A) marketed by the French company A and manufactured by the Spanish processing company B.

As of 6 March 2019, the number of children identified as having been infected with *S*. Poona reporting the consumption of one or multiple products, all based on rice proteins, from the same brand marketed by the French company A and manufactured by the Spanish processing company B increased to 28 (all confirmed cases). The products were: Product A (batch A, batch B, batch C, batch D and other unknown batches), Product B (batch E) and Product C (batch F, batch G and other unknown batches). Table 1 summarises the suspected products and batches consumed by the 28 infants and young children.

At French company A, the suspected products are usually received from the Spanish processing company B and do not undergo any processing. The French company A receives the finished products at their logistics service centre and they are ready to be placed on the market.

The French company A distributed the suspected products A, B and C in France and sent them to Libya, Syria, Tunisia and Vietnam. In addition, the suspected products were distributed from 14 French wholesalers (A–P; see Table 2 in Annex 2) through wholesalers, online shops and the e-commerce operator A, to EU, EFTA and other countries.

Table 3 (Annex 3) summarises the sampling of rice-based infant formula products produced by the Spanish processing company B tested for *Samonella* by the French company A and the French competent authorities.

Based on a commercial agreement preceding the current event between the French company A and the Spanish processing company B, final products undergo testing for *Salmonella* in both companies (i.e. 30 cans from each batch are sampled in respective laboratories). At the French company A no positive results for *Salmonella* were detected in the tests performed on the seven incriminated batches (listed in Table 1) before their release to the market. The analyses were performed within a week of the production date of each batch on sealed packages of final products received from the Spanish processing company B. From 11 January to 4 February 2019, the French company A commissioned additional analyses for *Salmonella* on open and sealed cans from the seven incriminated batches: the results of all tests were negative.

Moreover, between 22 January and 11 February 2019 the French competent authority performed analyses on multiple samples of infant formula from opened and/or sealed cans, provided by the parents of the infants, of Product A batches A, B and C, Product B batch E and Product C batch G: the results of all tests were negative for *Salmonella*.

Control measures

On 24 January 2019, the French company A recalled all its infant nutrition products based on rice proteins and, more broadly, all the products manufactured by the Spanish processing company B.

On 25 January 2019, the World Health Organization/United Nations Food and Agriculture Organization International Food Safety Authorities Network (INFOSAN) was directly notified by the INFOSAN Focal Point in France of this distribution. The INFOSAN Emergency Contact Points in the countries concerned were notified by the INFOSAN Secretariat and provided with the relevant distribution details. In response, risk management measures, including recalls and public messaging, were undertaken in all the countries concerned, except Syria. No illnesses associated with the consumption of suspected products have been reported in the countries concerned.

Furthermore, e-commerce operator A sent a message to all customers who bought the suspected products to inform them of the possible biological contamination.

In addition, product D, also manufactured by the Spanish processing company B but not linked to any suspected or confirmed case, was recalled by the French company C as a precautionary measure. In contrast to the products linked to suspected or confirmed cases, product D is not based on rice proteins.

 Table 1. List of suspected products and batches consumed by 30 outbreak-confirmed cases and one suspected case¹ in France, Belgium and Luxembourg as of 5 March 2019

Product	Batch	Production date		Number of confirmed cases	Number of cases reporting consumption in Belgium		Number of confirmed cases
			Use-by date	reporting consumption in France	reporting consumption in Suspected ² Confirmed confirmed	reporting consumption in Luxembourg	
Product A	Batch A	13/08/2018	13/08/2020	1			
	Batch B	19/10/2018	19/10/2020	4			
	Batch C	21/10/2018	21/10/2020	9			
	Batch D	22/10/2018	22/10/2020	2			
	Unknown	NA	NA	5		1	1
Product B	Batch E	18/08/2018	18/08/2020	2	1		
Product C	Batch F	23/10/2018	23/10/2020	3			
	Batch G	22/10/2018	22/10/2020	3			
	Unknown	NA	NA	5			

¹cases might have consumed several batches: Product A was consumed by a total of 18 confirmed cases; Product B was consumed by a total of two confirmed and one suspected case; Product C was consumed by a total of 10 confirmed cases. ²suspected symptomatic case of S. Poona infection with history of consumption of one of the three suspected products.

Belgium

In Belgium, two salmonellosis infant cases were reported in 2019, one confirmed *S*. Poona infection and one suspected case. The confirmed case consumed Product A from an unknown batch. The product was purchased at the French retail outlet A. The suspected case reported having consumed Product B batch E (Table 1). Testing for *Salmonella* was not performed on the suspected products. On 1 February 2019 a public warning was released in Belgium.

Luxembourg

In Luxembourg, one case of *S*. Poona infection was reported in 2019. The infant consumed product A, but the batch number was not available at the time of the investigation (Table 1). The product was purchased online directly from the website of retailer B and was no longer available for testing.

The Luxembourg Wholesaler Q supplies local pharmacies in Luxembourg on demand by purchasing the rice-based infant formula products marketed by the French company A from a French supplier and does not stock the product in their facilities. The identity of the French supplier was not available at the time of the assessment. After the

recall was initiated by the French company A, the Luxembourg Wholesaler Q recalled the suspected products. Testing for *Salmonella* was performed by the competent authority on Product A (Batch D) and Product B (Batch E) that had been recalled by the Luxembourg Wholesaler Q from local pharmacies. The results of the tests were all negative.

Spain

Information on Spanish processing company B

The Spanish processing company B produces different food products including: butter, cream, UHT milk, milk powder, processed cheeses, grated cheeses, desserts, sauces, dietary products, fractionated butterfat, ingredients for the pharmaceutical industry and infant formula, including rice-based infant formula.

The rice-based infant formula products are only produced for two companies: the French company A and the Spanish company D.

The manufacturing lines on which the Spanish processing company B processed infant formula include:

- three drying towers with different capacities (towers 1, 2 and 3)
- two can packaging lines for the processing of different can sizes (packing lines 1 and 2)
- one packaging line for bags.

The two can packaging lines have a sanitisation system using UV.

These facilities are used interchangeably to produce the infant formula for different customers. The decision to use one or the other depends on the product reference and (in the case of drying towers) on the volume to be dried or the particle size of the powder that should be achieved.

The production lines are washed approximately once per month. After washing, the non-allergenic or low allergenic products (such as the ones based on rice proteins) are dried before the milk-based infant formula products. To avoid cross-contamination at packaging, dry cleaning is carried out between product types.

The processing of all suspected infant formula products and batches was similar and consisted of the preparation of a wet mix, followed by heat treatments (one at 106°C for 44 seconds and a second at 75–80°C for 15 seconds) and dehydration in drying tower 2. After dehydration, microbiological analyses were performed on the intermediate products, including *Salmonella* detection. Finally, the dehydrated intermediate products were mixed with ingredient A, ingredient B, or ingredient C. Only for Product C was the ingredient D added. The products were then packaged in cans using packing line 2. Once the plastic cap was placed on the can, the final product was packed into cartons and microbiological testing, including *Salmonella* detection, was performed prior to shipment.

None of the products manufactured for other food business operators shared rice-based infant formula with the suspected products except for those of Spanish company D.

Table 3 (Annex 3) summarises the sampling of implicated rice-based infant formula products by Spanish processing company B and the Spanish competent authorities.

The Spanish processing company B performed analytical tests for *Salmonella* on samples from the seven suspected batches along the processing line. Sampling points were after product dehydration and on final products before delivery to the French company A. The results of all tests were negative for *Salmonella*.

On 24 January 2019, the official laboratory of Asturias performed analyses for *Salmonella* on 64 samples (25 g each) of Product B batch E; on 64 samples (25 g each) of Product C batch G; and on 30 samples (25 g each) of Product C batch F. In addition, 15 samples of other rice infant formulas using the same intermediate product as used for Product B batch E were tested. The results of all tests were negative.

All batches of ingredients used for the production of the implicated infant formula batches (ingredients A, B, C and D), were certified as *Salmonella*-negative by the suppliers. The same batches of ingredients were re-tested for *Salmonella* by the Spanish processing company B upon reception and on 24 January 2019 during the outbreak investigation. The results of all tests were negative.

Furthermore, the Spanish processing company B performed tests to detect *Salmonella* on 498 environmental samples taken at the premises of tower 2 (where the dehydration of the implicated batches was performed) and 336 samples taken at the packaging facilities. The results of all tests were negative.

The competent authorities of Asturias have confirmed that the Spanish processing company B produced the infant formula products involved in the Spanish *S.* Poona outbreak occurring in 2011 [1]: the product was dehydrated in drying tower 2 and packaged in cans using packaging line 1.

Control measures

On 22 January 2019, the Spanish processing company B ceased operations in drying tower 2 where all the suspected products had been dehydrated.

Moreover, as a precautionary measure, on 11 February 2019, the Spanish Agency for Consumer Affairs, Food Safety and Nutrition released a public warning concerning all infant formula products based on rice dried in tower 2 at the Spanish processing company B since the start of 2017.

The public warning was extended to Product E and Product F produced by the Spanish processing company B for Spanish company D although these products were not linked to any suspected or confirmed cases. The Spanish company D stated that a medical prescription is required in order to consume these preparations and that, given their rotation, the company believes that all the products provided before October 2018 have already been consumed. Nevertheless, Spanish company D has contacted all its clients, giving instructions to withdraw both of the two products with a valid sell-by date, and is managing the withdrawal of the products.

On 21 February 2019, the INFOSAN Secretariat was notified by RASFF that Product E and Product F of the Spanish company D were distributed internationally from Spain to Ecuador, Mexico, Peru, Saudi Arabia and the United Arab Emirates. The INFOSAN Secretariat informed the INFOSAN Emergency Contact Points in these countries and provided the relevant distribution details to enable appropriate risk management measures to be taken in response. Some of these countries, such as Ecuador, have already issued local alerts and initiated recalls. No illnesses associated with the consumption of implicated products have been reported in these countries.

Figure 2. Graphical representation of traceability and testing information reported by Member States in RASFF, as of 5 March 2019



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ECDC and EFSA threat assessment for the EU/EEA

Belgium, France and Luxembourg are affected by an outbreak of *S*. Poona involving 32 outbreak-confirmed cases. All patients are infants and young children under three years of age. Epidemiological evidence from interviews of the patients' parents in 30 of the 32 outbreak-confirmed cases identified three products of infant formula based on rice proteins from the same brand as the suspected vehicles of infection. WGS analysis of *S*. Poona isolates from all patients showed that all isolates are part of a tight genomic cluster, supporting the hypothesis of a common source of infection.

The implicated batches of the three products of rice-based infant formula (A, B or C) were produced on the same production line at the Spanish processing company B for the French company A. However, no detection of *S*. Poona has been reported in any of these batches of infant formula products or in their production environment to substantiate the epidemiological evidence. It is worth mentioning that the detection of *Salmonella* or other pathogens in dried products may be difficult due to the potentially low level and non-homogenous distribution of the contamination in this food matrix [10].

The products were distributed by the French company A to French wholesalers, retailers and pharmacies who sold the products to several EU-EFTA and other countries through wholesalers, on-line shops or the e-commerce operator A. In addition, the French company A distributed the products to four countries outside of Europe. All non-EU and non-EFTA countries have been informed by the INFOSAN Secretariat.

According to the French competent authorities, French company A initiated a recall and a withdrawal of infant formula and baby food products from the same brand in France on 24 January 2019, followed by a recall in Luxembourg. Moreover, public warnings were released in France, Belgium and Spain, and the e-commerce operator A informed all customers. In addition, recalls and public messaging were initiated in response to an INFOSAN alert in several non-European countries where the products had been distributed. The control measures undertaken should decrease the risk of new infections. However, additional outbreak-cases might be reported, particularly among those having consumed the implicated products already sold and not recalled.

Several previous outbreaks of other *Salmonella enterica* serotypes associated with the same type of food items have been reported in the past [11-15]. In late 2017–early 2018, France reported an outbreak of *Salmonella* Agona in infants associated with consumption of milk-based infant formula, where the outbreak strain had potentially persisted in the processing plant for 12 years [16].

In 2011, an outbreak of *S*. Poona in Spain was associated with milk-based infant formula, which was produced by the same company as this outbreak (Spanish processing company B). Furthermore, the French and Spanish National Reference Laboratories reported that the sequences of the French human isolates from the current outbreak and the sequences from the Spanish human isolates for the outbreak in 2011 are genetically related. The possible persistence of *S*. Poona in the processing line warrants further investigation.

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Annex 1. EU/EEA-level whole genome sequencing analysis

ECDC cgMLST pipeline: The sequences available at ECDC (two representative outbreak isolates from France, one isolate from Belgium and one isolate from Luxembourg) were assembled with SPAdes v.3.7.1 in BioNumerics version 7.6.3 (Applied-Maths, Sint-Martens-Latem, Belgium) including post-assembly optimisation by mapping reads back onto the assembly and keeping the consensus. The cgMLST analysis was done based on the assembly using the EnteroBase scheme in BioNumerics. Isolates were retained in the analysis if at least 2 702 (90%) of the 3 002 core loci were detected. Isolates differing by five or less cg-alleles from at least one of the representative sequences (EBI-ENA numbers ERR3156072 and ERR3156073) were considered as confirmed.

The four isolates formed a tight cluster with all isolates falling within one allelic difference of at least one other outbreak cluster isolate (Figure 3). A total of 2 911 of the 3 002 loci were detected in all isolates.

Figure 3. cgMLST-based (EnteroBase scheme) single-linkage clustering analysis including sequences from four human *S.* Poona isolates from three countries, EU/EEA 2018–2019



The French representative outbreak isolates are indicated with a circle.

Annex 2. Wholesalers and countries of distribution of the implicated products

Table 2. List of wholesalers and countries of distribution through the e-commerce operator A for the three suspected products

Wholesaler	Distribution through e-commerce operator				
(Country of origin)	Product A	Product B	Product C		
A (FR)	ES	UK			
B (FR)	МС				
C (FR)	BE, DE, IT, LU, ES, CH, UK, MA	BE, DE, IT, LU, NL, PT, CH, UK	BE, DE, LU, ES, CH, UK		
D (FR)	BE, LU, CH				
E (FR)	BE, MC	BE, LU, PT			
F (FR)	МС				
G (FR)	BE	BE	BE, DE		
H (FR)	BE, DE, IT, LU, ES, CH, UK, NO		BE, DE, IT, MC, NL		
I (FR)	BE		DE, CH		
L (FR)		BE, ES, UK			
M (FR)		DE, CH	IT		
N (FR)		LU			
O (FR)		DK			
P (FR)			BE, UK		

Country codes

Belgium	BE	Monaco	MC
Denmark	DK	Norway	NO
Germany	DE	Portugal	PT
France	FR	Spain	ES
Italy	IT	Switzerland	CH
Luxembourg	LU	The Netherlands	NL
Morocco	MA	United Kingdom	UK

Annex 3. Official and own check analyses

 Table 3. Sample overview for implicated rice-based infant formula products produced by Spanish processing company B tested for *Salmonella* by French company A, Spanish processing company B and authorities in France, Spain and Luxembourg

Product	Batch	Expiry date	Sampling date	Type of sample	Number of samples (total amount of product analysed in grams)	Analytical method ⁽¹⁾		
French company A - own check (2)								
	Α	13/08/2020	16/08/2018	release control	30 (750)	PCR		
A		-,,	21/01/2019	Final product, intact package	5 (1875)	PCR		
	В	19/10/2020	25/10/2018	Final product, intact package, release control	30 (750)	PCR		
			21/01/2019; 29/01/2019	Final product, intact package	26 (4150)	PCR; ISO 6579-1		
	С	21/10/2020	25/10/2018	Final product, intact package, release control	30 (750)	PCR		
			21/01/2019; 29/01/2019	Final product, intact package	26 (4150)	PCR; ISO 6579-1		
			04/02/2019	Final product, open at retail	61 (1479.5)	ISO 6579-1		
	D	22/10/2020	25/10/2018	Final product, intact package, release control	30 (750)	PCR		
	U	22/10/2020	21/01/2019	Final product, intact package	10 (3750)	PCR		
			04/02/2019	Final product, open at retail	42 (1029.9)	ISO 6579-1		
			21/08/2018	release control	30 (750)	PCR;		
В	E	18/08/2020	11/01/2019; 15/01/2019	Final product, intact package	12 (3800)	PCR; ISO 6579-1		
			01/02/2019; 29/01/2019; 01/02/2019	Final product, open from consumer	23 (669)	PCR; ISO 6579-1		
	F	23/10/2020	25/10/2018	Final product, intact package, release control	30 (750)	PCR		
			21/01/2019	Final product, intact package	10 (3750)	PCR		
С	~	11/10/2020	25/10/2018	Final product, intact package, release control	30 (750)	PCR		
	G	22/10/2020	21/01/2019; 29/01/2019	Final product, intact package	30 (4947)	PCR; ISO 6579-1		
			04/02/2019	Final product, open at retail	12 (286.5)	ISO 6579-1		
E	e	- 1 (3)						
French of	ficial contro	ol ⁽³⁾	29/01/2019	Final product intact package	NΔ	ΝΔ		
French of	ficial contro A	al ⁽³⁾ 13/08/2020	29/01/2019 04/02/2019	Final product, intact package Final product, open at	NA 10 (250)	NA		
French of	ficial contro A	ol ⁽³⁾ 13/08/2020	29/01/2019 04/02/2019	Final product, intact package Final product, open at consumer level	NA 10 (250)	NA NA		
French of A	ficial contro A B	a) ⁽³⁾ 13/08/2020 19/10/2020	29/01/2019 04/02/2019 11/02/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level	NA 10 (250) NA	NA NA NA		
French of	ficial contro A B C	a) (3) 13/08/2020 19/10/2020 21/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level	NA 10 (250) NA 17 (420)	NA NA NA ISO 6579-1		
French of A B	ficial contro A B C E	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level	NA 10 (250) NA 17 (420) 3 (75)	NA NA NA ISO 6579-1 ISO 6579-1		
French of A B	ficial contro A B C E F	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product	NA 10 (250) NA 17 (420) 3 (75) NA	NA NA NA ISO 6579-1 ISO 6579-1 NA		
French of A B C	ficial contro A B C E F G	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product Final product Final product	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700)	NA NA NA ISO 6579-1 ISO 6579-1 NA ISO 6579-1		
French of A B C	ficial contro A B C E F G	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product Final product Final product, open at consumer level Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500)	NA NA NA ISO 6579-1 ISO 6579-1 NA ISO 6579-1 ISO 6579-1		
French of A B C Spanish p	ficial contro A B C E F G orocessing o	 (3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 company B - 	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 own check ⁽⁴⁾	Final product, intact package Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product, open at consumer level Final product Final product Final product, open at consumer level Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500)	NA NA NA ISO 6579-1 ISO 6579-1 NA ISO 6579-1 ISO 6579-1		
French of A B C Spanish p	Ficial contro A B C E F G orocessing o	a) (3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 company B - 08/09/2018	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 own check ⁽⁴⁾ 04/08/2018	Final product, intact package Final product, open at consumer level Final product Final product, open at consumer level Final product, intact package Intermediate product after dehydration	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125)	NA NA ISO 6579-1		
French of A B C Spanish p	Ficial contro A B C E F G orocessing o A	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 08/09/2018 13/08/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 own check ⁽⁴⁾ 04/08/2018 13/08/2018; 14/08/2018	Final product, intact packageFinal product, open at consumer levelFinal product, intact packageIntermediate product after dehydrationFinal product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500)	NA NA NA ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1		
French of A B C Spanish p	Ficial contro A B C E F G Orocessing o A	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 08/09/2018 13/08/2020 24/10/2018	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 22/01/2019 own check ⁽⁴⁾ 04/08/2018 13/08/2018; 14/08/2018 19/09/2018	Final product, intact package Final product, open at consumer level Final product, intact package Intermediate product after dehydration Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380)	NA NA NA ISO 6579-1 ISO 6579-1		
French of A B C Spanish p	ficial contro A B C E F G G Orocessing o A B	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 08/09/2018 13/08/2020 24/10/2018 19/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 0wn check ⁽⁴⁾ 04/08/2018 13/08/2018; 14/08/2018 19/09/2018 19/10/2018; 21/10/2018	Final product, intact packageFinal product, open at consumer levelFinal product, intact packageIntermediate product after dehydrationFinal product, intact packageIntermediate product after dehydrationFinal product, intact packageIntermediate product after dehydrationFinal product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380) 12 (1500)	NA NA NA ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 IMmunoassay Immunoassay; PCR-rt Immunoassay;		
French of A B C Spanish p	Ficial contro A B C E F G Orocessing o A B	(3) 13/08/2020 19/10/2020 21/10/2020 18/08/2020 23/10/2020 22/10/2020 22/10/2020 08/09/2018 13/08/2020 24/10/2018 19/10/2020	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 0wn check ⁽⁴⁾ 04/08/2018 13/08/2018; 14/08/2018 19/09/2018 19/10/2018; 21/10/2018	Final product, intact package Final product, open at consumer level Final product, intact package Intermediate product after dehydration Final product, intact package Intermediate product after dehydration Final product, intact package Intermediate product after dehydration Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380) 12 (1500) 4 (1380)	NA NA NA ISO 6579-1 ISO 6579-1 IS		
French of A B C Spanish p	Ficial contro A B C E F G Processing o A B C	 (3) 13/08/2020 19/10/2020 21/10/2020 23/10/2020 23/10/2020 22/10/2020 22/10/2020 22/10/2020 3/08/2020 24/10/2018 19/10/2020 24/10/2018 21/10/2020 	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 0Wn check ⁽³⁾ 04/08/2018 13/08/2018; 14/08/2018 19/09/2018 19/10/2018; 21/10/2018 21/10/2018; 22/10/2018	Final product, intact package Final product, open at consumer level Final product, intact package Intermediate product after dehydration Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380) 12 (1500) 4 (1380) 12 (1500)	NA NA NA ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 Immunoassay Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt		
French of A B C Spanish p	Ficial contro A B C E F G Orocessing o A B C	 (3) 13/08/2020 19/10/2020 21/10/2020 23/10/2020 23/10/2020 22/10/2020 22/10/2020 22/10/2020 24/10/2018 19/10/2020 24/10/2018 21/10/2020 25/10/2018 	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 0wn check ^(a) 04/08/2018 13/08/2018; 14/08/2018 13/08/2018; 14/08/2018 19/09/2018 21/10/2018; 22/10/2018 21/10/2018; 22/10/2018	Final product, intact package Final product, open at consumer level Final product, intact package Intermediate product after dehydration Final product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380) 12 (1500) 4 (1380) 12 (1500) 4 (1380) 12 (1500) 4 (1380)	NA NA NA ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 Immunoassay Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay;		
French of A B C Spanish p	Ficial contro A B C E F G Orocessing o A B C D	 (3) 13/08/2020 19/10/2020 21/10/2020 23/10/2020 23/10/2020 22/10/2020 22/10/2020 22/10/2018 13/08/2020 24/10/2018 21/10/2020 25/10/2018 22/10/2020 	29/01/2019 04/02/2019 11/02/2019 04/02/2019 05/02/2019 29/01/2019 22/1/2019; 01/02/2019 22/01/2019 0wn check ⁽⁴⁾ 04/08/2018 13/08/2018; 14/08/2018 13/08/2018; 14/08/2018 19/09/2018 21/10/2018; 21/10/2018 21/10/2018; 22/10/2018	Final product, intact packageFinal product, open at consumer levelFinal product, intact packageIntermediate product after dehydrationFinal product, intact package	NA 10 (250) NA 17 (420) 3 (75) NA 28 (700) 20 (500) 3 (1125) 12 (1500) 4 (1380) 12 (1500) 4 (1380) 12 (1500) 4 (1380) 12 (1500) 12 (1500) 12 (1500)	NA NA NA ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 ISO 6579-1 Immunoassay Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt Immunoassay; PCR-rt		

				dehydration			
		10/00/2020	18/08/2018; 19/08/2018	Final product, intact package	12 (1500)	Immunoassay; PCR-rt	
C		18/08/2020	15/01/2019; 31/01/2019	Final product, intact package	34 (1550)	ISO 6579-1:2017; PCR-rt	
		26/10/2018	21/09/2018	Intermediate product after dehydration	4 (1380)	Immunoassay	
	Г 	23/10/2020	23/10/2018	Final product, intact package	12 (1500)	Immunoassay; PCR-rt	
		26/10/2018	21/09/2018	Intermediate product after dehydration	4 (1380)	Immunoassay	
	G	22/10/2020	22/10/2018; 23/10/2018; 31/01/2019	Final product, intact package	44 (2300)	Immunoassay; PCR-rt	
Spanish o	official cont	rol					
	А	13/08/2020	15/02/2019	Final product, intact package sampled at the stock of the Spanish processing company B	30 (750)	PCR-rt	
A	В	19/10/2020	15/02/2019	Final product, intact package sampled at the stock of the Spanish processing company B	30 (750)	PCR-rt	
	С	21/10/2020	15/02/2019	Final product, intact package sampled at the stock of the Spanish processing company B	30 (750)	PCR-rt	
	D	22/10/2020	15/02/2019	Final product, intact package sampled at the stock of the Spanish processing company B	30 (750)	PCR-rt	
В	E	18/08/2020	24/01/2019	Final product, intact package sampled at the stock of the Spanish processing company B	64 (1600)	PCR-rt	
	F	23/10/2020	15/02/2019	Final product, intact package sampled at the stock of the Spanish processing company B	30 (750)	PCR-rt	
С	G	22/10/2020	24/01/2019	Final product, intact package sampled at the stock of the Spanish processing company B	64 (1600)	PCR-rt	
Luxembourg official control							
Α	D	22/10/2020	2019	NA	NA	NA	
В	E	18/08/2020	2019	NA	NA	NA	

The results of all the analyses were negative (i.e. absence of Salmonella in the product samples).

NA = not available

- (1) PCR-rt: Real Time Polymerase Chain Reaction
- (2) At the French company A the analyses were performed within a week of the production date of each batch on sealed packages of final products received from the Spanish processing company B. In addition, from 11 January to 4 February 2019, French company A commissioned additional analyses for Salmonella on open cans collected from consumers or retailers.
- (3) From 22 January to 11 February 2019 the French competent authority performed analyses on multiple samples of infant formula from opened and/or sealed cans, provided by the parents of the infants.
- (4) The Spanish processing company B performed analytical tests for Salmonella on samples along the processing line. Sampling points were after product dehydration before the addition of ingredients A, B, C and D and before packaging (identified as intermediate product) and on final products before delivering to costumers. Moreover, for Product B batch E and Product C batch G, additional sampling was performed on sealed cans during the outbreak investigation.