

APPROVED: 15 January 2018

doi:10.2903/sp.efsa.2018.EN-1365

Multi-country outbreak of *Salmonella Agona* infections linked to infant formula

European Food Safety Authority
European Centre for Disease Prevention and Control

Abstract

An outbreak of *Salmonella Agona* linked to the consumption of infant formula (powdered milk) has been ongoing in France since August 2017. As of 11 January 2018, the outbreak had affected 39 infants (children <1 year of age): 37 in France, one in Spain confirmed by whole genome sequencing (WGS) and one in Greece, considered to be associated with this event based on the presence of a rare biochemical characteristic of the isolate. The date of symptom onset for the most recent case was 2 December 2017. Available evidence from epidemiological investigations in humans and traceability investigations in food identified seven different brands of infant formula from a single processing company in France as the vehicles of infection. After receiving the first notification on 2 December 2017 of an unusual number of *S. Agona* cases in France, the French authorities carried out investigations at the implicated factory. On 4 December 2017, they notified the Rapid Alert System for Food and Feed (RASFF) after confirming that some of the affected products were exported to other countries. Following investigations at the processing company, all products manufactured since 15 February 2017, including products other than infant formula, have been recalled and/or withdrawn, as a precautionary measure. The French competent authorities are verifying that the measures taken by the processing company in response to this event have been sufficient and appropriate. As of 15 January 2018, recalled products had been distributed to 13 European Union (EU) countries (Belgium, Bulgaria, Cyprus, the Czech Republic, France, Greece, Ireland, the Netherlands, Romania, Slovenia, Slovakia, Spain and the United Kingdom) and to 54 third countries. Most of the batches involved in the investigation have not yet passed their expiry date. However, broad withdrawal and/or recall measures, export bans and a suspension of market distribution of these batches, implemented since the beginning of December 2017 by the French competent authority and processing company A, are likely to significantly reduce the risk of human infection. The possibility remains, however, that new cases may be detected. Third countries, where the recalled products had been distributed, have been notified by RASFF through INFOSAN. ECDC offers WGS services to EU/EEA countries that do not have the capacity for a timely sequencing and analysis as part of this investigation. A multi-country WGS analysis is under way at the Pasteur Institute.

© European Food Safety Authority, European Centre for Disease Prevention and Control, 2018

Key words: *Salmonella Agona*, infant formula, infants, multi-country outbreak, Whole Genome Sequencing (WGS)

Requestor: European Commission

Question number: EFSA-Q-2017-00830

Correspondence: zoonoses@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the ECDC experts: Denis Coulombier, Margot Einöder-Moreno, Saara Kotila, Ettore Severi, Johanna Takkinen, Therese Westrell; EFSA experts: Domenico Deserio, Raquel Garcia Fierro, Ernesto Liebana Criado, Valentina Rizzi, Yves Van der Stede; and external experts representing national authorities (by alphabetical order of countries): France: Nathalie Jourdan-da Silva and Henriette de Valk (Santé publique France), Simon le Hello (Institut Pasteur), Roselyne Hureauux-Roy, Hubert Herber, Yasmine Abdallah and Ekaterina Bloch (Unité d’alerte - DGCCRF); Greece: Kassiani Mellou (Hellenic Centre for Disease Control and Prevention); Georgia Mandilara (National Reference Centre for Salmonella), Stella Stamati (National Organization for Medicines); the Netherlands: Kirsten Mooijman (EU Reference Laboratory *Salmonella*); Spain: Silvia Herrera-León and Carmen Varela Martínez (Instituto de Salud Carlos III - ISCIII), Milagros Nieto Martínez and Francisco José Fernández-Gayol Pérez (AECOSAN-MSSSI) for the support provided to this scientific output.

Erratum: on page 6, in the section on Greece, a reference to ‘Brand E’, which appeared in the version dated 17 January 2018, was corrected on 18 January 2018 to ‘Brand F’.

Suggested citation: EFSA (European Food Safety Authority) and ECDC (European Centre for Disease Prevention and Control), 2018. Multi-country outbreak of *Salmonella* Agona infections linked to infant formula. EFSA supporting publication 2018:EN-1365. 9 pp. doi:10.2903/sp.efsa.2018.EN-1365

ISSN: 2397-8325

© European Food Safety Authority, European Centre for Disease Prevention and Control, 2018

Reproduction is authorised provided the source is acknowledged.



JOINT RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of *Salmonella* Agona infections linked to infant formula

16 January 2018

Conclusions

An outbreak of *Salmonella* Agona linked to the consumption of infant formula (powdered milk) has been ongoing in France since August 2017. As of 11 January 2018, the outbreak had affected 39 infants (children <1 year of age): 37 in France, one in Spain confirmed by whole genome sequencing (WGS) and one in Greece, considered to be associated with this event based on the presence of a rare biochemical characteristic of the isolate. The date of symptom onset for the most recent case was 2 December 2017.

Available evidence from epidemiological investigations in humans and traceability investigations in food identified seven different brands of infant formula from a single processing company in France as the vehicles of infection.

After receiving the first notification on 2 December 2017 of an unusual number of *S. Agona* cases in France, the French authorities carried out investigations at the implicated factory. On 4 December 2017, they notified the Rapid Alert System for Food and Feed (RASFF) after confirming that some of the affected products were exported to other countries. Following investigations at the processing company, all products manufactured since 15 February 2017, including products other than infant formula, have been recalled and/or withdrawn, as a precautionary measure. The French competent authorities are verifying that the measures taken by the processing company in response to this event have been sufficient and appropriate.

As of 15 January 2018, recalled products had been distributed to 13 European Union (EU) countries (Belgium, Bulgaria, Cyprus, the Czech Republic, France, Greece, Ireland, the Netherlands, Romania, Slovenia, Slovakia, Spain and the United Kingdom) and to 54 third countries.

Most of the batches involved in the investigation have not yet passed their expiry date. However, broad withdrawal and/or recall measures, export bans and a suspension of market distribution of these batches, implemented since the beginning of December 2017 by the French competent authority and processing company A, are likely to significantly reduce the risk of human infection. The possibility remains, however, that new cases may be detected. Third countries, where the recalled products had been distributed, have been notified by RASFF through INFOSAN.

ECDC offers WGS services to EU/EEA countries that do not have the capacity for a timely sequencing and analysis as part of this investigation. A multi-country WGS analysis is under way at the Pasteur Institute.

Options for response

In order to prevent infections when using infant formula, both in infants and caregivers, Member States should consider providing the following advice to the public [1,2]:

- Not to use any of the infant formulas involved in this outbreak;
- Hand washing before and after the preparation of the bottle;
- Bottles should not be prepared in advance and contents should be discarded if not consumed within two hours.

Erratum: on page 6, in the section on Greece, a reference to 'Brand E', which appeared in the version dated 17 January 2018, was corrected on 18 January 2018 to 'Brand F'.

Suggested citation: European Centre for Disease Prevention and Control, European Food Safety Authority. Multi-country outbreak of *Salmonella* Agona infections linked to infant formula: Stockholm and Parma: ECDC, EFSA; 2018.
© European Centre for Disease Prevention and Control, Stockholm, 2018

Caregivers of children who have consumed infant formula and develop diarrhoea should be advised to contact their healthcare provider. Cases of *S. Agona* should be notified to the national health authorities.

New human cases associated with this event and the findings of public health investigations should be reported to EPIS-FWD (Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses).

ECDC and EFSA would encourage the competent authorities of food safety and public health sectors in the affected EU countries and at European level to continue sharing information on the epidemiological, microbiological and environmental investigations, including issuing relevant notifications using RASFF and the Early Warning and Response System (EWRS).

RASFF is the official EU system for sharing information on hazards found in food and feed, the trade of potentially contaminated batches between Member States and the tracing of such batches. EWRS is the official channel for notifying cross-border threats to humans from communicable diseases. 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.

Source and date of request

ECDC Round Table request, 15 December 2017.

Public health issue

This document provides an assessment of the public health risk associated with a multi-country outbreak of *Salmonella* Agona associated with consumption of potentially contaminated infant formula from France. The event was included in the Communicable Disease Threats Report (CDTR) on 15 December 2017.

Consulted experts

- ECDC experts (in alphabetical order): Denis Coulombier, Margot Einöder-Moreno, Saara Kotila, Ettore Severi, Johanna Takkinen, Therese Westrell.
- EFSA experts (in alphabetical order): Domenico Deserio, Raquel Garcia Fierro, Ernesto Liebana Criado, Valentina Rizzi, Yves Van der Stede.
- External experts representing national authorities (in alphabetical order of countries):
 - France: Nathalie Jourdan-da Silva and Henriette de Valk (Santé publique France), Simon le Hello (Institut Pasteur), Roselyne Hureauux-Roy, Hubert Herber, Yasmine Abdallah and Ekaterina Bloch (Unité d'alerte - DGCCRF);
 - Greece: Kassiani Mellou (Hellenic Centre for Disease Control and Prevention); Georgia Mandilara (National Reference Centre for Salmonella), Stella Stamati (National Organization for Medicines);
 - The Netherlands: Kirsten Mooijman (EU Reference Laboratory *Salmonella*);
 - Spain: Silvia Herrera-León and Carmen Varela Martínez (Instituto de Salud Carlos III - ISCIII), Milagros Nieto Martínez and Francisco José Fernández-Gayol Pérez (AECOSAN-MSSSI).

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 the European Food Safety Authority (EFSA) in accordance with Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety.

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

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

All data published in this rapid outbreak assessment are correct to the best of our knowledge on 15 January 2018. Maps and figures published do not represent a statement on the part of ECDC, EFSA or its partners on the legal or border status of the countries and territories shown.

Disease background information

Salmonella Agona isolations in humans

Salmonella Agona is the tenth most commonly reported *Salmonella* serotype in the EU/EEA. In the period 2012–2016, 26 EU/EEA countries reported an annual number of cases ranging from 400 to 581. The United Kingdom, Germany and France accounted for the highest proportion of confirmed cases (30%, 16% and 14%, respectively) during this period. Cases were most frequent among adults in the age group 25–44 years (23%), and children below five years (22%). No major differences were observed in the overall gender distribution. Information on travel during the incubation period was available for 76% of the cases: 65% of these were reported as non-travel-associated [3].

Foodborne outbreaks caused by *Salmonella* Agona

In 2016, *S. Agona* was rarely reported as a cause of foodborne outbreaks [4]. It was reported only by the United Kingdom as the causative agent of an outbreak based on weak evidence. The place of exposure was a public place (i.e. restaurant, café, pub, bar, hotel or catering service) and the food vehicle was not identified.

During the period 2010–2015, nine foodborne outbreaks due to *S. Agona* were reported at EU level by six EU countries. Three of these outbreaks were supported by weak evidence, one each being reported for Austria, Croatia and Denmark, causing 27 human cases and one hospitalisation. The food vehicles were not identified in these events.

The other six outbreaks were reported by the United Kingdom (three outbreaks), Germany (two outbreaks) and Finland (one outbreak), and caused 548 human cases, seven of which were hospitalised. For these outbreaks, the evidence supporting the association with the suspected food vehicle was reported to be strong: they were associated with the consumption of 'broiler meat (*Gallus gallus*) and products thereof' (two outbreaks); 'pig meat and products thereof'; 'other or mixed red meat and products thereof (roast beef and bacon)'; 'buffet meals' and 'other food (fresh curry leaves and herbs used uncooked in coconut chutney)' (one outbreak each). Information on phage type was only provided for one strong-evidence outbreak caused by *S. Agona* (PT 39), associated with the consumption of 'other or mixed red meat and products thereof'.

In addition, two national *S. Agona* outbreaks were reported in France during the period 2004–2005 associated with the consumption of infant formula [5].

Salmonella Agona isolations in food, animals and feed

In 2016, 25 units positive for *S. Agona* were reported from food, the majority of which (68.0%) were reported in meat from poultry and broilers. These isolations were reported by four Member States and one non-Member State: Croatia (n=10), Austria (n=3), Belgium (n=1), Slovenia (n=1) and Switzerland (n=2). Additional isolations were reported in meat from bovine animals by the Czech Republic (n=3), meat from unspecified origin by Italy (n=2), meat from pigs by Estonia (n=1), cheeses made from unpasteurised milk by Italy (n=1) and dried seeds by Greece (n=1) [4].

From 2004 to 2015, 1 312 units were reported positive for *S. Agona* from several food categories. The food categories for which *S. Agona* was mainly reported were meat and meat products. The highest number of isolates were retrieved in meat from pigs (n=512) followed by meat from broilers (*Gallus gallus*) (n=422), other unspecified meat (n=140), and meat from bovine animals and pigs (n=105). *S. Agona* was less frequently reported in food categories such as eggs and egg products, fish and fish products and fruits and vegetables.

No positive samples were reported in the food categories 'foodstuffs intended for special nutritional uses' and 'infant formula' for which 548 and 367 units respectively were tested between 2004 and 2016. The 548 units of foodstuffs intended for special nutritional use were mainly tested during the periods 2004–2005 and 2010–2011 and reported by three Member States (Austria, Ireland and Slovakia). The 367 tested units of infant formula were reported between 2005 and 2013 by five Member States (Austria (n=17), the Czech Republic (n=44), Greece (n=16), Ireland (n=142) and Slovakia (n=148).

In 2016, 242 units positive for *S. Agona* were reported from animals. The majority of these (n=86.4%) were derived from fowl (*Gallus gallus*), followed by turkey (10.3%). Positive results for *S. Agona* in fowl (*Gallus gallus*) were reported in 2016 by 10 Member States (Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Greece, Italy, Malta, Portugal and the United Kingdom) and two non-Member States (Iceland and Switzerland), with the highest numbers reported by the United Kingdom (n=17) and Austria (n=16). In 2016, the United Kingdom also reported most *S. Agona* isolates in turkeys (n=18) [4].

From 2004 to 2015, 4 144 units were reported positive for *S. Agona* in different animal species. *S. Agona* was mainly isolated in chickens (*Gallus gallus*) (n=3 236) followed by cattle (n=322), pigs (n=271), sheep (n=183), and turkeys (n=61). It is noteworthy that reporting of *S. Agona* in fowl (*Gallus gallus*) and non-poultry populations

is not mandatory. Therefore, reporting countries can decide not to report on *S. Agona* in animal species and this may lead to a reporting bias.

In 2016, 29 units positive for *S. Agona* were reported from feed, of which 69% were related to isolates in 'feed material of oil seed or fruit origin' (n=10) and 'compound feeding stuffs for poultry' (n=10). In 2016, positive results were reported by six Member States: the Netherlands (n=8), the United Kingdom (n=6), Romania (n=5), Germany (n=5), Italy (n=2), Sweden (n=1)) and one non-Member State (Norway (n=2) [4].

From 2004 to 2015, 608 units were reported positive for *S. Agona* in different feed categories. *S. Agona* was mainly isolated from feed material of oil seed or fruit origin (n= 243), followed by feed material of land animal origin (n=64) and compound feed, not further specified (n=64). A substantial number of *S. Agona* isolates were also detected in feed of marine animal origin (n=43), pet food (n=30) and compound feed for poultry (n=28). Information on the *S. Agona* isolations reported in food, animals and feed between 2004 and 2016 are summarised in the Annex, Table 1.

Event background information

On 6 December 2017, France reported through EPIS-FWD an urgent inquiry related to an outbreak of *S. Agona* in infants (children <1 year of age) linked to consumption of infant formula based on epidemiological investigation. Different brands of infant formulas from the same producer in France, distributed to different countries inside and outside the EU were implicated as the vehicle of infection in this outbreak.

Two previous *S. Agona* outbreaks in France during the period 2004–2005 were associated with consumption of infant formula manufactured by the same producer of the infant formula linked to the current outbreak [5].

Epidemiological and microbiological investigation of human cases

As of 11 January 2018, France had reported 37 cases of *S. Agona* in infants associated with this outbreak [6]. One of these cases was retrospectively identified, with date of onset in late April 2017. For all other cases, onset of symptoms ranged from 14 August to 2 December 2017. Cases were reported in ten different French regions. Among the 36 infants whose parents have been interviewed, 18 were hospitalised and all have fully recovered. Information on food exposure is available for 36 infants: all but one (for whom exclusive breast-feeding was reported) had consumed one of the implicated infant formulas.

France performed WGS on 88 human isolates of *S. Agona* among the 94 isolated since the beginning of 2017 and two strains from Spain. All the isolates presented the MLST ST13 profile associated with the Agona serovar based on the 7-MLST scheme. The phylogenetic analysis of the 88 genomes of *S. Agona* isolates sequenced between 1 January and 12 December 2017 indicated 9 519 single nucleotide polymorphisms (SNP) in total by alignment with the *Salmonella* Agona SL483 reference genome (Genbank accession no. NC_011149) and revealed a cluster of 37 isolates (36 in France and one in Spain), with a maximum distance of 26 SNPs that included all the isolates linked to the infant formula consumption. Raw reads of a representative strain are available under the EBI-ENA number ERR2219379 and under Enterobase Name 'SAL_NA11229AA'. This strain had cluster type 704, based on the Enterobase scheme implemented on Seqsphere.

A multi-country WGS analysis, including sequences of human isolates from France and other EU countries, is being performed by the Institut Pasteur in Paris.

Fifteen EU countries replied to the French urgent inquiry in EPIS FWD. Some of these reported *S. Agona* in 2017 in infants or young children: Belgium (n=4), Germany (n=2), Greece (n=1), Norway (n=1), Spain (n=2) and Sweden (n=1). For the United Kingdom, Health Protection Scotland reported one infant affected, with WGS of the isolate still pending. Meanwhile Public Health England (PHE) reported a small increase in the number of *S. Agona* reports in children up to one year during 2017. However, the nearest isolate in the PHE database is 39 SNPs away from the sequence provided by France.

Austria, Denmark, Finland, Ireland, Luxembourg, the Netherlands and Slovenia reported no *S. Agona* cases in infants without a travel history outside of the EU/EEA.

On 13 December 2017, France reported that the outbreak strain displayed atypical biochemical characteristics and, contrary to the majority of *Salmonella* populations, this strain did not produce H₂S and gas after 18 hours incubation on Kligler-Hajna media. This particular biochemical trait was found in 39 investigated isolates: 37 in France, one in Spain and one in Greece. These isolates include all the 37 isolates clustering by WGS reported by France (36 from French cases and one Spanish case). The date of symptom onset for the cases in Greece and Spain was October 2017. Results of WGS testing are not available for two isolates that present the biochemical trait, one in France and one in Greece. Information on biochemical characteristics is not available for the isolate from the infant in Scotland. None of the isolates reported by Belgium, Germany, Norway and Sweden presented the biochemical trait.

Microbiological and environmental investigations of food

This section summarises country-specific information on food and environmental investigations associated with this outbreak that has been reported through RASFF (alert notification 2017.2095); EPIS FWD (UI- 450); press releases issued by the countries involved; alerts issued by INFOSAN and/or information reported directly to EFSA by national competent authorities between 4 December 2017 and 15 January 2018 (see Figure 1 below for details on traceability and testing.) The alert notification 2017.2198 was not included in the assessment, as it was not considered relevant. In fact, this notification related to a country which, according to the information available, has neither reported human cases linked to the outbreak nor received suspected batches.

France

After receiving the first notification on 2 December 2017 of an unusual number of *S. Agona* cases in France, the French authorities carried out investigations at the implicated factory [7]. The French authorities notified the RASFF on 4 December 2017 (RASFF alert notification 2017.2095), after confirming that some of the affected products were exported to other countries.

On 6 December 2017, France launched the EPIS Urgent Inquiry UI-450. For 35 *S. Agona* infection cases, the consumption of one of the potentially contaminated infant formulas was reported.

For all the cases mentioned, the investigations highlighted the consumption of brand A, brand B, brand C, brand D or brand E infant formula. These brands are manufactured by the group company A in France at the same facility (processing company A) and dried in the same tower.

As of 2 December 2017, the processing company A voluntarily withdrew and recalled 12 batches of three of the implicated infant formulas that had been sold from the beginning of July, representing 200 000 units. These batches had not yet expired at the time of the withdrawal and recall.

Following the reporting of new cases related to consumption of products from the processing company A during the week 4–10 December 2017, the French competent authorities carried out investigations at the processing company. Suspension of marketing and an export ban were implemented. On 10 December 2017, a compulsory withdrawal and recall was launched in relation to products manufactured at the processing company A in the same drying tower since 15 February 2017. This measure concerned 620 batches. At the time of the withdrawal, 616 of these batches had not yet passed their expiry date, three had already expired and one was close to its expiry date.

As stated in follow-up No. 7 of RASFF 2017.2095, eight other batches omitted from the recall list on 10 December 2017 were withdrawn and recalled by the processing company A in Spain and other third countries on 13 December 2017. All of these batches had expiry dates in 2019.

On 21 December 2017, the French General Directorate for Competition Policy, Consumer Affairs and Fraud Control issued a press release with information on the withdrawal and recall of an additional 720 batches by the processing company A. The withdrawal and recall was carried out on 22 December 2017 by the company as a precautionary measure, and concerned all products manufactured or processed in the facility since 15 February 2017, including products other than infant formula.

It has been reported that these recalled products had been distributed to 13 EU countries (Belgium, Bulgaria, Cyprus, the Czech Republic, France, Greece, Ireland, the Netherlands, Romania, Slovenia, Slovakia, Spain and the United Kingdom) and 54 third countries. The products distributed to countries may have been held up before distribution on the market. Investigations into the distribution of these products are still ongoing. The involvement of 83 countries in total, as announced in certain press reports, has not been confirmed as of today.

Following the recall of the products involved in the investigation, the French Paediatric Society has given recommendations on replacements for the recalled infant formulas [7].

No positive results for *Salmonella* have been detected in the incriminated products. So far, presence of *Cronobacter* spp. have been reported in the final product distributed to the Netherlands, as reported in follow-up No. 20 of RASFF 2017.2095.

The processing company, in collaboration with the French competent authorities, is carrying out an investigation at the production site to identify the origin of the contamination. In addition, the French competent authorities are verifying that the measures taken by processing company A in response to this event have been sufficient and appropriate.

Third countries, where the recalled products had been distributed, have been notified by RASFF through established channels. In addition, an alert was published on the International Food Safety Authorities Network (INFOSAN) Community Website and all INFOSAN Members were notified. The same information was also posted on the Event Information Site for the International Health Regulations (IHR) National Focal Points (NFPs). The INFOSAN Secretariat at the World Health Organization (WHO) contacted each INFOSAN Emergency Contact Point

(ECP) from affected third countries to provide distribution details and enquire about risk management measures and cases of illness linked to recalled products, as well as to offer technical support, if required.

Greece

The investigation carried out in Greece established that the infant involved had consumed infant formula brand F, produced by the implicated French processing company A.

Following the information on the distribution to Greece, shared in follow-up No. 4 of RASFF 2017.2095 on 11 December 2017, on the same date the Greek competent authority issued a press release [8]. In addition, on 14 December 2017, the Greek competent authority issued a decision to withdraw and recall the products concerned (46 batches), as reported in follow-up No. 18 of RASFF 2017.2095. On 21 December 2017, a Greek company that distributes the recalled products informed the competent authority of the precautionary recall of five additional batches, two of them concerning Brand F. The Greek competent authority then issued a new decision for the additional withdrawal and recall. None of these batches had expired.

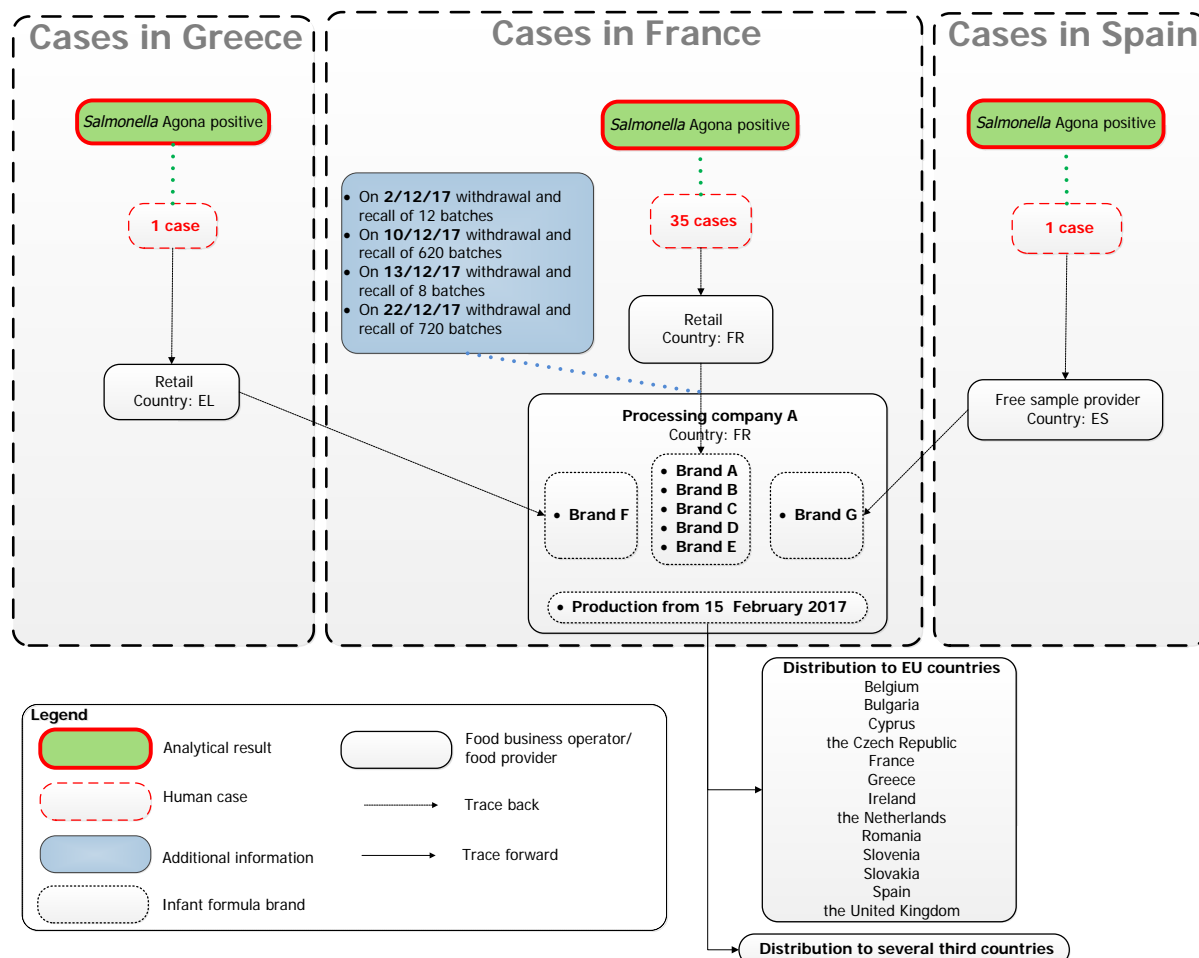
Spain

The investigation related to the infant case identified in Spain revealed the consumption of the infant formula Brand G, produced by the processing company A. This food was given as a free sample to the mother of the child. The food was consumed completely and the package was thrown away. Therefore, there was no food available for analysis and the batch number of the product was unknown.

On 11 December 2017, a public warning was issued by the Consumer Affairs and Food Security Spanish Agency (AECOSAN) concerning the list of batches implicated in the recall and making recommendations to consumers to avoid consumption of these products if they had them at home [9].

The Spanish competent authority is verifying the withdrawal of recalled batches from the market, as reported by Spain on 12 December 2017 in follow-up No. 6 of RASFF notification 2017.2095.

Figure 1. Graphical representation of traceability and testing information available in RASFF or provided by Member States to EFSA, as of 15 January 2018



ECDC and EFSA threat assessment for the EU

Following investigations at the processing company, all products manufactured since 15 February 2017, including products other than infant formula, have been recalled and/or withdrawn, as a precautionary measure. The processing company, in collaboration with the French competent authorities, is carrying out investigations at the production site to identify the origin of the contamination. In addition, the French competent authorities are verifying that the measures taken by the processing company in response to this event have been sufficient and appropriate.

The recalled products have been distributed to 13 EU countries (Belgium, Bulgaria, Cyprus, the Czech Republic, France, Greece, Ireland, the Netherlands, Romania, Slovenia, Slovakia, Spain and the United Kingdom) and fifty-four non-EU countries. Product tracing investigations are still ongoing.

Most of the batches involved in the investigation have not yet passed their expiry date. However, broad withdrawal and/or recall measures, export bans and a suspension of market distribution of these batches, implemented since the beginning of December 2017 by the French competent authority and processing company A, are likely to significantly reduce the risk of human infection. Nevertheless, new cases may be detected. Withdrawal, recall, and/or destruction of these batches has also been undertaken by some EU and third countries concerned.

In addition, following the recall of the products involved in the investigation, the French Paediatric Society has given recommendations on replacements for the recalled infant formulas [7].

The same manufacturer was linked to two consecutive *S. Agona* outbreaks in 2005. However, unlike the 2017 outbreak strains, the isolates from the 2005 outbreak did produce H₂S and gas after 18 hours of incubation. WGS of the 2005 outbreak isolates is being performed in France. WGS analysis may confirm the relatedness of the three outbreaks and possibly help to identify weaknesses in the production process.

Infants and very young children are most at risk of infection and/or developing severe disease, which may require hospitalisation. Infant formula handlers (parents, relatives and children's caregivers) may also be at risk of infection, albeit with a lower risk of developing a severe disease, unless they are immunocompromised.

References

1. World Health Organization in collaboration with Food and Agriculture Organization of the United Nations. Safe preparation, storage and handling of powdered infant formula: guidelines. Geneva: WHO; 2007. Available from: <http://www.who.int/foodsafety/publications/powdered-infant-formula/en/>
2. Santé publique France. Épidémie de Salmonellose à *Salmonella enterica* sérotype Agona chez des nourrissons en France – Point au 9 janvier 2018 2017. Available from: <http://www.santepubliquefrance.fr/Actualites/Epidemie-de-Salmonellose-a-Salmonella-enterica-serotype-Agona-chez-des-nourrissons-en-France-Point-au-9-janvier-2018>.
3. European Centre for Disease Prevention and Control. The European Surveillance System (TESSy) [Database]. Stockholm: ECDC, 2016.
4. EFSA (European Food Safety Authority) and ECDC (European Centre for Disease Prevention and Control). The European Union summary report on trends and sources of zoonoses, zoonotic agents, and food-borne outbreaks in 2016. EFSA journal. 2017;15(12):228.
5. Brouard C, Espie E, Weill FX, Kerouanton A, Brisabois A, Forgue AM, et al. Two consecutive large outbreaks of *Salmonella enterica* serotype Agona infections in infants linked to the consumption of powdered infant formula. The Pediatric infectious disease journal. 2007 Feb;26(2):148-52.
6. Jourdan-da Silva N, Fabre L, Robinson E, Fournet N, Nisavanh A, Bruyand M, et al. Ongoing nationwide outbreak of *Salmonella* Agona associated with internationally distributed infant milk products, France, December 2017. Eurosurveillance. 2018;23(2):17-00852.
7. Direction générale de la santé France. Contamination à *Salmonella* Agona de jeunes enfants: extension des mesures de retrait-rappel de produits de nutrition infantile 2017. Available from: https://www.economie.gouv.fr/files/files/directions_services/dgccrf/presse/communiqu2017/251-CP-produits-de-nutrition-extension.pdf.
8. National Organization for Medicines G. Press releases of other products (food supplements, biocides, baby food). Infant milk produced by LACTALIS 2017. Available from: https://www.eof.gr/web/guest/pressother?p_p_id=62_INSTANCE_r5qY&p_p_lifecycle=0&p_p_state=maximize&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=2&_62_INSTANCE_r5qY_struts_action=%2Fjournal%2Farticles%2Fview&_62_INSTANCE_r5qY_groupId=12225&_62_INSTANCE_r5qY_articleId=2571534&_62_INSTANCE_r5qY_version=1.0.
9. Agencia Española de Consumo Seguridad Alimentaria y Nutrición (AECOSAN). Retirada de fórmulas infantiles fabricadas en Francia 2017. Available from: http://www.aecosan.msssi.gob.es/AECOSAN/web/seguridad_alimentaria/ampliacion/lactalis_francia_alerta.htm.

Annex

Table 1. Reported isolations of *Salmonella* Agona from food, animals and feed in EU Member States and other reporting countries, 2004–2016

Source	No. of positive units, 2004-2010	Np. of positive units, 2011	No. of positive units, 2012	No. of positive units, 2013	No. of positive units, 2014	No. of positive units, 2015	No. of positive units, 2016	Total positive units, 2004-2016
Food								
Meat from pig	401	89	5	6	4	7	1	513
Meat from broilers (<i>Gallus gallus</i>)	300	26	29	11	17	39	6	428
Meat from bovine animals and pig	105							105
Meat from other animal species or unspecified ^a	67	60	2	3	3	5	2	142
Meat from bovine animals	49	11					3	63
Meat from poultry, unspecified	2		5			5	11	23
Meat from turkey	19			3	1			23
Meat from other poultry species	11							11
Meat from sheep	1	2						3
Eggs	5		1					6
Egg products	1							1
Dairy products (including cheeses) ^b	3						1	4
Fish and fishery products ^c			1			1		2
Fruits and vegetables ^d	1			1				2
Other food ^e	4	1		2		3	1	11
Total isolations in food	969	189	43	26	25	60	25	1 337
Animals								
<i>Gallus</i> (fowl)	942	782	109	1,271	56	76	209	3,445
Cattle (bovine animals)	17	1	1	274	23	6	1	323
Pigs	212	2	21	12	4	20	2	273
Sheep	168		15					183
Turkeys	18	18	4	9	5	7	25	86
Dogs	4		4	1		1	1	11
Goats	3		2	3				8
Other poultry or unspecified ^f	25	2	4			3	4	38
Other animals ^g	2		15	2				19
Total isolations in animals	1 391	805	175	1 572	88	113	242	4 386
Feed								
Feed material of oil seed or fruit origin	160	29	21	12	14	7	10	253
Feed material of land animal origin	32	12			1	19	3	67
Compound feeding-stuffs, not specified	19	31		4	10		2	66
Compound feeding-stuffs for fish	3	1	14	3	1	1		23
Compound feeding-stuffs for fur animal	12		1					13
Compound feeding-stuffs for pigs	22		3		1			26
Compound feeding-stuffs for poultry	24		1	1		2	10	38
Compound feeding-stuffs for cattle	4					1		5
Feed material of cereal grain origin	11				2	3	2	18
Feed material of marine animal origin	18	2		23				43
Other feed ^h	34	6	2	3	1	2	2	50
Pet food	22	3			1	4		30
Complementary feeding-stuffs		3	2					5
Total isolations in feed	361	87	44	46	31	39	29	637

- a: 'Meat from other animal species or not specified' includes 'Meat from duck', 'Meat from other animal species or not specified', 'Meat from wild game - land mammals', 'Meat, mixed meat', 'Meat, red meat (meat from bovines, pigs, goats, sheep, horses, donkeys, bison and water buffalos)', 'Meat from spent hens (*Gallus gallus*)'.
- b: 'Dairy products (including cheeses)' includes 'Dairy products (excluding cheeses)', 'Cheeses made from cows' milk', 'Cheeses, made from unspecified milk or other animal milk'.
- c: 'Fish and fishery products' includes 'Fish' and 'Live bivalve molluscs'.
- d: 'Fruits and vegetables' includes 'Fruits' and 'Fruits and vegetables'.
- e: 'Other food' includes 'Other processed food products and prepared dishes', 'Ready-to-eat salads', 'Seeds, dried', 'Spices and herbs', 'Cocoa and cocoa preparations, coffee and tea', 'Coconut'.
- f: 'Other poultry or unspecified' includes birds, ducks and geese, guinea fowl, other poultry, pheasants, quails, other poultry and poultry unspecified.
- g: 'Other animals' include foxes, guinea pigs, minks, rabbits, turtles and water buffalos.
- h: 'Other feed' includes other feed material and all feeding-stuffs.