JOINT ECDC–EFSA RAPID OUTBREAK ASSESSMENT

Multi-country outbreak of *Salmonella* Agona infections possibly linked to ready-to-eat food

26 July 2018

Conclusions

A multi-country outbreak of *Salmonella enterica* subspecies *enterica* serovar Agona (*S.* Agona) is under investigation in the European Union (EU), with cases retrospectively identified back to 2014. Overall, 147 outbreak cases have been reported by five EU countries: 122 cases since 1 January 2017, and 25 historical cases between 2014 and 2016. The United Kingdom is reporting most outbreak cases (129), with Finland (15), Denmark, Germany and Ireland (one case each) reporting the other cases. The Irish case was probably infected while visiting the United Kingdom.

The outbreak was first detected in the United Kingdom using whole genome sequencing (WGS). All *S.* Agona isolates from the five countries are genetically close with a maximum difference of 2 alleles from any other single isolate by core genome multilocus sequence typing scheme (cgMLST) using the ECDC Enterobase pipeline. The cases peaked in April 2017 and 2018. The close genomic relationship and the distinct seasonal spring peaks suggest that cases are part of an intermittent common source outbreak.

Seventeen *S.* Agona food isolates from 2018, detected in the United Kingdom, were found to be closely genetically related to the human strains. The food isolates were from cucumbers sampled during processing before and after washing (11 isolates) and ready to eat (RTE) food products containing cucumbers (six isolates). The contaminated food isolates were sampled in the United Kingdom at four plants owned by Company A and a Company C plant.

At present, there is insufficient epidemiological information available on the consumption of contaminated products by humans to support the microbiological evidence provided by the isolation of the outbreak strain in food. The epidemiological investigations in the other affected countries did not generate any strong hypothesis about the vehicle or source of infection.

Although the cucumbers used in all final contaminated products originated from Spain for a limited period (from November 2017 to April 2018), no connection between supply chains was identified: primary producers of cucumbers were different (producers A and B), and cucumbers were delivered to different processing companies through different distributors in the United Kingdom. The laboratory results for *Salmonella* in all cucumber samples, taken either at primary production level in Spain or during distribution to/within UK, were negative.

Based on the information available, the microbiological evidence suggests RTE products containing cucumbers as a possible vehicle of infection but so far it has not been possible to identify the specific point in the production chain where the contamination occurred.

Further investigations along the food chain are needed to identify the source of contamination. These should include collection of information about various production and processing stages for the RTE products implicated in this event, as well as thorough sampling and testing.

Suggested citation: European Centre for Disease Prevention and Control/European Food Safety Authority. Multi-country outbreak of *Salmonella* Agona possibly linked to ready-to-eat food – 26 July 2018. Stockholm and Parma: ECDC/EFSA; 2018.

Until the source of infection and the specific point of contamination along the food production chain have been identified and controlled, new outbreak cases may occur, with a high likelihood that the outbreak strains will re-emerge in early 2019, as happened in previous years.

Options for response

Competent authorities are encouraged to report new human cases associated with this event and the findings of public health investigations to the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD) and consider interviewing new and recent *S.* Agona cases about consumption of RTE products, including their ingredients.

ECDC is supporting WGS analysis of human *S.* Agona isolates from cases possibly related to this outbreak and reported in countries that are not routinely performing WGS. Since the European case definition of this outbreak is based also on the ECDC cgMLST pipeline, ECDC suggests that countries with sequenced isolates could share with ECDC *S.* Agona sequences differing by a maximum of 15 alleles from the representative outbreak strains to confirm or exclude the isolates as part of the outbreak.

The European Union Reference Laboratory for *Salmonella* (EURL-*Salmonella*) is providing support to those Member States who do not have WGS capacity by performing WGS analysis of non-human isolates for strains possibly related to this outbreak.

Competent authorities of public health and food safety sectors in the affected EU countries should share information at the European level on the 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

The European Commission asked EFSA to produce this Rapid Outbreak Assessment on 19 June 2018 and the request was accepted by EFSA on 25 June 2018. The European Commission asked ECDC to produce this Rapid Outbreak Assessment on 3 July 2018 and ECDC accepted the request on the same day.

Public health issue

This document provides an assessment of the potential cross-border public health risk related to *S.* Agona infections possibly linked to consumption of contaminated ready-to-eat food.

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

[2] 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. 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.

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 our knowledge on 19 July 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 isolation in humans

S. Agona is the tenth most commonly reported *Salmonella* serotype in the European Surveillance System (TESSy). During the period 2012–2016, *S.* Agona was reported by 26 EU/EEA countries with an annual case number ranging from 378 to 582. The United Kingdom, Germany and France accounted for the highest proportions of confirmed cases (30%, 16%, and 14%, respectively). Cases were most frequently reported among adults in the age group 25–44 years (23%), and children under 5 years (22%). Cases were more common in females (61%) than males among those over 65 years. Travel information was available for 68% of the cases and, of these, 65% were reported as domestic infections.

S. Agona isolates most often belong to sequence type (ST) 13 (MLST based on 7 loci), but several different nodes can be distinguished after cgMLST analysis (MLST based on > 2500 loci) which makes cluster analysis/outbreak investigation feasible (personal communication with the EURL-*Salmonella).*

Foodborne outbreaks caused by *Salmonella* Agona

This section summarises country-specific data on foodborne outbreaks associated with *S.* Agona reported by the Member States during the period 2007–2016 in accordance with the Zoonoses Directive 2003/99/EC and published annually in the European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks [1].

During the period 2007–2016 in the EU, *S.* Agona accounted for 13 outbreaks responsible for 636 human cases and 12 hospitalisations. No deaths were reported. For nine of these outbreaks, the evidence supporting the implication of the food vehicle was reported to be strong (see Table 1 in the annex). These strong-evidence outbreaks were attributed to 'broiler meat (*Gallus gallus*) and products thereof' (two outbreaks in 2013), 'other or mixed red meat and products thereof' (one outbreak in 2014), 'pig meat and products thereof', buffet meals (one outbreak each in 2012), 'other, mixed or unspecified poultry meat and products thereof' (one outbreak in 2008), and mixed food and bakery products (one outbreak each in 2007).

In 2016, no strong evidence outbreaks due to *S.* Agona were reported. Only one weak-evidence outbreak due to *S.* Agona was reported by the United Kingdom. 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 [1].

Information on the *S.* Agona foodborne outbreaks are summarised in Table 1 (annex).

Salmonella Agona isolation in food, animals and feed

This section summarises country-specific data on the occurrence of *S.* Agona in food, animals and feed reported by the Member States during the period 2004–2016 in accordance with the Zoonoses Directive 2003/99/EC and published annually in the European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks [1].

In 2016, 25 units positive for *S.* Agona were reported as having been isolated from food, the majority of which (68.0%) were reported in meat from poultry and broilers by four Member States and one non-Member State. Additional isolations were reported in meat from bovine animals (n=3), meat from unspecified origin (n=2), meat from pigs (n=1), cheeses made from unpasteurised milk (n=1) and dried seeds (n=1) [1].

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'. Only one positive sample from fruit and vegetables was reported in 2007 but no details were provided on the specific food.

In 2016, 242 units positive for *S.* Agona were reported as having been isolated from animals. The majority of these (n=86.4%, 209) came from chicken (*Gallus gallus*), followed by turkey (10.3%, 25), reported by 11 Member States and two non-Member States [1].

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 as having been isolated from feed, 69% of which 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 and one non-Member State [1].

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 Table 2 (annex).

In addition to the data mentioned above, data are also collected in the context of investigating multi-country outbreaks at EU level. *S.* Agona-contaminated samples of infant formula have been reported in the context of the multi-country outbreak of *S.* Agona infections in infants occurring in the EU between August 2017 and January 2018 and during two consecutive *S.* Agona outbreaks in 2005 in France [2-4].

Event background information

On 22 May 2018, the United Kingdom (Public Health England – PHE) reported in EPIS-FWD a cluster of cases of *S.* Agona, with isolates being closely related by whole genome sequencing (WGS)-based analysis. All isolates fell into a five single nucleotide polymorphism (SNP) single linkage microbiological cluster (t5 cluster). The majority of the reported cases had sampling dates in 2017 and 2018, but the earliest case in the cluster was reported in April 2014.

Multi-country investigations

EU/EEA outbreak case definition

Confirmed outbreak case:

- A laboratory-confirmed *S.* Agona case with symptom onset on or after 1 January 2017 (date of sampling or date of receipt by the reference laboratory if date of onset is not available)

AND

- Fulfilling one of the following additional laboratory criteria:
  with a clinical *S.* Agona isolate within 5 allelic differences by cgMLST (Enterobase scheme containing 3002 loci) to any other isolate in the multi-country cluster (representative sequences SRR7110599 and SRR7091930) by ECDC cgMLST pipeline
  AND/OR
  with a clinical *S.* Agona isolate sharing the same t5-level SNP address as defined in the United Kingdom outbreak cluster based on WGS analysis: 1.1.1.29.32.37.%

Historical confirmed outbreak case:

- A laboratory-confirmed *S.* Agona case with symptom onset before 1 January 2017 (date of sampling or date of receipt by the reference laboratory if date of onset is not available)

AND

- Fulfilling one of the following additional laboratory criteria:
  with a clinical *S.* Agona isolate within 5 allelic differences by cgMLST (Enterobase scheme) to any other isolate in the multi-country cluster (representative sequences SRR7110599 and SRR7091930) by ECDC cgMLST pipeline
  AND/OR
  with a *S.* Agona isolate sharing the same t5-level SNP address as defined in the United Kingdom outbreak cluster based on WGS analysis: 1.1.1.29.32.37.%

Exclusion criteria:

- Cases with travel history outside of the EU/ EEA in the seven days prior to onset
- Secondary cases defined as those confirmed cases that have had person-to-person contact with a confirmed case in the seven days prior to onset and no known exposure to a common source.

Epidemiological and microbiological investigations of humans

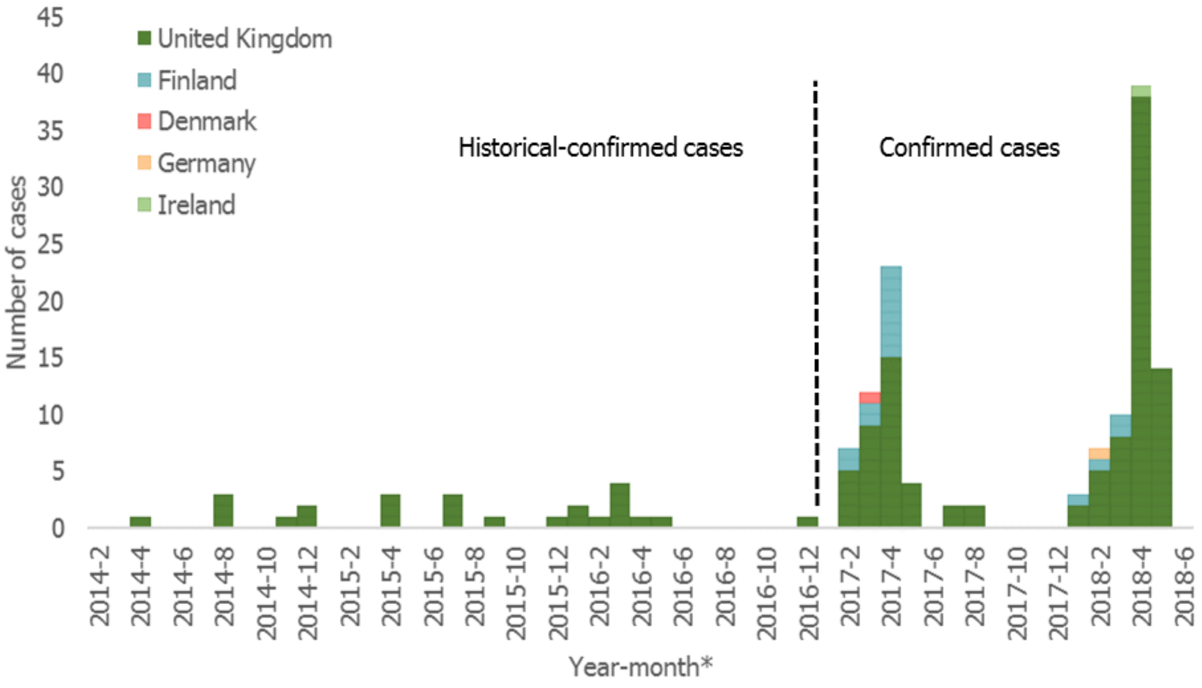
As of 17 July 2018, five EU countries had identified 122 confirmed cases reported on or after 1 January 2017 and 25 historical confirmed cases reported from 2014 to 2016 (Table 1).

Table 1. *Salmonella* Agona outbreak cases by country and case classification, EU 2014–2018 (as of 17 July 2018)

Reporting country	Confirmed cases (reported on or after 1 Jan 2017)	Historical confirmed cases (reported before 1 Jan 2017)	Total number of cases
Denmark	1	0	1
Finland	15	0	15
Germany	1	0	1
Ireland	1	0	1
United Kingdom	104	25	129
Total	**122**	**25**	**147**

Most cases were reported by the United Kingdom (104 confirmed and 25 historical confirmed). The confirmed case reported by Ireland had a travel history to the United Kingdom in the days preceding onset of symptoms. Four additional United Kingdom cases had a travel history before onset: two in Spain and one in continental Europe (the travel destination of the fourth case is unknown). For the 122 confirmed cases the median age is 40 years (interquartile range (IQR): 21-67 years), and 77 (63%) are females. For the 25 historical confirmed cases the median age is 28 years (IQR: 15-52 years), and 15 are females. Twelve patients were reported as asymptomatic. One patient with several underlying illnesses died. Most cases were reported in 2018 and 2017, with pronounced peaks in April (Figure 1).

Figure 1. ***Salmonella* Agona outbreak cases by month and country of reporting, European Union 2014-2018 (n=147; as of 17 July 2018)**



** Month of sampling or month of receipt by the reference laboratory when month of onset not available.*

In EPIS FWD, Italy and Sweden have reported increases in *S.* Agona notifications. Italy reported 20 cases in 2016 and 19 in 2017, compared to five or six cases in the previous years. Sweden reported 17 cases in 2017, which was higher than in previous years. No WGS information is available for the *S.* Agona cases reported in both countries, although a selection of the Italian isolates is currently being sequenced.

Belgium, Germany and Spain reported no increase in *S.* Agona notifications in 2018. Estonia, Greece, Luxembourg, Norway and Slovenia reported no isolates closely related to the outbreak strain or no *S.* Agona notifications in 2018.

Information on patient interviews

Patient interviews carried out in the UK in 2018 have not provided sufficient epidemiological evidence to link infection with the outbreak strain to cucumbers and/or cucumber-containing RTE foods or to generate a firm hypothesis of an alternative vehicle of infection.

The investigations in the other affected countries also did not generate any strong hypothesis about the vehicle(s) or source of infection.

Microbiological and environmental investigations of food

This section summarises country-specific information on food and environmental investigations associated with this outbreak that have been reported through RASFF (notification 2018.1343) and directly to EFSA by national competent authorities (up to 19 July 2018).

It is important to note that only the competent authorities of the United Kingdom and Spain have provided information on microbiological and environmental investigations of food. A total of 17 positive samples were detected in the United Kingdom and none in Spain.

United Kingdom

Overall, 17 non-human isolates matched the multi-country outbreak strain:

- Ten isolates from cucumbers sampled during processing (before and after washing) at company A plant a,
- One isolate from cucumbers sampled during processing before washing at company A plant b,
- Three isolates for RTE food products containing cucumbers (products A, B and C) sampled at company A plant c,
- Two isolates for RTE food products containing cucumbers (products D and E) sampled at company A plant d,
- One isolate from a salad that contained cucumbers sampled at company C.

On 4 May 2018, the United Kingdom Food Standards Agency (FSA) issued an RASFF notification (notification 2018.1343) regarding the detection at company A in the UK of *Salmonella* in ten out of 73 food samples of cucumbers.

This sampling took place on 10 April 2018 at company A plant a during processing (before and after the cucumber washing stage), in the context of the company's own checks (RASFF 2018.1343 fup23). UK company A notified FSA on 16 April and began investigating. The isolates were forwarded to the *Salmonella* Reference Laboratory at PHE and, following analysis of WGS data, were found to match the human outbreak strain at t5 level.

A further sample of cucumbers during processing (unwashed) taken on 11 April at another site of UK Company A, plant b was found positive for *S.* Agona. WGS analysis also confirmed that this isolate matched the human outbreak strain through analysis of WGS data (RASFF 2018.1343 fup23).

Five *Salmonella* isolates had been previously detected at company A in 2018 in five RTE food products containing cucumbers collected between 28 March and 5 April: product A (use by date 31/03), product B (use-by date 31/03), product C (use-by date 02/04) at its plant c, product D (use by date 05/04) and product E (use by date 06/04) at its plant d. These five isolates were confirmed as *S.* Agona and also matched the human outbreak strain through analysis of WGS data (RASFF 2018.1343 fup7).

A United Kingdom Incident Management Team was set up to lead the investigation chaired by PHE with the food investigations led by the FSA. All 10 positive samples of cucumbers taken on 10 April 2018 at company plant a were delivered on 6 April 2018 to company A plant a by the UK distributor A. Distributor A in the UK received them on 6 April from the primary producer A in Spain through vessel A. The positive sample detected at plant b was traced back to the UK distributor A and the primary producer A.

Previous batches of cucumbers from the same distributor A and producer A were used in the five RTE products, though it is unclear if other cucumber sources were also used in two of them. All cucumbers had been used when the results of the five products were made available (RASFF 2018.1343 fup23).

On 16 April, distributor A informed the Spanish primary producer A that cucumbers originating from its premises and sampled at company A had tested positive for *Salmonella.* On 10 April, UK company A took 38 samples of cucumbers from the facility of distributor A. A few days later (on 16 April), distributor A took 15 further cucumber samples at its facility. Some samples came from the batches of cucumbers that had previously tested positive. All samples tested negative for *Salmonella* (RASFF 2018.1343 fup8, fup29). Company A took over 1 000 samples of all their products across all their plants from 31 March for a six-week period. All results were negative for *Salmonella*.

At UK company A, across all of its sites, a specific area is dedicated to the receipt of raw materials. On receipt, all raw materials are checked to determine compliance with company's specifications. Samples for microbiological analysis are taken according to a sampling schedule. After the delivery is accepted, the raw materials are stored in designated areas. Cucumbers are transferred to the wash area. Using a sanitised knife, operators remove the ends before transferring the cucumbers (with ends removed) to a wash tank dosed with sodium hypochlorite or peracetic acid, dependent on the site. Once washed, the cucumbers are unloaded from the tank in an area where they are sliced or diced, as required, before being used to assemble sandwiches or sushi (RASFF 2018.1343 fup11).

The same *S.* Agona strain was found in a salad containing diced cucumbers. It had been sampled by UK company C who was supplied with cucumbers from UK company B on 17 April (RASFF 2018.1343 fup13). UK Company B had ordered them from the Dutch trader A. On this one occasion the cucumbers had been produced by their parent company, the primary producer B in Spain, then distributed by UK distributor B through Distributor C to UK Company B. The commercial operation between distributor B and Company B was performed by Dutch trader A; however the product was always in the UK (RASFF 2018.1343 fup9, fup10, fup16).

The Dutch trader A usually provides cucumbers that are of Dutch origin to UK company B; but on this occasion it provided Spanish cucumbers that were not unloaded in the Netherlands.

Spain

No *S.* Agona contaminated food samples were detected in Spain.

Primary producer A

The cucumbers found contaminated with *S.* Agona at company A in the UK supposedly originated from primary producer A in Spain and corresponded to lots X1, X2, X3 and X4. These were loaded for shipment on 23 March 2018 onto Vessel A and on 29 March 2018 onto Vessel B. Both shipments were delivered on 6 April to distributor A in the UK (RASFF 2018.1343, fup8). Previous batches of cucumbers had been supplied to company A and used in a number of their RTE finished products.

On 16 April the primary producer A learned from distributor A that cucumbers from its premises had tested positive for *Salmonella* at company A. The food crisis plan at primary producer A was activated and the company suspended further distribution of cucumbers. Between 16 April and 2 May, primary producer A took eight samples of cucumbers and one water sample from its premises. Another water sample had been previously taken on 27 October 2017. All samples tested negative for *Salmonella*. At that time, the cucumber harvesting period had finished. Consequently, no additional measures were implemented. An inspection was conducted by company A and distributor A at primary producer A, but it was not possible to conclude that the *Salmonella* contamination occurred at that level for either companies (RASFF 2018.1343, fup8, fup 29).

At the Spanish primary producer A farming is carried out in closed greenhouses, with a controlled environment in order to prevent the access of animals (RASFF 2018.1343, fup28). At the farm, the cucumbers undergo the following steps: selection, plastic wrapping (optional), sizing, packaging, palletisation. The pallets are not reopened until arrival at the final destination in the UK (RASFF 2018.1343, fup29).

The cucumber production of primary producer A is seasonal and takes place between November and April (RASFF 2018.1343, fup8). Cucumbers are distributed to the UK and the Netherlands. The latter country further distributes to Denmark, Finland, France, Germany, Netherlands, Sweden and one third country (Republic of Belarus). Some of the customers who received cucumbers in the Netherlands may have re-exported the cucumbers to the UK (RASFF 2018.1343, fup24).

There is no evidence that cucumbers from this producer have been in contact with products from the primary producer B, since the companies do not share farms or packaging plants (RASFF 2018.1343, fup24).

Primary producer B

Cucumbers found to be contaminated with *S.* Agona at company C in the UK supposedly originated from primary producer B in Spain and were dispatched through distributor B in the UK.

The Spanish primary producer B provided the analytical reports of three cucumber samples, one taken on 27 February and two on 17 April at its premises, all negative for *Salmonella*. The result of a sample taken from distributor B on 21 October 2017 was also negative for *Salmonella* (RASFF 2018.1343, fup29).

At the Spanish primary producer B farming is carried out in closed greenhouses, with a controlled environment in order to prevent the access of animals. When arriving at the packaging centre, the cucumbers are cleaned with cleaning cloths specific for this use, with a strict hygiene check (the cloths are washed at 90°C and rinsed with water and bleach). The primary producer B individually packs the cucumbers in plastic film, which are placed in cardboard boxes and the boxes are then prepared and sealed (RASFF 2018.1343, fup28). These containers are not reopened until arrival at the final destination in the UK (RASFF 2018.1343, fup29).

The entire production of primary producer B is marketed by distributor B in the UK.

The primary producer B and the primary producer A do not have any connection in terms of production (cultivation), packaging, transport or final marketing. The sources of irrigation are also completely independent (RASFF 2018.1343, fup24).

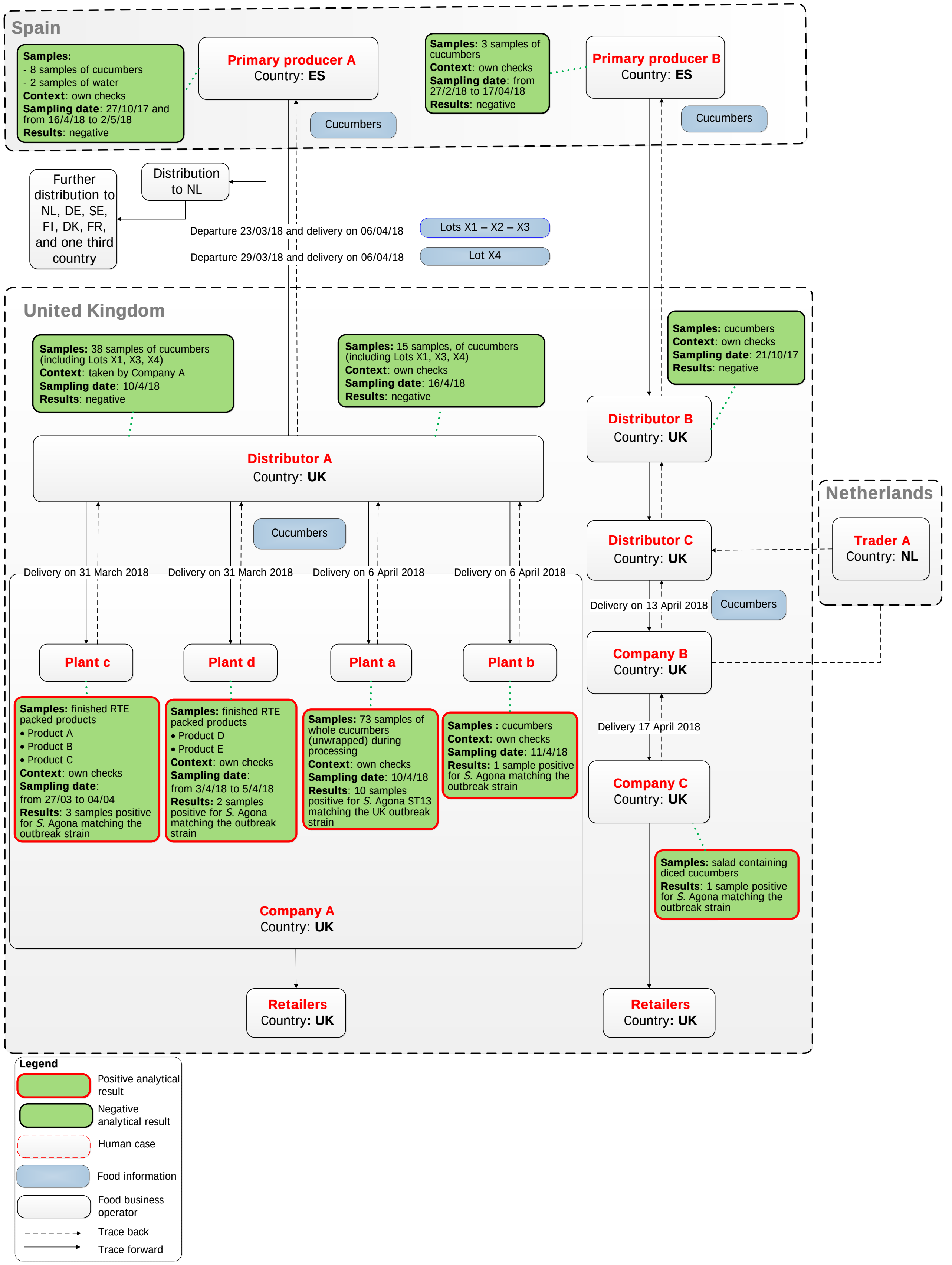
Table 2. Testing results of non-human samples collected in March–April 2018

Sampling Country	Food business operator	Sampling context	Sampling stage	Sampling date	Sample type	Best Before Date	Samples tested	No. positive samples	Test results for *Salmonella*		
									Serotype	MLST	WGS[1]
United Kingdom	Company A, plant a	Own checks	During processing, before washing	10/4/18	Whole cucumber	NA	44	7	Agona	ST13	match
United Kingdom	Company A, plant a	Own checks	During processing, after washing	10/4/18	Whole cucumber	NA	29	3	Agona	ST13	match
United Kingdom	Company A, plant b	Own checks	During processing, before washing	11/4/18	Whole cucumber	NA	1	1	Agona	ST13	match
United Kingdom	Company A, plant c	Own checks	After packing	28/3/18	Product A containing cucumbers	31/3/18	1	1	Agona	ST13	match
United Kingdom	Company A, plant c	Own checks	After packing	3/4/18	Product B containing cucumbers	31/3/18	1	1	Agona	ST13	match
United Kingdom	Company A, plant c	Own checks	After packing	4/4/18	Product C containing cucumbers	2/4/18	1	1	Agona	ST13	match
United Kingdom	Company A, plant d	Own checks	After packing	5/4/18	Product D containing cucumbers	5/4/18	1	1	Agona	ST13	match
United Kingdom	Company A, plant d	Own checks	After packing	3/4/18	Product E containing cucumbers	6/4/18	1	1	Agona	ST13	match
United Kingdom	Distributor A	Own check (by Company A)	Warehouse	10/04/18	Whole cucumber, chilled	NA	38	0	-	-	-
United Kingdom	Distributor A	Own check	Warehouse	16/04/18	Whole cucumber, chilled	NA	15	0	-	-	-
United Kingdom	Company C	Own check			Salad containing cucumbers	NA	1	1	Agona	ST13	match
Spain	Primary producer A	Own check		16/04/18-02/05/18	Whole cucumber, chilled	NA	8	0	-	-	-
Spain	Primary producer A	Own check		27/10/17-27/4/18	Water	NA	2	0	-	-	-
Spain	Primary producer B	Own check		27/2/18-17/4/18	Whole cucumber	NA	3	0	-	-	-

Note: NA= not applicable

[1] WGS match with the multi-country outbreak strain

Figure 2. Graphical representation of traceability and testing information available in RASFF or provided by Member States to EFSA, as of 19 July 2018



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

ECDC cgMLST pipeline: For human isolates, the sequences collected by ECDC 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 any other outbreak isolate were considered as confirmed.

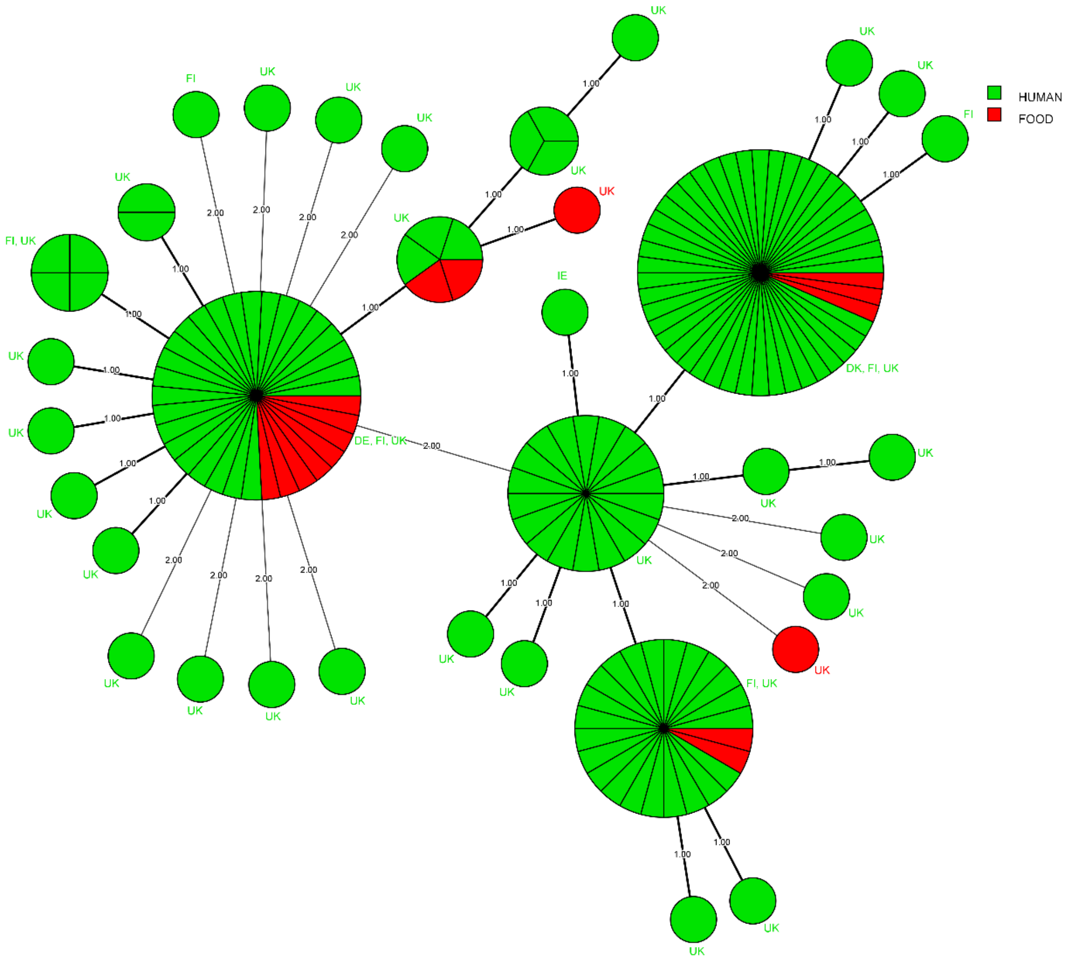
PHE pipeline: in parallel with the ECDC cgMLST pipeline, PHE's in-house SNP-based pipeline and nomenclature for WGS analysis were used for case confirmation, considering isolates falling within five SNPs of any other outbreak isolate as confirmed (SNP address 1.1.1.29.32.37.%) [5-7].

WGS analysis concluded that 147 human isolates were part of this outbreak, forming a tight cluster within two allelic differences of at least one other outbreak cluster isolate (Figure 1). Of these, 104 isolates reported in 2017 and 2018 in the United Kingdom were analysed using the PHE and ECDC pipelines; 18 human isolates reported in 2017 and 2018 in Finland (15), Denmark (1), Germany (1) and Ireland (1) were analysed using the ECDC cgMLST pipeline; 25 human isolates reported in the United Kingdom before 2017 were analysed using the PHE pipeline.

Using the ECDC cgMLST pipeline, two additional isolates, one from Denmark and one from Finland, were excluded because of too low proportion of core loci detected.

WGS analysis also confirmed that 17 non-human isolates reported in 2018 in the United Kingdom were part of the same tight cluster within two allelic differences of at least one other outbreak cluster isolate. The non-human isolates were analysed using the PHE and ECDC pipelines using the same criteria as for human isolates.

Figure 3. cgMLST-based (Enterobase scheme) minimum spanning tree including sequences from 145 human and 17 non-human *S.* Agona isolates (two sequences from UK human isolates are missing) from five countries, EU/EEA 2014–2018



Software: BioNumerics version 7.6.3

A representation of human (11) and non-human (4) isolates detected in the United Kingdom were phenotypically fully sensitive to all antimicrobials tested, consistent with the fully sensitive genotypic antimicrobial sensitivity profile of all tested outbreak isolates.

The strains associated with this event and the representative outbreak strain from the *S.* Agona outbreak in infants associated with consumption of infant formula investigated at the end of 2017 have a difference of at least 29 cg-alleles [3]. Therefore, the two events are considered distinct.

ECDC and EFSA threat assessment for the EU/EEA

A multi-country *S.* Agona outbreak is under investigation in the EU, with cases retrospectively identified back to 2014 and pronounced peaks of cases reported in April in 2017 and 2018. As of 17 July 2018, 147 cases had been identified in five EU countries: Denmark, Finland, Germany, Ireland and the United Kingdom. Close genetic relatedness of human isolates is suggestive of a common source of infection. The distribution of confirmed cases over different years suggests an intermittent common source outbreak. The detection of confirmed cases without a travel history in different EU countries indicates that the vehicle of infection is possibly distributed to different EU countries. The seasonal peak in notifications in April indicates that it is possible that the vehicle of infection is distributed mostly in these months.

Seventeen food isolates matching the outbreak strain by SNP analysis were detected in the UK. The contaminated foods, sampled in the UK in four plants of the same company A and in company C were cucumbers collected during processing, before and after washing (11 samples) and RTE food products containing cucumbers (six samples).

At present, there is no sufficient epidemiological information available on the consumption of contaminated products by human cases to support the microbiological evidence provided by the isolation of the outbreak strain from cucumbers sampled during processing and RTE products containing cucumbers. The investigations in the other affected countries did not generate any strong hypothesis about the vehicle or source of infection.

Although the cucumbers used in all final contaminated products originated from Spain for a limited period (from November 2017 to April 2018), no connection between supply chains was identified: primary producers of cucumbers were different (producers A and B), and cucumbers were delivered to different processing companies through different distributors in the United Kingdom. The laboratory results for *Salmonella* in all cucumber samples, taken either at primary production level in Spain or during distribution to/within UK, were negative.

Based on the information available, the microbiological evidence suggests RTE products containing cucumbers as a possible vehicle of infection but it is not possible to identify the specific point in the production chain where the contamination took place.

The food chain of the RTE products implicated in this event includes several stages. More information about the various production and processing stages and related data from test results will help strengthen the assessment of the point and source of contamination.

Further investigations along the food chain are needed to identify the source of contamination, including thorough sampling and testing.

Until the source of infection and the specific point of contamination along the food chain have been identified and controlled, new outbreak cases may occur in the EU, with a higher likelihood of a re-emergence in the early months of 2019, as happened in previous years. Based on the demographic characteristics of the outbreak cases so far reported and the usual salmonellosis patterns, it is expected that most patients will have a mild presentation of the infection and that those at higher risk of serious outcomes are infants, the elderly and immune-compromised persons.

Further studies on the risk of *S.* Agona infections associated with the consumption of foods, and vegetables and RTE products in particular, could help clarify some important aspects, such as its ecology and clonality.

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Annexes

Table 1. **Strong-evidence foodborne outbreaks due to *Salmonella* Agona in the EU, 2007–2016**

Year / Food vehicle	No. outbreaks	No. human cases	No. hospitalised	No. deaths
2007				
Bakery products	1	27	1	0
Mixed food	1	13	0	0
2008				
Other, mixed or unspecified poultry meat and products thereof	1	11	3	0
2012				
Buffet meals	1	97	2	0
Pig meat and products thereof	1	14	0	0
2013				
Broiler meat (*Gallus gallus*) and products thereof	2	17	3	0
Other foods	1	413	0	0
2014				
Other or mixed red meat and products thereof	1	7	2	0
Total	**9**	**599**	**11**	**0**

Table 2. 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 (*Gallus gallus*)	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								
Chicken (*Gallus gallus*)	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.*