Report of an International Outbreak Investigation into a Multi–country Outbreak of *Salmonella* Agona, Europe, 2008

February 2011

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Abbreviations

CDSC-NI	Communicable Disease Surveillance Centre, Northern Ireland
CI	Confidence Interval
CIDR	Computerised Infectious Disease Reporting System
Company A	A large producer of ready to eat cooked meats, based in Ireland
CVRL	Central Veterinary Research Laboratory
DAFF	Department of Agriculture, Fisheries and Food, Ireland
ECDC	European Centre for Disease Prevention and Control, Sweden
EHOs	Environmental Health Officers
EWRS	Early Warning Response System of the European Commission
FWD	Food and Waterborne Disease Network
FSA	Food Standards Agency, UK
FSAI	Food Safety Authority of Ireland
HPA CfI	Health Protection Agency, Centre for Infections, UK
HPS	Health Protection Scotland
HPSC	Health Protection Surveillance Centre, Ireland
IOCT	International Outbreak Control Team
mOR	Matched Odds Ratio
NSRL	National Salmonella Reference Laboratory, Ireland
OCT	Outbreak Control Team
OR	Odds Ratio
PFGE	Pulsed Field Gel Electrophoresis
PL1	Production Line 1, a production line in Company A
PT	Phage Type
RASFF	The EU's Rapid Alert System for Food and Feed
RTE Food	Ready to Eat food
S. **Agona**	*Salmonella enterica* serovar Agona
SSRL	Scottish Salmonella Reference Laboratory
UK	United Kingdom

1.0 SUMMARY

In July 2008, the National Salmonella Reference Laboratory in Ireland reported a cluster of six cases of *Salmonella* Agona (*S.* Agona) infection to the Irish Health Protection Surveillance Centre. Further investigation demonstrated these to be part of a large international outbreak of *S.* Agona phage type 39 with a distinctive pulsed field profile (SAGOXB.0066).

An international outbreak investigation was conducted by a team representing a number of statutory agencies from Ireland, the UK and a number of other European countries led by the Health Protection Surveillance Centre in Ireland, with support from the European Centre for Disease Prevention and Control. Communications were facilitated by the European Commission via Early Warning Response System (EWRS) and Rapid Alert System for Food and Feed (RASFF).

The International Outbreak Control Team (IOCT) had established that between the beginning of February and the end of October 2008 when the outbreak was declared over there had been 163 cases identified from 10 countries. Cases ranged from infants to the very elderly. Twenty five cases were hospitalised; two elderly patients died. Most cases were identified in the UK (96 in England, 34 in Scotland, 11 in Wales and two in Northern Ireland), 11 were detected in Ireland and nine cases on mainland Europe.

S. Agona with the distinctive pulsed field profile (SAGOXB.0066) identified in cases was also identified in the production facilities of a company that was a large producer of ready to eat cooked meats in Ireland (Company A) and in food supplied by Company A to food service outlet chains in Ireland, Northern Ireland and Wales. Following hypothesis generation which considered all credible exposures and risk factors, a retrospective case control study confirmed the association of human illness with consumption of food from a number of food service outlet chains supplied by Company A. The analytical study in Ireland showed that eight of 11 cases ate in chains supplied by Company A as compared with four out of 34 controls (the eating habits of controls being representative of the eating habits of general population). This meant that cases were at least eighteen times more likely than controls to have eaten in chains supplied by Company A. In the descriptive study, 56 out of 163 cases were questioned and 29 of those interviewed (or a little over 50% of cases in the descriptive study) had consumed products from chains supplied by Company A). As a result of the epidemiological evidence and detection of *S.* Agona in Company A's ready to eat products, Company A voluntarily withdrew from the market and removed from the food chain, cooked beef, chicken and bacon products. Further to these interventions, the outbreak was successfully controlled.

Subsequent to the declaration of the outbreak being over, members of the IOCT learned that the outbreak strain had been identified in another supplier of raw food product to one of the outlet chains implicated in the outbreak. While it is possible that this source may have accounted for some of the sporadic cases of illness identified during this outbreak, the IOCT was satisfied that product from Company A explained the majority of the cases in this outbreak and this opinion was supported by the successful resolution of the outbreak following implementation of control measures in Company A.

This final report includes the description of the outbreak, the results of the epidemiological, microbiological and environmental methods used to investigate it, and their results, and a discussion on the lessons learnt, and recommendations of the International Outbreak Control Team.

2.0 BACKGROUND

2.1 Declaration of the outbreak

On 15th July 2008, the Irish human National Salmonella Reference Laboratory (NSRL) informed the Health Protection Surveillance Centre (HPSC) of a temporal cluster of six cases of salmonellosis due to *Salmonella enterica* serovar Agona (*S.* Agona) that occurred during the first two weeks of July 2008. *S.* Agona is not a common serovar in humans in Ireland; three cases were reported in 2007, five in 2006 and 10 in 2005. The appearance of this number of *S.* Agona isolates within a short period suggested the possibility of an outbreak.

The same day, HPSC issued a national alert in Ireland. Directors of Public Health and the Food Safety Authority of Ireland (FSAI) were informed of the cluster of cases of *S.* Agona. HPSC and NSRL requested that all *Salmonella* isolates be referred immediately to NSRL for definitive typing and that all cases of *S.* Agona should be interviewed using the HPSC *Salmonella* trawling questionnaire (http://www.hpsc.ie/hpsc/A-Z/Gastroenteric/Salmonellosis/Forms). On 16th July 2008, HPSC declared an Irish outbreak and issued an alert to the Health Protection Agency (HPA), Health Protection Scotland (HPS) and the Communicable Disease Surveillance Centre - Northern Ireland (CDSC-NI) in the United Kingdom (UK).

On 17th July 2008, UK colleagues informed HPSC of a recent increase in reports of human cases of *S.* Agona in the UK. The Scottish Salmonella Reference Laboratory (SSRL, now renamed as Scottish *Salmonella*, *Shigella* & *Clostridium difficile* Reference Laboratory - SSSCDRL) received four isolates between 9th May 2008 and 2nd June 2008, and 15 isolates from cases with dates of onset after 25th June 2008. Usually, Health Protection Scotland (HPS) would report 12 to 15 cases of *S.* Agona per year. In addition, the Health Protection Agency Centre for Infections (HPA CfI) in London reported 32 isolates of *S.* Agona received since 20th February 2008 from England & Wales (n=30) and Northern Ireland (n=2).

In Scotland, PFGE profiling of all human isolates of *Salmonella* is carried out in real time and SSRL had characterised 13 isolates from Scottish cases using Pulsed Field Gel Electrophoresis (PFGE). The isolates had a PFGE profile which was initially uploaded to the PulseNet Europe database on 9th June 2008 (designated SAGOXB.0066 in the PulseNet Europe molecular database). In England, HPA CfI had designated a group of *S.* Agona isolates as a new phage type 39 (PT39) and at that time most of the recent isolates tested (n=11/12) also shared the PFGE profile SAGOXB.0066. The strain was fully susceptible to the standard suite of antimicrobial agents tested. This outbreak strain had not been previously documented in clinical specimens or in food or environmental samples in the UK prior to its appearance in the first half of 2008.

Results on the first Irish PFGE profiles became available on 22nd July 2008. The profile identified in Ireland was indistinguishable from that found in the UK.

An international outbreak was declared on the 18th July 2008 by HPSC. An International Outbreak Control Team (IOCT) led by HPSC with representatives of:

- Health protection services in England, Scotland, Wales, Northern Ireland and Ireland,

- Laboratory Services in England, Scotland, Wales, Northern Ireland and Ireland

- National food safety agencies from Ireland and the UK and

- Ireland's Department of Agriculture, Fisheries and Food

was established to investigate this outbreak. The IOCT agreed to use a standardised *Salmonella* trawling questionnaire for all cases. In addition, an Irish Outbreak Control team coordinated the investigation into the Irish source for the outbreak. The IOCT met by teleconference on 11 occasions beginning on 21st July 2008 until the last meeting on 8th September 2008.

2.2 Prevalence and incidence of *Salmonella* Agona

S. Agona is not a common cause of human illness in Ireland. In 2005, 2006 and 2007 there were ten, five and three sporadic *S.* Agona cases respectively notified to HPSC. In the past *S.* Agona had been identified as being responsible for one outbreak of foodborne illness; in 2005 it caused an outbreak comprising six cases, five of which were hospitalised. The clinical isolate had a distinctive antibiogram (Ampicillin and Streptomycin resistance), and had a single indistinguishable PFGE profile. This PFGE profile was different to that of the 2008 outbreak strain described here. With regard to non-clinical isolates, *S.* Agona, according to the DAFF National Reference Laboratory for Salmonella (NRLS), is the third most frequently isolated serovar from official and food business operators' samples and was isolated in 320 samples in the period 2005-2009. It is associated with pork and poultry production and has been isolated from cooked beef and animal feed.

In the context of this outbreak all human isolates and certain, selected non-human *S.* Agona isolates were typed by PFGE. Isolates with the PFGE profile SAGOXB.0066 had been observed previously in Ireland when it was isolated in 2003 in a milk filter residue from a dairy farm in Cork. In 2005 it was isolated from broiler carcasses from a poultry processing plant in Cork and from a poultry farm supplying the same poultry plant in Cork. In 2005 it was also isolated from a goat milk filter on a farm in Monaghan.

2.3 Initial investigation

On 25th July 2008, DAFF indicated that *Salmonella* isolates with the outbreak PFGE profile had been detected in bacon batches sampled on 10th April 2008[*] and again from an undercooked bacon batch produced on 25th April 2008. The bacon was produced by a food establishment in Ireland, Company A, one of the largest cooked meat operations in the UK and Ireland with international distribution of product. The bacon samples had been examined in private laboratories in April 2008 as part of Company A's own checks, and the *Salmonella* isolates had been submitted to the NSRL for definitive typing.

Company A operated four production lines. The undercooked bacon resulted from a cooker failure on one line, Production Line 1 (PL1), on 25th April, 2008 reported by Company A. The cooker failure was identified, all product was quarantined and sampled, and all production was suspended. Undercooked product had entered the high risk area and passed through a chiller before being diverted for discarding.

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[*] It is now unclear whether this batch was cooked or uncooked.

The high risk area and equipment was subjected to a deep clean and environmental swabs were taken. *Salmonella* was not detected in the post-cook environment and when these results became available production recommenced. None of the undercooked product was placed on the market.

The identification of the distinctive pulsed field profile (SAGOXB.0066) of *S.* Agona, seen in human cases and in Company A's production facility, and the fact that Company A distributed product internationally, raised suspicions that this company may be associated with the outbreak. The initial descriptive epidemiology showed a predominance of young adults among the cases (unlike the normal pattern in *Salmonella* outbreaks where young children and elderly people make up the majority of cases). This trend suggested a potential association with food service outlets chains, and this was confirmed in the history of the initial cases interviewed. It was subsequently established that Company A was a major exporter of food products with a weekly production volume in excess of 800 tonnes of cooked food (principally meat) distributed across Europe and also in Kuwait. It was also a supplier of cooked meat products to a number of food service outlets (sandwich and fast food pizza chains). At an early stage of the investigation, three main retail chains were known to receive product directly from Company A– referred to here as Chain A, Chain B and Chain C. Given the early descriptive and microbiological evidence available, the working hypothesis was that Company A was connected to the outbreak, and that this possible association should form the primary hypotheses for investigation.

As a result of the suspicion that the outbreak may have originated from a source in Ireland, an Irish national OCT tasked with investigating the suspected Irish source of the outbreak, was convened on 29th July to ensure a unified approach to investigation within Ireland. The Irish national OCT brought together HPSC, HSE, NSRL, FSAI and DAFF. This group met subsequently on 30th and 31st July and 6th, 11th, 19th and 26th August 2008.

In Ireland, the epidemiological investigations were led by HPSC and the microbiological investigations were performed at the NSRL and in the UK at the HPA Cfi and the SSRL. FSAI and the Food Standards Agency (FSA) in the UK supervised the investigation into food business operations and the implementation of control measures in their respective countries. DAFF led the regulatory investigations in Company A, while Environmental Health Officers (EHOs) from the HSE in Ireland and Environmental Health Practitioners (EHPs) in the UK did the same in retail and other food chains.

2.4 Objectives of investigation

The objectives of the investigation were to:

1. Protect consumer health

2. Define the extent of the outbreak

3. Determine the most likely source(s) of the outbreak and to identify potential vehicles of transmission in order to take the appropriate action necessary to bring the outbreak under control

4. Make recommendations to assist the food industry in producing safer systems that would benefit everyone.

3.0 METHODS

3.1 Epidemiological investigation

3.1.1 Case definition

The following case definition was agreed by the IOCT on 22nd July.

A. Diagnostic/laboratory criteria

- Confirmed case – *S*. Agona with PFGE SAGOXB.0066 profile
- Probable case – *S*. Agona PT 39 and unknown PFGE profile
- Possible case – *S*. Agona where PT unknown or PFGE profile unknown (In Ireland and the UK only) [†]

B. Time and place

During the process of active case finding, potentially linked cases in England were identified retrospectively to February 2008 by review of existing data and further typing of *S.* Agona isolates in the HPA reference laboratory's archive. To ensure that as many cases as possible were included in the initial assessment, it was agreed that the case definition would include any cases (confirmed, probable or possible) arising since 1st January 2008, in the UK and Ireland (and of confirmed cases only outside the UK and Ireland).

Cases were considered to be secondary if another household member had a diarrhoeal illness in the 24 to 72 hours before the onset of their own illness. Secondary cases were excluded from the descriptive epidemiological and analytical studies.

3.1.2 Case finding

In Ireland and in the UK, case finding was coordinated by the respective national public health institute for each country. In Ireland, Departments of Public Health were requested to ask primary microbiological laboratories to ensure all untyped *Salmonella* isolates were immediately forwarded to the NSRL in order to ensure rapid, definitive identification. As cases were identified, each was interviewed using a standardised *Salmonella* trawling questionnaire, as promptly as possible to minimise the potential for recall bias.

In order to determine if the outbreak extended beyond Ireland and the UK, alert notices were posted through the Food and Waterborne Disease Network (European Centre for Disease Prevention and Control - ECDC) and through the European Union's (EU) Early Warning and Response System (EWRS) on 23rd July 2008. In addition, an alert paper was published in *Eurosurveillance* Weekly on 14th August 2008[‡] to ensure heightened awareness of the outbreak within Europe, to emphasize the need to identify cases of *S*. Agona and to definitively type in order to determine quickly whether they were part of the outbreak.

[†] It was considered impractical to include all cases of *S*. Agona in Europe as possible cases (unless known to have the outbreak PFGE profile).

[‡] O'Flanagan D, Cormican M, McKeown P *et al*. A multi-country outbreak of Salmonella Agona, February - August 2008. *Euro Surveill* 2008 14;13(33).

3.2 Epidemiological studies

Hypothesis Generation: At the IOCT on 31st July 2008, following a review of information from 17 trawling questionnaires, coupled with emerging microbiological evidence of the outbreak strain being found in the environment of Company A's property and in food service outlet chains supplied by Company A, the hypothesis was put forward that multiple food items produced by Company A were propagating the outbreak through a range of food chains. The initial information obtained from the results of the trawling questionnaires indicated that food from take-away chains and eating sandwiches with chicken or pork (ham) were reported by three quarters of cases. With respect to specific food chains, there was no robust evidence indicating any particular chain or retail group.

As there were several food products under investigation, it was concluded that the possibility should be considered that there may be multiple vehicles or pathways of transmission. In addition, as Company A distributed to intermediate distributors, it was difficult to identify the nature of final products in which ingredients supplied by Company A were incorporated and made available to consumers.

Other possible sources were considered at this point in the investigation. However, while the possibility of another source contributing to the outbreak could not be ruled out, no other credible source became apparent during the enquiry.

The IOCT noted that the outbreak strain had been circulating for some time in Ireland (but not reported in the UK). However, it had only been detected in raw material and not in ready to eat foods or cooked products. Despite this, there had been no outbreaks or clusters of human illness identified by HPSC in Ireland prior to 2008 and only a single sporadic human case with the same PFGE profile, was identified in 2005.

The emergence of human illness preceded a reported failure of a cooker in Company A coupled with the appearance of the outbreak strain on the premises of Company A and in products in chains supplied by Company A.

On the 31st July it was agreed to use a questionnaire focusing on the likely exposures in chains selling ready to eat foods, the results of which could be used for either a descriptive or an analytical case control approach.

3.2.1 Descriptive study

In this study, more complete information was gathered on 56 out of 109 of the cases in Ireland and the UK, with a date of onset after June 1st, looking in greater depth at their demographic information and a wide range of potential exposures; food, food chain types, travel history, in an attempt to draw a fuller picture of the possible exposures of the cases. Cases were included from June 1st onwards to reduce the possibility of recall bias (the inability of people to remember what they ate, due to the passage of time). Cases were asked about their shopping habits and included in this were a number of fast food chains in Ireland and separately in the UK, and including, but not limited to, those known at the time to be supplied by Company A. The purpose of this study was to provide evidence as to which were the most likely sources(s) of this infection.

Given that information on distribution pathways was incomplete at this stage, information could only be sought on the chains and franchises operating in Ireland and the UK rather than using targeted exposure information on the final product. Any link with Company A would be made retrospectively once the distribution pathway became available. The IOCT became aware subsequently of further manufacturers (of products such as frozen meals, sandwich fillers, pasta sauces etc) using ingredients supplied by Company A that were not included in the questionnaire, as these were unknown to the IOCT at the time the study was carried out. As a result, the IOCT had no epidemiological evidence that any of these products were involved in the outbreak.

Preliminary information from the trawling questionnaires was used to develop a customised *Salmonella* descriptive questionnaire, which was then administered to those confirmed cases whose date of onset was after 1st June 2008. This date was chosen as a cut-off as cases from before this time might have only a very incomplete memory of where they had purchased food and what foods they had eaten. However, in Ireland, where the number of cases was small, eight cases had previously been interviewed with the initial trawling questionnaire so the decision was made to re-interview them with the new questionnaire. The questionnaire was circulated from the 2nd August 2008[§]. It sought to identify the names of chains and shops used by cases and attempted to identify these outlets' suppliers.

[§] This standard questionnaire collected data on clinical symptoms, disease severity, travel history and food exposures in the three days before symptom onset concentrating on fast/take away food, meat consumption, pizza, sandwiches, pre-packed food, type of chain and place where the food was purchased.

3.2.2 Analytical case control study

A case control study was undertaken in Ireland between 13th and 17th August. A case control study was not undertaken in the UK for a number of reasons: 1) recruitment of case-nominated controls proved not to be feasible; 2) a concomitant national outbreak was being investigated by the HPA which depleted available resources; 3) once the results of the Irish case control study had shown a conclusive association with Company A, in addition to microbiological evidence of the pathogen in food distributed by Company A, it was not felt necessary to complete a full analytical study; and 4) the food distribution network in the UK proved to be more complex.

Case selection: All 11 confirmed cases notified to the Public Health Authorities in Ireland were included.

Control selection: Thirty-four controls were used, chosen between the 13th and 19th of August. Cases and controls were matched on age, sex and area of residence in Ireland. Random digit dialling was used to identify and contact potential controls (although it was decided upon three controls per case, in fact 34 controls in total were enrolled). Controls were questioned about the same three day exposure period (as applied to their equivalent cases) two weeks before the day of the interview.

The exclusion criteria for the controls were:
- People who had diarrhoea or contact with an individual with diarrhoea in June/July/August 2008.
- People living in the same household as someone who had diarrhoea in June/July/August 2008.
- Refusal to participate in the study.
- Inability to answer questions because of a language barrier.
- Travel abroad in the exposure period determined for the control questionnaire.

The hypothesis being tested was that "cases were more likely to have eaten in outlet chains, supplied by Company A, than controls".

A three day food exposure was sought for each control mapped to the respective matched case by day of week during a two week period before the first media release. Controls were interviewed with the same questionnaire that was used for the cases.

Data analysis: Data was entered into Epidata software (http://www.epidata.dk). Data analysis was performed with Stata V9.2 (Stata Corporation, College Station, TX, USA). Chain specific matched odds ratios (mOR) and food items specific mOR and their 95% confidence interval (CI) were calculated using conditional logistic regression.

3.3 Laboratory investigation/Molecular typing

It was requested that any *S.* Agona isolates should undergo rapid PFGE testing for prompt reporting of confirmed outbreak cases. Ireland offered PFGE diagnostics for strains from other countries if necessary. Molecular subtyping of all *S.* Agona isolates (from cases and food samples) was performed using standard methods for PFGE and compared with the Pulsenet Europe database. In Ireland, all confirmatory microbiological analyses were performed at the NSRL based in Galway following preliminary identification in primary laboratories. In the UK, microbiological analyses were performed at the Laboratory of Gastrointestinal Pathogens (LGP) at the HPA CfI in London, and at SSRL in Glasgow. PFGE

testing was performed in accordance with the standard Pulsenet protocol using restriction endonuclease *Xba*I. PFGE profiles were compared using Bionumerics software (Applied Maths, Sint-Martens-Latem, Belgium).

3.4 Environmental investigation

DAFF was responsible for the investigation in Company A. The FSAI co-ordinated the environmental investigation in Ireland, whilst EHOs in Ireland and the UK conducted investigations in the retail and food service sectors. The production plant was inspected and samples were taken from finished products and from environmental surfaces. Samples were tested at the Central Veterinary Reference Laboratory (CVRL) and further definitive typing was undertaken at the NSRL.

One main production line formed the focus of investigation; the line on which food, from where the outbreak strain was retrospectively identified (April and July 2008), was produced. This line is referred to in this report as Production Line 1 (PL1). Workers in the plant were screened for *Salmonella* and food safety management procedures were reviewed. Moreover, a number of chains known to be supplied by Company A, in addition to those already mentioned by cases, were investigated with food and environmental samples taken. EHOs followed up on retail and other chains identified by cases or suspect cases. Many outlets were inspected and investigated both in Ireland and the UK.

Once Company A was informed that there was a significant basis for concern that certain of their products were contributing to the outbreak it closed its entire plant voluntarily and commenced an in-depth investigation to attempt to identify what might have gone wrong.

The entire plant was subjected to a pharmaceutical grade clean. This is a bio-marker validated de-contamination using vaporised hydrogen peroxide technology, more commonly applied in the pharmaceutical, medical device and healthcare sectors. The scope of the de-contamination included the plant environment, equipment, drains and associated staff facilities.

The implicated product identified in Chain A had been produced on the PL 1, as had much of the other products supplied to this chain and the destination of output from this line was identified. The majority of the production of this company was sold to the food service sector or food businesses for further processing.

FSAI notified the European Commission of all withdrawn products exported from Ireland resulting in 19 Alert Notifications to EU Member States issued by the RASFF. Additionally, there were national alerts issued in Ireland by FSAI.

3.5 Incident communication

Media communication during this outbreak in Ireland was managed by the FSAI. Press releases were issued on 4th, 8th and 13th August. Regular responses to press queries were provided by FSAI for media in Ireland and the UK. The outbreak generated more than 30 articles in different newspapers in Ireland and the UK between 1st August and 29th August 2008. In addition FSAI issued seven national food alerts with information for the industry, EHOs, food inspectors and the general public. HPSC provided daily epidemiological situation reports for all members of the international and Irish OCTs.

4.0 RESULTS

Each section of the investigation generated its own set of results.

4.1 Epidemiological results

There were three elements to the epidemiological investigation (Figure 1):

- **Preliminary Active Case Finding**: This resulted in the identification of 163 cases and obtaining detailed high level information about them including age, sex, reporting area, outcome, hospital admission status and a proxy onset date;

- **Descriptive Epidemiological Study**: In this, more complete information (including basic identifiers, where they lived, what they ate and where they ate in the days before the onset of their illness, as well as other simple demographic and exposure information) was gathered on 56 out of 109 of the cases in Ireland and the UK.

Case Control Study: This was an analytical study looking at 11 Irish cases and 34 matched controls to determine whether cases were more likely to have been exposed to product from food outlet chains supplied by Company A. It was carried out in Ireland only.

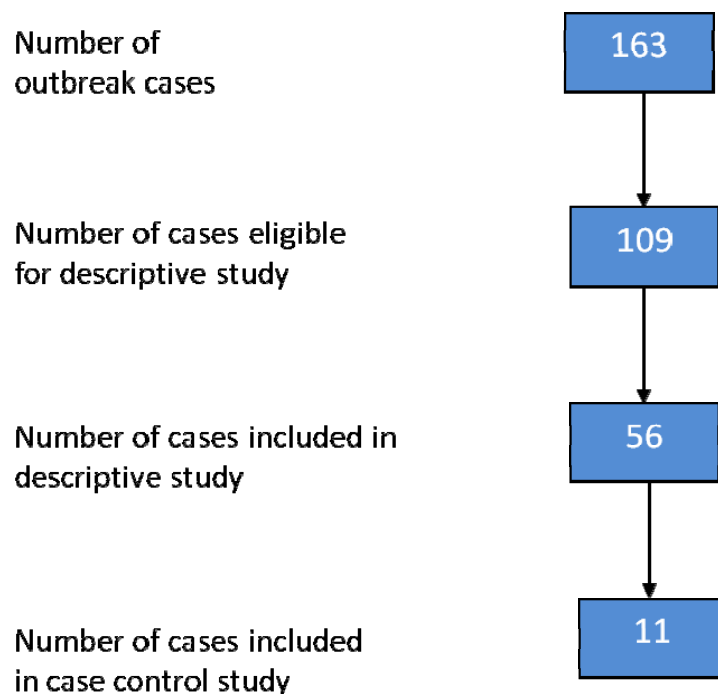|	
Number of outbreak cases	163
Number of cases eligible for descriptive study	109
Number of cases included in descriptive study	56
Number of cases included in case control study	11

Figure 1. Patient Analysis Study of Cases, *S.* Agona Outbreak, Europe, Summer 2008.

4.1.1 Preliminary active case finding

Person and place

A total of 163 confirmed cases (all probable and possible cases were ultimately classified as being confirmed cases when results of PFGE became available) across Europe were reported between February and September 2008. Cases ranged in age from 3 months to 87 years with a median age of 27 years. A three month old infant was a secondary case. Figure 2 shows the age and sex distribution of cases. Fifty seven percent of cases were males (92 cases). Twenty-five cases (15%) were hospitalised. Two elderly patients infected with the outbreak strain of *S.* Agona died. The first, a 77 year old female in the UK contracted *S.* Agona whilst an inpatient; cause of death was reported as ischemic colitis secondary to *Salmonella* infection. A second death occurred in a 78 year old male in the UK. Neither of these two cases were identified as being linked to the consumption of products from Company A. A company that operated as a subsidiary of Company A provided product to the hospital in which the 77 year old female case died. However, the subsidiary company indicated that the meat was not sourced from Ireland. It was not possible to obtain a food history for the second fatal case.
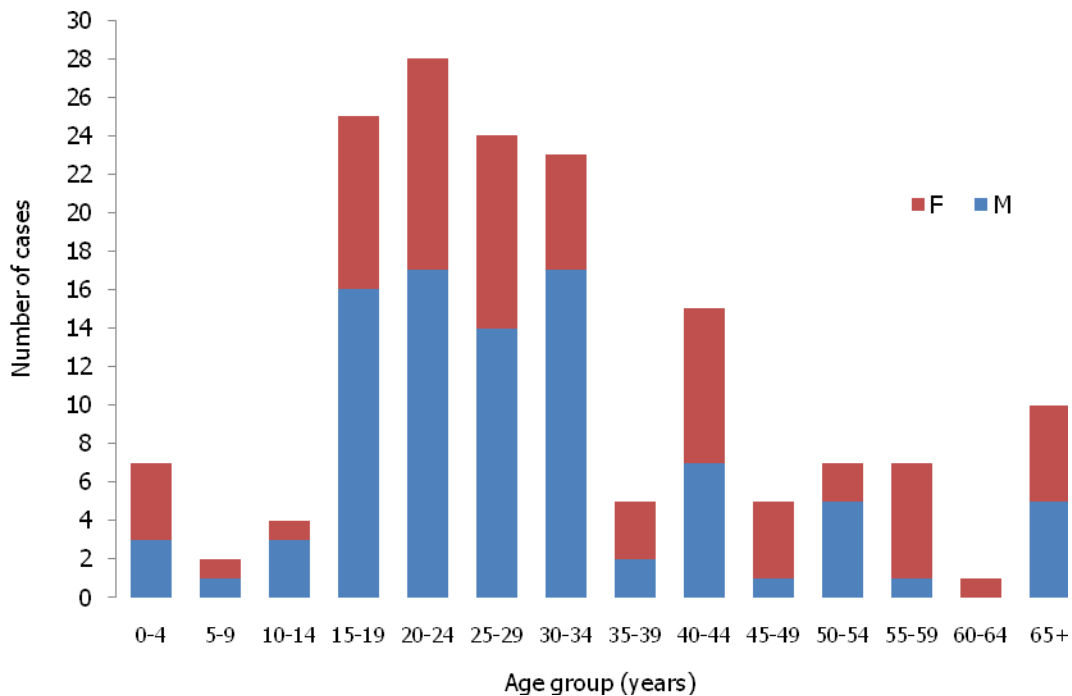

Figure 2. Reported number of confirmed *S.* Agona cases by age and gender, *S.* Agona Outbreak, Europe, Summer 2008 (N=163).

Eleven cases were reported in Ireland. England reported the majority of cases - 96. Thirty four cases were identified in Scotland and 11 in Wales. Two cases were reported in Northern Ireland. In addition, a further nine cases from other European countries were identified following an EWRS alert sent out on 23rd July: one case each in Finland and Austria, two each in Sweden and Luxembourg and three in France.

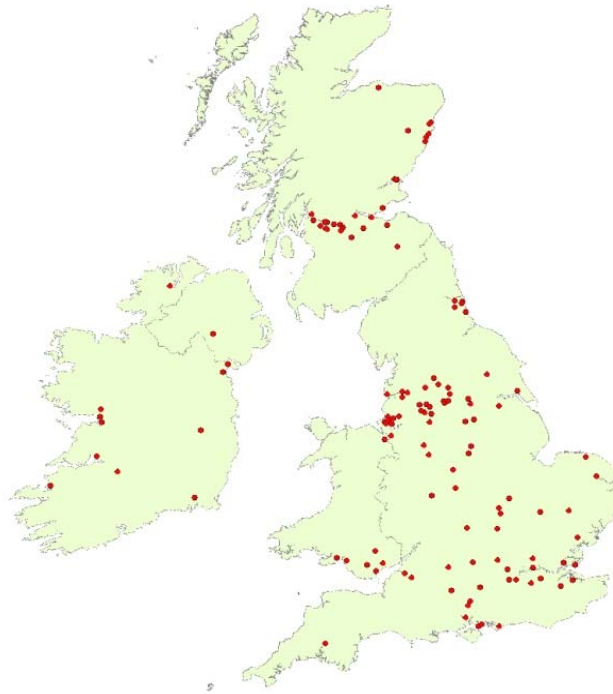Geographically, cases were distributed widely in Ireland and the UK (Figure 3), with no geographical clustering.

Figure 3. Distribution of confirmed *S.* Agona cases, *S* Agona Outbreak, Ireland and the UK, Summer 2008[**].

Date of Onset

The epidemic curve (Figure 4) showed two separate peaks; the first between week 14 and week 22 and the second between week 25 and week 35. The second peak was much more pronounced than the first.

The cases occurring in April were identified in the UK retrospectively. As a result of the information from Ireland together with the identification and designation of a new phage type in England and Wales, cases of *S.* Agona in England and Wales were reviewed prospectively and retrospectively. In addition to the increase in cases concomitant to the outbreak in Ireland, a small cluster was identified as having occurred in the UK between weeks 14 and 22 that year. This cluster was not above expected levels for that period, and hence no investigation was initiated. The retrospective phage typing indicated, however, that this was the first phase of the new outbreak.

[**] GPS map courtesy of HPA CfI, London, United Kingdom

Limited food histories were available from a small proportion of these early cases in the UK. Two of the early cases in England with onset in late April ate products from chains known to be supplied by Company A. One of the cases had a date of onset on 24th April. However, this case had eaten product in Chain A which was supplied by Company A; further batches of this product were subsequently shown to be contaminated. Seven cases had a date of onset before the incident of the oven failure on 25th April, while the remaining 156 cases appeared after this date. The outbreak was declared over on 01/10/2008.
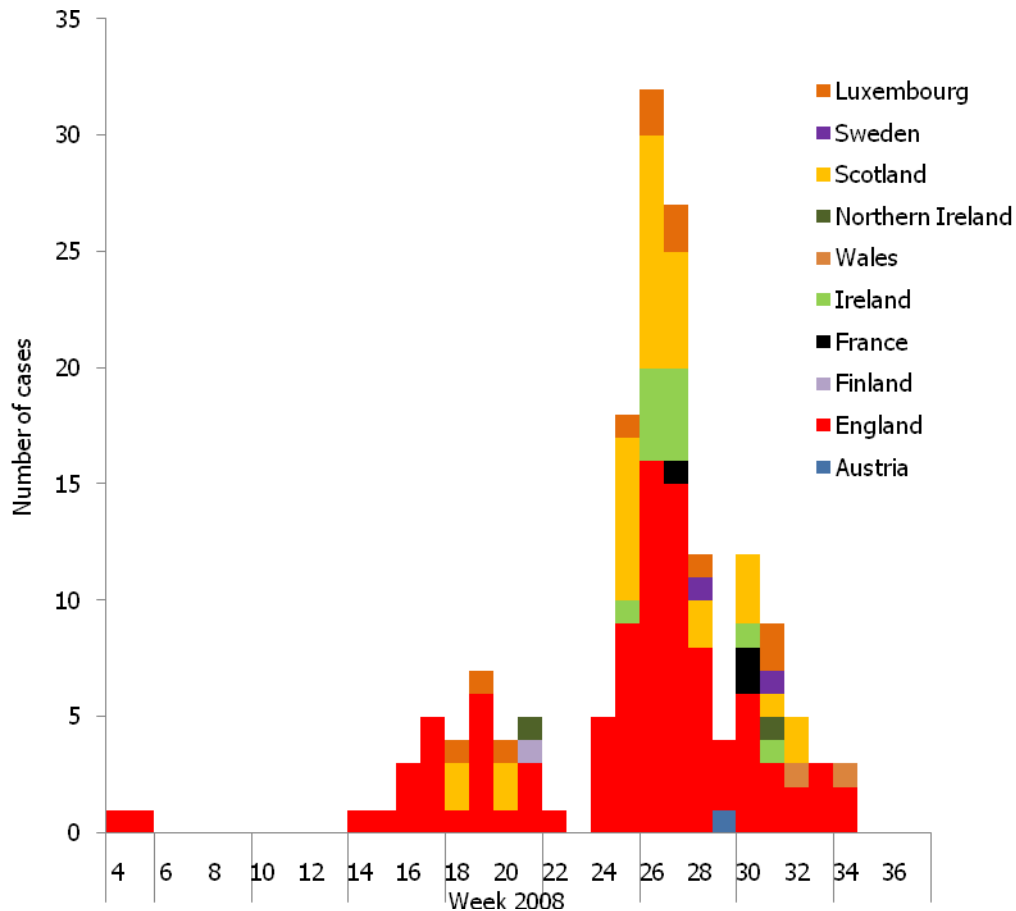
Date onset unknown n=10; Where the date of onset is unknown, the specimen date or a calculated date is used.

Figure 4. Epidemic Curve: Reported number of confirmed cases by date of onset and country of infection, *S.* Agona Outbreak, Europe, Summer 2008 (N=163).

4.1.2 Descriptive Study

1) Characteristics of cases

Fifty-six cases were included in the descriptive epidemiological study. This represents a little over one third of all the outbreak cases. The descriptive epidemiological study was a more detailed study of cases

in Ireland and the UK. One hundred and nine confirmed and probable cases with a date of onset after June 1st were included (see Figure 1). Overall, of 56 cases interviewed, 40 (71.4%) ate take away food and 38 (67.8%) ate made-to-order sandwiches. Certain food items were not sought in the descriptive study (frozen meals, sandwich fillings) as these items were not known about at the time the questionnaire was being developed.

The characteristics of the cases are laid out in the following Table:

Table 1. Characteristics of the cases in the Descriptive study, *S.* Agona Outbreak, Ireland and the UK, Summer 2008 (N=56).

Parameter		%
Country Response rate		
	TOTAL	51
	England	48
	Scotland	31
	Wales	86
	Northern Ireland	100
	Ireland	100
Symptoms		
	Diarrhoea	98
	Nausea	73
	Abdominal pain	93
	Fever	54
	Vomiting	41
	Blood in stool	39
Visited GP		93
Hospitalised		18
Travel		10
(7 days before onset of symptoms)		
Food Exposure		
	Pizza	30.4
	Sandwiches	67.8
	Fast food	71.4

From the descriptive analysis, the following associations with Company A were demonstrated as below.

2) Retrospective linkage of the cases to Company A

In total 29 cases out of 56 in the descriptive study ate food from premises known to be supplied by Company A. Two additional cases in late April were shown to have eaten at chains supplied by Company A. However, a significant element to this investigation was attempting to trace the distribution pattern of products from Company A. The investigation became aware of multilayered distribution network for the distribution of food products which made the food trace back imprecise and the linkage to the cases difficult. In addition, interviews of the European continental cases indicated that a case in Finland ate steak pieces in Chain A in Finland, providing important supplementary linking of that particular chain to the outbreak.

The remaining cases could not be directly linked to Company A. In investigation of outbreaks such as this, the complexity of food distribution pathways, and the difficulty of cases remembering exactly what they ate and when meant that it is normal to have a certain percentage of cases that remain unlinked to the known point source of the outbreak.

4.1.3 Case control study in Ireland

The Irish case control study tested the hypothesis that "cases were more likely to have eaten food from chains supplied by Company A than controls" and found a significant association (mOR=18.3, 95%CI=2.0-149.2). Chains A and B were strongly associated with being a case (Table 2). From this Table, cases (i.e. those with gastroenteritis caused by the outbreak strain) were 18.3 times more likely to have eaten in Chain A or B than controls who were not ill (this is highly statistically significant, p=0.001).

Table 2. Matched odds ratio associated with various exposures, *S.* Agona Outbreak, Irish case control study, Summer 2008.

	CASES (N=11)	CONTROLS (N=34)	mOR	p
	Exposed n (%)	Exposed n (%)	mOR [95% CI]	p
Pizza	3 (27.3)	6 (17.6)	1.9 [0.3 - 10.8]	0.46
Sandwiches*	10 (90.9)	14 (41.2)	15.1 [1.8 - 127.9]	0.013
Sandwiches made to order†	10 (90.9)	13 (38.2)	15.8 [1.9 - 132.6]	0.011
Chain A	4 (36.4)	2 (5.9)	10.2 [1.1 - 93.0]	0.04
Chain B	4 (36.4)	2 (5.9)	10.2 [1.1 - 93.0]	0.04
Chain A or Chain B	8 (72.7)	4 (11.8)	18.3 [2.0 – 149.2]	0.001
Fast food or take away*	10 (90.9)	18 (52.9)	13 [2.0 - 552.5]	0.001

*excluded sandwiches made at home
†excluded one prepacked sandwiches

4.2 Laboratory results

The investigation hinged on the definitive methods used to identify the *Salmonella* isolates.

S. Agona strains isolated from cases, food and environment were either indistinguishable or distinguishable by one band, line 7 (Figure 5). Their PFGE profile was SAGOXB.0066.

In Ireland and the UK where phage-typing was performed, all but one isolate were found to be phage type 39.

Salmonella Agona PFGE Gel IE08018
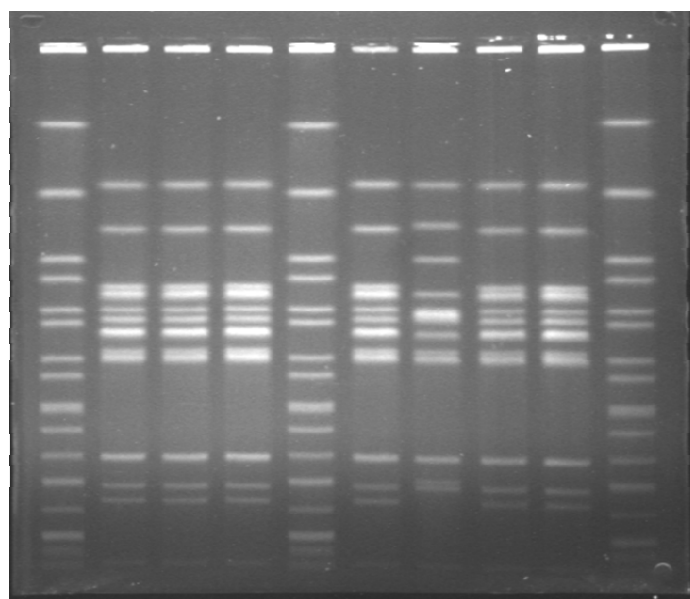
Lane	Isolate	Source	Lab no
•	Control		
•	S07-0947	Food	
•	S08-0681	Stool	50
•	S08-0724	Stool	7
•	Control		
•	S08-0734	Stool	53
•	S08-0740	Food	1
•	S08-0742	Food	1
•	S08-0743	Food	1
•	Control		

All plugs digested with *Xba*I. All indistinguishable apart from lane 7.

Figure 5. *S.* **Agona gel profile, S. Agona Outbreak, Europe, Summer 2008.**

(Source: National Salmonella Reference Laboratory, NUI)

A *Salmonella* isolate indistinguishable from the PFGE profile of the outbreak strain was identified in a cooked beef steak strip taken from an opened pack of beef in a Chain A outlet in Northern Ireland sampled on 3rd July 2008. *Salmonella* was not detected from a second sample taken from an unopened pack in the premises. The beef sample contaminated with the outbreak strain had originated from Company A.

Subsequently in the course of the investigation samples of beef steak strip pieces taken in a Chain A outlet in Ireland in week 32 (4th – 10th August 2008) tested positive for *S.* Agona; this subsequently turned out to be indistinguishable from the outbreak strain.

On 6th and 11th August 2008, samples of crispy bacon, produced by Company A, taken in Chain B in Ireland, were both reported as *S*. Agona with the PFGE of the outbreak strain. Other steak samples taken in Chain A were subsequently found to be positive for *S.* Agona on the 19th August.

A total of eight steak samples from two unopened bags from a Chain A outlet in Wales taken on 11th August were reported positive on 18th August 2008 for *S.* Agona.

On the 11th August 2008, *S*. Agona was isolated from an unopened package of Chain A steak pieces manufactured by Company A on 11th July 2008 and isolated in the Public Health laboratory in Northern Ireland.

A number of *Salmonella* isolates identified in the low risk area on product and in the environment between April and July 2008 were forwarded for definitive typing and found to be the unique pulsed field profile SAGOXB.0066/PT39. It appears that there was a high load of *S.* Agona in the low risk area and to such an extent that it overcame the existing control mechanisms designed to protect the high risk area from material in the low risk area. Such an amount of a single serovar indicated a hygiene failure sufficiently to propagate such an outbreak. SAGOXB.0066 has been shown to be an aberrant, aggressive biofilm former which can evade routine environmental monitoring. [*Personal Communication*: Professor Patrick Wall].

It was known at that time that the outbreak clone had been identified in samples of raw product in a small number of locations in Ireland since 2005. In addition, during the course of the investigation *S.* Agona SAGOXB.0066 was detected in river water in central Scotland, the source of which was never found.

5.O CONTROL MEASURES

Production and distribution ceased voluntarily and did not resume until the control authorities were satisfied with revised conditions of production and a regime of positive release introduced by Company A. Very large quantities of almost fifty different products produced on PL1 were progressively withdrawn voluntarily from the market and legally detained and destroyed by DAFF.

Initially, it appeared as if there had been a once-off hygiene failure and the product directly implicated in the failure was withdrawn, but as time went on and further evidence came to hand, it became progressively apparent that the contamination was likely to be more widespread. The withdrawal then had to be extended to be certain that all contaminated product was being removed from the market. This included a variety of cooked meat products such as sliced bacon, flavoured bacon, streaky bacon, chicken fajita, diced chicken, halal beef strips, Wiltshire bacon, roast chicken strips and frozen back bacon. Much of the product from Company A went to distribution depots and from there to franchisees of the various chains supplied. Recalling product from the distribution depots was relatively straightforward but given the complexity of the distribution network across numerous jurisdictions, the recall of some products continued for some time as the disposition of implicated batches was identified.

FSAI notified the European Commission of all withdrawn products exported from Ireland which resulted in 19 Alert Notifications to EU Member States issued by the RASFF. Additionally, there were national alerts issued in Ireland by FSAI.

In investigating this outbreak, a significant factor was traceability or the tracing of the distribution pattern of products from Company A. As the investigation progressed, a multilayered distribution network of food products was identified. Company A met its obligations under food law to be able to identify those businesses to which it had supplied food. However, the extensive further distribution was such that the ultimate end use of the products would not be known by Company A. The inexact nature of the information made the food trace back longer or more difficult and, as a result, a direct linkage of individual cases in certain instances to the consumption of product from Company A could not be made, and the possibility of source(s) of contamination other than products from Company A remains.

5.1 The Plant

On 31st July 2008, Company A, following discussions with DAFF and with FSAI, agreed to suspend all shipments of food products from the plant.

On 1st August 2008, following consultations with DAFF, Company A agreed to voluntarily close the plant and agreed to recall beef steak strips and chicken fajitas from PL1. Following on-site investigations, permission was given by DAFF, on 2nd August 2008 to resume cooking in the batch cookers only. The continuous cook lines (PL1 and PL2) remained closed.

Between August and September, DAFF's veterinary inspectors examined the food safety management system in place at Company A and identified areas which required attention. DAFF made a series of

recommendations addressing these shortcomings and requested Company A to modify their food safety management system and to implement specific corrective actions.

On 17th October 2008, Company A provided revised food safety management procedures to DAFF. These were discussed at length and after amendment were subsequently agreed on 6th November 2008.

As a result of the agreed procedures PL2 was allowed to be returned to use on 6th November 2008 but the PL1 cooker was decommissioned by Company A.

On 14th January 2009, DAFF audited the new food safety management system which was found to be operating satisfactorily.

In addition to voluntary closure and recalling products, the key corrective actions implemented by Company A included staff training in food safety, a pharmaceutical grade clean of the entire plant that was validated using biomarkers as controls, stool sampling of all staff that worked in areas where food cooking was undertaken (all staff were tested and salmonella was not detected), all cookers in the other 3 lines in the plant were validated by an expert consultancy company, enhanced bio-security measures and zoning introduced with new protocols for the movement of maintenance staff, and outside contractors, in the plant, enhanced surveillance was introduced in both the low risk and high care areas of the plant with definitive typing of all isolates identified in the environment and processed products.

Both analytical and microbiological studies identified precooked meats steak and bacon in sandwiches, descriptive studies (particularly in Wales) suggested a link between pizza and illness.

5.2 The food service outlets

Environmental Health Officers under the direction of the food agencies visited the chain outlets associated with many of the cases in order to investigate the premises on the basis of suppliers and to inspect the levels of hygiene and to review the food safety management systems in place. Samples were taken from finished products and from environmental surfaces. *Salmonella* was not detected on environmental surfaces.

6.0 DISCUSSION

6.1 Background

A multi-country European outbreak of *S.* Agona in 2008 resulted in 163 laboratory confirmed cases of illness. The real number of cases is difficult to estimate as in general, laboratory confirmed infections with *Salmonella* represent only a subset of the actual number of cases and most likely represent the severe end of the spectrum of disease. The thresholds for presenting to health services, for having a faecal sample taken for analysis and the surveillance and laboratory capabilities may vary between jurisdictions.

The distinctive pulsed field profile of *S.* Agona identified in cases was also identified in Company A's production facilities and in Company A's product in chains in Ireland, Northern Ireland and Wales and was detected in product from Company A's premises earlier in 2008 from a batch of product that was not placed on the market. The definitive typing techniques allowed this outbreak to be investigated and brought effectively under control; an outbreak which in the past could readily have gone undetected.

S. Agona was also known to have been in circulation in Ireland since 2005 and the distinctive PFGE profile was found in raw poultry and flash fried poultry products which were circulated both in Ireland and the UK. The outbreak strain, *S.* Agona PT39 had not been seen clinically or in food or environmental samples in the UK prior to its appearance in the first half of 2008.

In the past, *S.* Agona – an uncommon *Salmonella* serovar in humans - has been associated with several outbreaks. Various vehicles responsible for these outbreaks were identified: animal feed [Clark, 1973 200 /id], precooked turkey [Synnott, 1998 98 /id], toasted oats cereal [1998 102 /id and 2008 CDC: Investigation of Outbreak of Infections Caused by Salmonella Agona available at http://www.cdc.gov/salmonella/agona/], aniseed drink preparation [Koch, 2005 34 /id], infant milk formula [Brouard, 2007 1 /id], a peanut flavoured snack [Killalea, 1996 107 /id;Shohat, 1996 106 /id] and puffed rice. Our report identified another vehicle, precooked meat (steak and bacon) used in the preparation of sandwiches and pizzas.

6.2 Outbreak identification

This international outbreak was identified following the appearance of an unexpected cluster of cases of *S.* Agona in Ireland. Active case finding led to the discovery of an extensive outbreak in a number of countries. The outbreak comprised two separate peaks in the epidemic curve; the first was between week 14 and week 22 and the second between week 25 and week 35. The second peak was much more pronounced than the first. In the first wave, seven cases of illness appeared prior to the thermal failure on April 25th .

6.3 Descriptive epidemiology and hypothesis generation

The descriptive study looked at 56 out of the 163 identified cases. It considered only cases with onset dates after June 1st, as to include cases before that time would have introduced the issue of recall bias. These cases therefore differed from the main body of cases solely in having a later date of onset. Of these cases, 29 (or a little over 50%) were demonstrated to have eaten food from a chain known to have been supplied by Company A. This was based on the information that was available to the IOCT at the

time of the study. Cases were not questioned about a number of exposures of additional products originating on PL1 that were subsequently identified (such as frozen meals, sandwich fillers and pasta sauces). In outbreak investigations, it is never possible to completely identify every case that has been made ill by a contaminated food product and to link them directly to that food product. In practical terms, investigators will attempt to identify and designate the suspected source on the basis that the most likely source is that which explains the greatest proportion of the cases identified. Investigators at the end of the outbreak agreed that, where the results of descriptive epidemiology are sufficiently strong, an analytical study is not necessarily required prior to taking the appropriate control measures.

6.4 Analytical case control study

Eight of 11 cases included in the analytical study ate in chains supplied by Company A as compared with four out of 34 controls (controls being representative of the general population). This means that cases were more than eighteen times more likely than controls to have eaten in chains supplied by Company A, which was highly statistically significant.

6.5 Supporting microbiological and environmental evidence

In addition to the epidemiological evidence obtained during this investigation, important microbiological and environmental evidence was also obtained. All cases were infected by the same outbreak strain. This strain was found in the environment in food production areas of Company A. In addition it was found in product sampled within Company A and was subsequently found in product obtained from chains supplied by that company. Product from the company and contaminated by the same bacterial strain was found contemporaneously in three jurisdictions. In addition, the distribution of cases mirrored closely the distribution pattern of food product supplied by Company A. Microbiological findings suggested that there was a high load of *S.* Agona in the low risk area that may have overcome control mechanisms.

6.6 International aspects

Once the international nature of the outbreak had been recognised, international active case finding was facilitated by the EWRS and the ECDC-FWD alerts. Collaboration with ECDC worked well and allowed identification of additional cases in France, Luxembourg, Sweden, Austria and Finland through the Food and Waterborne Disease network. With globalisation of food and ingredient distribution, such alerting systems are crucial. The identification of the international dimension to this outbreak was greatly assisted by microbiological typing. Strain comparison was facilitated by electronic exchanges of PFGE data through the Pulse-Net Europe network. However, despite the identification of the same unique pulsed field profile in the cases in this outbreak, no clear epidemiological link between all cases and food identified were established.

6.7 Other sources

The IOCT did not identify any other potential sources at the time of the outbreak investigation but subsequent to the completion of the investigation information on raw chicken contaminated with the same strain of *S.* Agona, being identified in a producer in Ireland, became available. Contamination of raw chicken is common, and may account for some of the outbreaks cases for which no link could be found to specific food items, but does not warrant targeted public health intervention.

As this isolate was in a raw product it may have accounted for some sporadic cases. However it is unlikely to account for the large number of cases identified in this outbreak. While *S.* Agona SAGOXB.0066 is a distinctive strain of the relatively uncommon serovar *S.* Agona, it is not exclusively associated with the premises or products of Company A. As outlined, indistinguishable strains have been detected from other sources in Ireland and in the course of the investigation *S.* Agona SAGOXB.0066 was detected in river water in central Scotland. The source of this isolate was never found.

While the IOCT did consider other possible sources, no other sources became apparent during the investigation. It is possible that some of the cases associated with this outbreak could have been part of the sporadic background activity of this pathogen. The outbreak strain had been circulating for some time in Ireland, but had only ever previously been detected in raw material, not ready to eat food or cooked product. Despite that, there were no documented outbreaks of *S.* Agona caused by this strain before 2008. When cases began to appear in 2008, they were closely temporally associated with a reported failure of a cooker in Company A, coupled with the identification of the outbreak strain on the premises of Company A and in products in chains supplied by Company A provided strong evidence of an association between Company and this outbreak. Another important indicator that Company A was the primary, if not the sole, source of this outbreak was that the geographical distribution of cases in the British Isles mirrored to a close extent the distribution of product from Company A. The volume of product did not mirror the volume of cases identified on the continent of Europe. The sensitivity of the case definition used by the IOCT differed in the different countries. For logistical reasons, a PFGE result was required before investigating cases occurring on the continent. In many areas of the continent cases are not routinely sent for PFGE analysis. And as is known from previous experience and from the evidence of other outbreaks, only a minority of more severe cases will ever be reported to the public health authorities in the different countries.

S. Agona was responsible for another notable outbreak at around the time this outbreak was occurring. In the United States, an outbreak of foodborne illness was investigated between April and June 2008 that was linked to puffed processed cereals (see http://www.cdc.gov/salmonella/agona). However, there was no evidence that either of these two events contributed to this outbreak; in fact the strain responsible for the US outbreak had a different PFGE profile to this outbreak strain [Dr Peter Gerner-Smidt, personal communication]. In addition, the outbreak responded to outbreak control measures directed at Company A and the outbreak was declared over in October 2008. In 2009 there were six clinical cases of S. Agona in Ireland. One human isolate (from a urinary sample) displayed the SAGOXB.0066 profile. All other clinical isolates were different to the 2008 outbreak strain. There was a number of *S.* Agona isolates from non-human sources with the SAGOXB.0066 (or closely related) profile. It was not possible to link the single SAGOXB.0066 case occurring in 2009 to any environmental or food production source.

6.8 Limitations of the investigation

As with all investigations, there were limitations but these were not sufficient to impact on the findings of the IOCT. In the descriptive study not all cases were examined, only the cases that it was feasible to consider. In the analytical study, only the eleven Irish cases were included. In the study, the matched odds ratio at the lower 95th centile was two; this meant that the finding was statistically significant. The same cases were included in the analytical study as had been investigated in the descriptive study because the analytical cases were Irish and because Ireland had only 11 cases, this meant that this was the only feasible way to conduct the study. Under ideal conditions, one would not include cases from a descriptive study in an analytical study. No analytical study was undertaken in the UK.

The date of onset of seven cases during the first peak (between weeks 14 and 22) and the two cases identified in January 2008 in the UK, predate the documented cook failure on PL1 in Company A. It is possible that these two cases in January were not associated with the outbreak. However, two of the early cases in April had eaten product from a chain in the UK supplied by Company A.

The peak of the outbreak curve and subsequent initial decline predated the control measures implemented in Company A. This could indicate that a batch or batches of contaminated product had passed through the factory and were subsequently placed on the market. It is likely however, that the control measures interrupted further episodes of contamination from the infected production line at a later stage. Similarly cases continued to appear for four to five weeks after initiation of control measures. While production of food was stopped on the implicated production line, it took a number of weeks to implement recall. All product from PL1 was recalled and destroyed. Overall, the information available to the IOCT was such that, in the interests of public health, the decision was taken to act based upon the findings of the descriptive epidemiology and the identification of *S.* Agona in Company A's ready to eat products, the results of the analytical study providing an additional supplementary support.

However, despite the limitations documented above, the IOCT considers the investigation provided sufficient evidence to support the actions that were taken.

6.9 Trace back

In investigating this outbreak, a significant factor was traceability or the tracing of the distribution pattern of products from Company A. As the investigation progressed, an extensive network for the distribution of food products was identified. However, the inexactitude of this information made the food trace back longer or more difficult and, as a result, a direct linkage of individual cases in certain instances to the consumption of product from Company A, could not be made, and the possibility of other source(s) remains. This resulted in a lengthy investigation and a longer time elapsing before the application of control measures than would otherwise have been the case. In general, where the results of descriptive epidemiology are sufficiently strong, an analytical study is not necessarily required prior to taking the appropriate control measures.

Traceability systems are a legal requirement for food business operators (including intermediary food product distributors). Company A complied by providing control authorities with information on the identity of other businesses to which their products have been supplied on demand.

6.10 Conclusions

Investigators identified and brought under control an outbreak of *S.* Agona in which 163 confirmed cases were identified in the period between January and October 2008. A source of contamination (Company A) was identified and the associated production facilities ceased operation pending investigation and remedial action on August 1st 2008. Links between the contaminated foods (chains supplied by Company A) and a number of the cases could be demonstrated. Large volumes of food were recalled by the Company A. The action resulted in the prevention of many more cases of *S.* Agona infection. Similar large food recalls were instigated in the UK and Ireland.

As with all outbreaks of this nature, it was not possible to link all the cases to the identified source of contamination. Moreover, the possibility existed that there might have been more than this one source

for the outbreak. That said, it is likely that Company A accounted for the majority of cases identified during the course of the investigation. The detection of the identified source would not have been possible without the use of molecular typing techniques and the sharing of data and co-operation between numerous agencies.

This was a particularly important outbreak that might have gone undetected were it not for the availability of excellent surveillance data allowing the source to be identified, effective control measures to be put in place and important lessons to be learned.

7.0 RECOMMENDATIONS

The international outbreak control team makes the following recommendations:

7.1 Control agencies

1. There is a requirement for each of the affected countries to review the way in which the outbreak investigation was conducted and to recommend actions accordingly.

2. There is a need for more joint exercises between different agencies.

3. All isolates from clinical, food, animal and environmental sources should be, at a minimum, serotyped to assist with tracking problems through the food chain to where corrective actions are needed, stored for two years, have antibiotic sensitivity documented and be definitively typed using molecular techniques in an outbreak setting.

4. Consideration should be given to a requirement for private laboratories to forward isolates to the National Salmonella Reference Laboratory and similar institutes in the UK for definitive typing.

5. Data on food, animal and human isolates must be more accessible and more integrated in order to improve the efficiency of outbreak investigation allowing appropriate control measures to be applied as early as possible.

7.2 Food business operators

1. Traceability systems are a legal requirement for food business operators (including intermediary food product distributors). These should be capable of providing essential information without undue effort or delay. Food business operators are reminded of the importance of being able to provide traceability information to control authorities "on demand". Food business operators are reminded of the importance of having systems and procedures in place capable of meeting this stringent, time based requirement.

2. Failure of cooking in a continuous line cooker should not result in undercooked (raw) material entering a high risk (cooked product) zone in a food plant. In future designs, product should be diverted using a sealed divert mechanism.

3. FBOs are reminded of the need to operate a food safety management system based on HACCP principles, and not to rely on end product testing.

4. Major FBOs should give consideration to regular serotyping of salmonellas which would be subject to regular review and analysis to determine if patterns of emergence of particular serovars suggest a problem with colonisation in the plant.

5. Manufacturers of food processing equipment should accept responsibility for how the design and operation of their equipment impacts on food safety.

6. Research into management of biofilm formation should be supported with a view to developing strategies to countering their effects.

7.3 Policy makers

1. Policy makers should ensure that all food business operators recognise their obligations under EC Regulation 178/2002 not to place unsafe food on the market. In the event of a suspected or emerging problem relating to sourcing or manufacturing of food then the food business operator should inform the appropriate regulatory authority with details of the findings in a timely manner.

8.0   SELECTED BIBLIOGRAPHY

1.   Clark GM *et al*. Epidemiology of an international outbreak of *Salmonella* Agona. *Lancet*. 1973; **2(7827):**490-3.
2.   Synnott MB *et al*. An outbreak of *Salmonella* agona infection associated with precooked turkey meat. Commun Dis Public Health. 1998; **1(3):**176-9.
3.   Centers for Disease Control and Prevention. Investigation of Outbreak of Infections Caused by *Salmonella* Agona available at http://www.cdc.gov/salmonella/agona. Accessed 17/3/2009.
4.   Koch J *et al.* Salmonella agona outbreak from contaminated aniseed, Germany. *Emerg Infect Dis.* 2005; **11(7):**1124-7.
5.   Brouard C *et al.* Two consecutive large outbreaks of *Salmonella* enterica serotype Agona infections in infants linked to the consumption of powdered infant formula. *Pediatr Infect Dis J.* 2007; **26(2):**148-52.
6.   Shohat T *et al.* International epidemiological and microbiological study of outbreak of *Salmonella* agona infection from a ready to eat savoury snack--II: Israel. *BMJ*. 1996; **313(7065):**1107-9.
7.   Killalea D *et al*. . International epidemiological and microbiological study of outbreak of *Salmonella* agona infection from a ready to eat savoury snack--I: England and Wales and the United States. *BMJ*. 1996; **313(7065):**1105-7.
8.   Centers for Disease Control and Prevention. Multistate outbreak of *Salmonella* serotype agona infections linked to toasted oats cereal--United States, April-May, 1998. *JAMA*. 1998; **280(5):**411.

Appendix 1: Members of the International Outbreak Control Team

IRELAND

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HPSC (Ireland): Darina O'Flanagan (Chair), Lelia Thornton, Suzanne Cotter, Nathalie Nicolay, Patricia Garvey, Mairead Skally, Orla Bannon, Paul McKeown

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Appendix 2: Acknowledgements