European Food Safety Authority

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SCIENTIFIC REPORT OF EFSA

Tracing of food items in connection to the multinational hepatitis A virus outbreak in Europe[1]

European Food Safety Authority[2,3]

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ABSTRACT

In May 2013, Germany reported cases of hepatitis A virus (HAV) genotype IA infection in persons with a travel history and Italy reported a national increase in the number of HAV cases and declared an outbreak. Confirmed cases (outbreak strain KF182323) have been reported in Denmark, Finland, France, Germany, Ireland, Norway, the Netherlands, Poland, Sweden and the United Kingdom (331 in total). HAV contamination was detected in frozen mixed berries (14 lots) and mixed berry cakes/pastries (2 lots) in Italy, France and Norway. In Ireland, the Netherlands and Sweden, analysis of food histories and questionnaires identified suspect berries and berry products consumed by confirmed cases. Tracing began with 38 lots/cases from Italy, Ireland and the Netherlands, an additional 5 lots/cases were added from France, Norway and Sweden in spring 2014. The tracing data were exchanged via the European Rapid Alert System for Food and Feed. The final dataset comprises 6227 transactions among 1974 food operators. Bulgarian blackberries and Polish redcurrants were the most common ingredients in the traced lots/cases; however, Poland is the largest producer of redcurrants in Europe, and Bulgaria is a major exporter of frozen blackberries. No single point source of contamination linking all 43 lots/cases could be identified. HAV cases/lots in five countries could be linked to seven Polish freezing processors and/or to five frozen berry suppliers in Bulgaria. This indicates that HAV contamination could be occurring at the freezing processor or in primary production of berries and therefore compliance with Good Hygiene Practice, Good Manufacturing Practice and Good Agricultural Practice is recommended for countries producing berries for freezing. It is possible that contaminated product related to this outbreak could still be circulating in the food chain. Hence, for the public health domain, enhanced surveillance, risk communication, vaccination and further research are recommended.

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KEY WORDS

hepatitis A virus, foodborne outbreak, outbreak investigations, back-tracing, berries

SUMMARY

On 8 May 2013, Germany reported seven cases of hepatitis A virus (HAV) genotype IA infection in persons with a travel history to ski resorts in northern Italy. Subsequently, Italy reported an increase in the number of HAV cases at national level and declared an outbreak. At European Union (EU) level, confirmed and probable epidemic case definitions were adopted, with reference to the outbreak strain (OS) genotyping sequence result (GenBank accession number KF182323). Since 1 January 2013, 1444 cases associated with this HAV outbreak have been reported by 12 EU/European Economic Area (EEA) countries. Of these, 331 were confirmed cases. Italy reported 90% of the cases. Dispersed or clustered cases without any travel history were also reported in Finland, France, Germany, Ireland, the Netherlands, Norway and Sweden. To date no deaths associated with this outbreak have been reported; however, surveillance systems for HAV infections are not always able to capture this information.

Since August 2013, the majority of the cases in the affected Member States (MSs) have been interviewed using questionnaires adapted from the questionnaire initially developed by the Health Protection Surveillance Centre (HPSC), Ireland. At the European level, 245 completed questionnaires from confirmed cases were analysed, and 198 (80.1 %) reported consumption of berries during the relevant exposure period. In Italy, a retrospective matched case–control study identified berries as the highest associated risk factor for developing the disease (matched odds ratio (OR) 4.99; 95 % confidence interval (CI) 1.3–18.92), followed by raw seafood (matched OR 4.46; 95 % CI 1.10–18.04). A matched case–control study conducted in Ireland found that 91 % of cases had consumed at least one of four products containing frozen berries, compared with 39 % of controls (matched OR 12, 95 % CI 1.5–94). Two case–control studies were conducted in Norway. In the first study, none of the exposures was significantly associated with the disease; however, in the second study, evaluating exposure to a specific suspect cake containing berries, the matched OR was 13 (95 % CI 1.7–110). A descriptive epidemiological study in the Netherlands identified consumption of fresh soft fruit as a risk factor. Food histories from two Swedish domestic cases reported consumption of berry smoothies at a resort. It is important to note that the exposure to berries may have been underestimated, owing to recall bias caused by the long interval between exposure and onset of symptoms/diagnosis and the fact that berries may be a minor ingredient or used as a decoration in food.

In addition to the epidemiological evidence, laboratory testing identified 16 HAV-contaminated lots of frozen berries or berry products. Two lots were confirmed by sequence analyses to be contaminated with HAV OS. The intensive sampling regime for frozen berries in Italy identified 15 of the confirmed batches, i.e. batches with a positive analytical result for the presence of HAV RNA, and 45 suspect lots, i.e. lots consumed by at least one confirmed case in 2013, manufactured by 11 frozen berry packing companies. A preliminary result for one Italian lot of mixed frozen berries showed contamination with a HAV OS. In France, in February 2014, a cluster of three confirmed cases of HAV infection with an epidemiological link to a catering service was detected. Official sampling of leftovers of the suspect lot of frozen mixed berries used to produce the pastries and of the suspect lot of pastries tested positive for the presence of HAV RNA. Samples of a suspect berry mix cake in Norway were examined and found to be positive for HAV OS. Interpretation of the microbiological evidence should take account of the fact that HAV contamination is not necessarily homogeneously spread throughout a food item. This means that detection of the virus can be difficult and multiple samples need to be taken—a negative result is not sufficient to exclude the possibility of HAV contamination. In addition, genotyping of food items is more difficult than genotyping of human samples as the level of viral contamination is often too low to allow sequencing. For these reasons, HAV OS status could not be confirmed for many of the HAV-contaminated lots associated with this HAV outbreak.

The starting points for tracing were classified based on the strength of evidence (microbiological and epidemiological) of the association between food vehicle (berries) and the HAV outbreak. Therefore, evidence was rated as being of very high strength when food was confirmed to be contaminated with HAV OS or HAV-contaminated food items were known to have been consumed by confirmed cases. The strength of evidence was rated high when a suspect lot was consumed by at least one confirmed

case and the exact lot and brand could be identified from the food history or when a lot had a positive analytical result without further genotyping. Possible lots, lot or lots that confirmed cases may have consumed during their exposure period (i.e. 15 to 50 days) before onset of illness, were rated as evidence of medium strength. Starting points with low strength of evidence were not traced. The tracing activities in winter 2013 started with 38 lots/cases in Italy, Ireland and the Netherlands. In spring 2014, an additional five lots/cases were added from France, Norway and Sweden. Primarily, frozen blackberries, raspberries, blueberries/bilberries and redcurrants were traced. In total, 8 starting points were classified as having very high-strength evidence, 14 as having high-strength evidence and a further 21 starting points were classified as having medium-strength evidence. The tracing data compiled for this report were collected, using a standard data format and template, by the national and regional authorities via the European Rapid Alert System for Food and Feed (RASFF). The tracing dataset comprises 6 227 transactions from 1 974 food operators (i.e. freezing processors, primary producers).

Descriptive analysis of the berry ingredients of the traced lots showed that all lots classified with very high or high strength of evidence contained blackberries, and the majority contained redcurrants. The most frequently identified origin of berries for all evidence classes was Poland or Bulgaria. Only two lots with the evidence class very high- or high- did not contain Polish redcurrants. Bulgaria was the most frequently identified origin country for blackberries, but Bulgarian blackberries were not found in all lots for any of the evidence classes. When evaluating the descriptive analysis it is important to remember that these two countries are major producers and exporters of frozen berries, while Poland is known to be the largest producer of redcurrants in Europe. In addition, there was a high level of completion of tracing data for products of Polish origin (either to the primary producer or to the freezing processor), but for other countries final end points were often missing and therefore the origin country may not be correctly identified.

The Federal Institute for Risk Assessment (BfR) in Germany has developed an open-source software tool called “FoodChain-Lab”, under a General Public License (GPL), which supports tracing back and forward analysis of suspicious food items along food supply chains. This software was used to analyse and visualise the large and complex dataset resulting from the tracing activities. Starting at the locations identified as the most probable sites of exposure, the tool allows tracing along the supply chain to identify connections between different disease clusters. This is accomplished by constructing and visualising interactive network graphs. A network graph consists of nodes and connections (edges) between the nodes. A node or station is defined as a food operator which produces, trades, stores or handles a suspect food item. The network analysis was used to identify possible “hotspots”. “Hotspots” are stations in the tracing net that are connected to a large number of starting points and therefore able to explain a large number of contaminated lots or HAV cases. A contamination event could occur at a “hotspot” or at a point prior to the “hotspot” in the supply chain.

No single point source of contamination (“hotspot”) linking all cases and contaminated lots (starting points) identified during the multinational outbreak could be determined. For redcurrants, one or more of three “hotspots” (PL#273, PL#98 and PL#115) are linked to Italian and French lots plus the Irish cases. Four common primary producers of redcurrants were identified linking these hotspots. A further two Polish freezing processors are linked to Italian lots (PL#61, PL#1237). The Norwegian lots are linked to Polish freezing processor PL#1810 and the Swedish cases to Polish freezing processor PL#260. Possible cross-contamination at stations further down the food chain (e.g. at IT#25) could link additional cases and lots to these freezing processors. Seven Polish freezing processors are linked to a total of 31 cases and lots. For blackberries, “hotspot” BG#8 plus two additional Bulgarian frozen suppliers (BG#1222 and BG#1260) are linked to Italian lots. The French lot and Irish cases are linked to the Bulgarian frozen supplier BG#1807 and BG#1884 and the Norwegian lot is linked to Bulgarian company BG#1808. Five Bulgarian suppliers of blackberries are linked to a total of 23 cases and lots. In most of the cases the tracing could not be completed to the level of primary producer or fresh berry supplier in Bulgaria. Some lots of Bulgarian blackberries comprised fruit that had been collected from public areas and forests by local pickers.

Reviewing the strongest evidence, the two lots contaminated with HAV OS contained both redcurrants and blackberries. The redcurrants were produced in Poland by two different production sites (PL#115 and PL#1810) over two harvest years (2011, 2012). The Norwegian lot contains blackberries delivered from Bulgaria (BG#1808), while the blackberries in the Italian lot were supplied by Serbia (RS#186). In addition, there is strong evidence of HAV contamination of berries at Polish freezing processor PL#273. Berry mixes from this freezing processor were used in the contaminated pastry from France and supplied to the berry product manufacturer in Ireland whose products were consumed by nine confirmed Irish cases. Suppliers of Polish redcurrants and Bulgarian blackberries were common to both the Irish and French berry mixes. Four primary producers that supplied redcurrants to PL#273 (harvest 2012) also supplied redcurrants to "hotspot" PL#98 (harvest 2011).

Overall, there are two possible conclusions. The first is that there was a single point source for the outbreak; however, information that would confirm this, relating to the sharing of resources among the berry freezing processors, e.g. exchange of temporary workers, shared use of equipment during harvest, storage or processing, a common contaminated reservoir of water for irrigation, fungicide/pesticide application or cleaning, or flooding of a wider production area, is lacking. Alternatively, a high-risk practice in the production or freezing of berries or endemic occurrence of HAV OS in the region of production or the subpopulation of seasonal workers resulted in HAV contamination in multiple locations and at multiple time points. However, several factors prevent a final conclusion being reached: uncertainties related to different investigation and sampling strategies in the affected countries; a lack of background information on berry production methods, berry products on the market and prevalence of HAV strains; the fact that only information relating to confirmed/suspect lots was analysed; recall bias on the part of cases; and the possibility of errors in the collation of the tracing data. Further local investigations are necessary to identify whether a single point source or a continuous source of contamination exists.

Based on the findings of the investigation that HAV contamination could be occurring at the freezing processor or in primary production of berries, compliance with Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP) and Good Agricultural Practice (GAP) is recommended for countries producing berries for freezing. It is possible that contaminated product related to this outbreak could still be circulating in the food chain; hence, for the public health domain, enhanced surveillance, risk communication, vaccination and further research are recommended. Finally, to support future investigations and tracing activities, use of multidisciplinary teams, data exchange protocols and access to improved data management and analytical tools is recommended.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION (EC)

As given in Ares (2013)2576387 of 4th July 2013:

> "In multinational foodborne outbreak investigations, The European Commission and Member States are responsible for risk management activities such as control activities (inspections, sampling and analyses) aimed at the confirmation of suspected food sources and their tracing back and forward, the management and use of the Rapid Alert System for Food and Feed (RASFF) and the adoption of possible trade restrictions. Several European risk assessment bodies are involved in the coordination of multinational investigations of outbreaks of foodborne pathogens to support Member States. While both the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) share activities and collaborate in the area of foodborne outbreak investigations, it is important that their respective tasks and responsibilities are clearly defined. ECDC identifies, assesses and reports on human cases (public health threats) in accordance with Regulation (EC) No 851/20044
>
> EFSA is responsible for risk assessments in all fields which have a direct or indirect impact on food and feed safety and has been mandated by the European Commission in accordance with Directive 2003/99/EC to directly collect and publish information on the monitoring of zoonoses, zoonotic agents and food-borne outbreaks."

As further specified in Ares (2013)3322396 of 23rd October 2013:

> "The EU is currently facing an extended multinational outbreak of hepatitis A, which led to numerous human cases predominately in Italy, but also in other Member States.
>
> A joint EFSA/ECDC rapid outbreak assessment has been published (last update on 10th July 2013). An identical virus strain was identified in several batches of mixed berries, which have been withdrawn from market using the RASFF-system.
>
> The Italian authorities have conducted a tracing back & forward exercise on the suspected food batches; however, until now no common link between the contaminated batches was established. The authorities in Ireland are contributing to the Italian exercise by investigating on the epidemiology and the incriminated foodstuffs of their domestic human cases. Noteworthy are the efforts of the Polish authorities to deliver information on the possible source of the batches containing hepatitis A virus via the RASFF-system.
>
> The Commission is coordinating the investigations on the food safety side at EU level. Audio conferences with experts involved in the outbreak investigations and EFSA/ECDC were held. All information regarding these investigations is circulated through the RASFF. The most recent discussion took place during the SCFCAH meeting on 16th October 2013. The affected Member States supported the Commission to have a integrated coordination on the EU-level."

[4] OJ L 142, 30.4.2004, p. 1.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

As given in request Ares (2013)2576387 of 4th July 2013:

> In accordance with article 31 of EU Regulation 178/2002, EFSA is requested to provide scientific assistance in the area of food-borne outbreak investigation. In particular, EFSA is requested to:
>
> 1. Contributing to the ECDC rapid outbreak assessment by providing information from he monitoring of zoonoses, zoonotic agents and food-borne outbreaks.(…)
>
> 2. When more information on a specific outbreak becomes available, and upon specific request of the Commission**5**, to further collaborate with ECDC in the food-borne outbreak assessment by providing in-depth analysis of the food data including the robustness of the link to the suspected food source, based on epidemiological data.
>
> 3. Upon specific request of the Commission[6], to provide technical assistance to the Commission in its conduct of tracing-back and forward analysis of incriminated batches of animals, food or feed in the affected Member States.
>
> 4. Pending the further course/evolution of the outbreak and new information becoming available, to provide an update of the joint rapid outbreak assessment jointly with ECDC.
>
> Task two and three do require a specific request, to be decided on ad hoc basis, taking into account the severity and/or exceptional character of the outbreak, the available information and available resources.

The specific request is given in letter Ares (2013)3322396 of 23rd October 2013:

> (…) Therefore, in line with the general request for scientific and technical assistance as mentioned above, and I particular as indicated in ToR 3, I would like to ask EFSA for assistance in the ongoing investigations.
>
> Under the coordination of Unit G4: Food, Alert System and Training, the tracing back & forward exercises of the affected Member States should be merged and analysed to identify the potential links and also data gaps. Moreover, advice on the common source of the outbreak should be given and guidance on the robustness of evidence pointing towards suspected sources based on epidemiological links and laboratory analysis (including molecular testing) should be given.

[5] Pending the urgency by email or letter referring to this general request.
[6] Pending the urgency by email or letter referring to this general request.

CONTEXT OF THE SCIENTIFIC OUTPUT

APPROACH TO THE MANDATE

EFSA was mandated by the European Commission (EC) to coordinate the tracing activities of affected Member States during their investigations in a multinational, foodborne outbreak of HAV in 2013 and 2014.

In November 2013, a working group was established comprising epidemiologists and tracing analysts from Italy, Ireland, the Netherlands and Poland. Specialists on tracing analysis from the German Federal Institute on Risk Assessment (BfR, Berlin) and on foodborne outbreak investigations from European Centre for Disease Control (ECDC, Stockholm) were also included in the group.

The most recent rapid outbreak assessment by ECDC and EFSA (ECDC and EFSA, 2014), in May 2014, reported on ongoing infections in France, Norway and Sweden. Therefore, the working group was further enlarged by including epidemiologists and tracing analysts from France, Norway and Sweden.

The first task of the working group was to define and classify the starting points for common tracing activities. Starting points are stations in the food chain (e.g. processors, restaurants) where a confirmed or suspect lot was produced, or delivered to a confirmed or possible case. A data format and template for sampling and exchange of tracing data was developed and distributed. Tracing data are collected and exchanged using the Rapid Alert System for Food and Feed (RASFF), which has contact points in all Member States and associated countries.

An intermediate report summarised the results of the back-tracing from starting points in Italy, Ireland and the Netherlands as defined in November 2013. The updated results are included in Appendices A and B.

Since spring 2014, new starting points for tracing activities have been identified in France, Norway and Sweden. The results were used to strengthen and revise the results of the intermediate report. This final report summarises the evidence the working group found by tracing the food items from the starting points in all countries. The possible sources of contamination of the food trace are discussed, as are data gaps, which result in uncertainties of the findings. One additional outbreak cluster was reported in Finland at the beginning of June because of the short time available to obtain and include additional data, this outbreak is not included in this report.

Data collection for this report closed at the end of June.

STRUCTURE OF THE SCIENTIFIC REPORT

This EFSA scientific report is structured in seven sections:

Sections 1 and 2 describe the multinational outbreak of hepatitis A in Europe with information available until the end of June 2014. Special emphasis is given to the investigations in Italy, Ireland, the Netherlands, France, Norway and Sweden. Because the outbreak is still ongoing, albeit at a lower level, in summer 2014, it is possible that some of the most recent developments have not yet been reported, or that investigations had not yet been finalised at the closing date of this report.

Section 3 defines and summarises the starting points for the tracing activities in the affected countries and provides some general information necessary for the interpretation of the tracing results.

Section 4 describes the methods used and tools used for analysing the obtained tracing data.

Section 5 presents and discusses the results of the back-tracing of food items to identify a common source for the multinational outbreak. The results and uncertainties are discussed, to evaluate final hypothesis.

The conclusions in Section 6 summarise the outcome of the back-tracing investigations and result in the recommendations in Section 7.

More detailed information on the findings can be found in the appendices, including information on the starting points (Appendix A) and the evaluation of "Hotspots" (Appendix B), data on berry production and trade (Appendix C) and the Food Questionnaire used in several EU Member States (Appendix D).

ASSESSMENT

1. Outbreak description

1.1. General background

Hepatitis A virus (HAV) is a small, non-enveloped hepatotropic virus classified in the genus Hepatovirus within the family Picornaviridae. Its genome consists of a 7,500-nucleotide, linear, positive-stranded RNA. Genotypes have traditionally been defined based on analysis of a 168-nucleotide segment of the VP1–2a region, and more recently on the complete VP1 region. Based on this sequence, six HAV genotypes with >15% nucleotide difference have been defined: genotypes I to VI. Genotypes I, II and III are further divided into subtypes A and B, with genetic difference of ~7–7.5% between subtypes in the VP1–2a region. Genotypes I, II and III have been associated with infections in humans, while genotypes IV–VI are simian in origin. HAV genotypes and subtypes exhibit a particular geographic distribution. Worldwide, genotype I is the most prevalent, with subtype IA being more common than IB. In general, sampling of HAV strains results in identification of co-circulation of IA and IB strains, with the minority subtype usually accounting for <5% of HAV strains. Subtype IA constitutes a major fraction of genotype I strains circulating in South and North America, Europe, Asia and Africa. Subtype IB is predominant in the Middle East, South Africa and in certain areas of South America. Genotype II is less common than genotype I, while genotype III has a global distribution and has been identified in certain countries of Europe and Asia (Desbois et al., 2010; Vaughan et al., 2013).

HAV infection is highly transmissible. The disease, often asymptomatic or mild, particularly in children under five years old, has an average incubation period of 28 to 30 days (range 15–50 days). In adults, the onset of illness is usually abrupt, with fever, malaise and abdominal discomfort. Jaundice is the predominant symptom. Symptoms may last from one or two weeks to months. Prolonged, relapsing hepatitis for up to one year occurs in 15% of cases. No chronic infection is known to occur and infection confers lifelong immunity (Heymann, 2008).

The case-fatality ratio is low (0.1–0.3 %) but might be higher (1.8%) in adults over 50 years of age or in persons with underlying chronic liver disease (Koff, 1998; Heymann, 2008). The maximum infectivity is in the second half of the incubation period (i.e. while asymptomatic) and most cases are considered non-infectious after the first week of jaundice. No pharmacological treatment exists for HAV. Strict control measures, such as enforcing personal hygiene, contact tracing and immunisation of exposed persons, have shown to be effective (Latimer et al., 2007; Sunthornchart et al., 2008). Active (antigen) and passive (antisera) immunisation is effective if administered within two weeks of exposure. Several inactivated vaccines are available for prevention.

HAV can be transmitted through consumption of water or food which is contaminated with human faeces and via the faecal–oral route among close contacts (e.g. household contacts, sexual contacts, in day-care centres or schools (Pebody et al., 1998; Hanna et al., 2001; Blystad et al., 2004; Dakic and Musa, 2013)). The following risk factors or risk groups have also been associated with illness in outbreaks: use of contaminated blood products (Vonberg and Gastmeier, 2007); people who inject drugs (Widell et al., 1983; O'Donovan et al., 2001; Ngui et al., 2008) or use other illicit drugs (James et al., 2009); men having sex with men (MSM) (Blystad et al., 2004); and homeless people (Tjon et al., 2005; James et al., 2009).

EU/EEA MSs report HAV infections notified in their countries to The European Surveillance System of ECDC (TESSy) once per year. The MS surveillance systems are heterogeneous, and only a proportion of countries perform molecular surveillance for HAV. The notification rate in the EU for HAV has been steadily decreasing over the past 15 years, from 14.0 in 1997 to a relatively low rate of 2.5 per 100 000 population in 2011, despite the fact that some countries are still experiencing high notification rates (ECDC, 2007, 2013; see also Table 1). This overall decline in the notification rate most likely reflects improved living conditions, as HAV seroprevalence rates are strongly correlated

with socioeconomic status and access to clean water and sanitation (Jacobsen and Koopman, 2004). In terms of geographical distribution, the highest case rates and number of laboratory-confirmed cases in the past few years have consistently been observed in Bulgaria and Romania (ECDC, 2013). The highest notification rates in the EU are reported among the young (under 15 years old) (ECDC, 2013). The overall male-to-female ratio is 1.15 and there is a marked seasonal pattern, with a peak in the autumn, which may reflect increases following travel to endemic countries during summer holidays (ECDC, 2013). The low incidence in the EU population can result in a high proportion of susceptible individuals if vaccination coverage is low.

Table 1: Confirmed cases of hepatitis A reported to TESSy (The European Surveillance System) and notification rates per 100 000 population in the EU/EEA, 2007–2011 (source: ECDC Annual Epidemiological Report 2013)

Country	2011 Confirmed cases & rates		2010 Confirmed cases & rates		2009 Confirmed cases & rates		2008 Confirmed cases & rates		2007 Confirmed cases & rates	
	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate
Austria	5	0.06	54	0.65	1	0.01	4	0.05	5	0.06
Belgium	167	–	137	–	130	–	365	–	209	–
Bulgaria	5587	74.45	2350	31.07	1064	13.99	907	11.87	2790	36.33
Cyprus	0	0.00	2	0.24	4	0.50	4	0.51	4	0.51
Czech Republic	264	2.51	862	8.20	1104	10.55	1649	15.89	126	1.23
Denmark	13	0.23	47	0.85	45	0.82	44	0.80	306	5.62
Estonia	153	11.42	6	0.45	19	1.42	13	0.97	10	0.75
Finland	14	0.26	14	0.26	22	0.41	22	0.42	15	0.28
France	1115	1.71	1244	1.92	1547	2.40	1204	1.88	1010	1.59
Germany	820	1.00	775	0.95	929	1.13	1072	1.30	936	1.14
Greece	41	0.36	58	0.51	86	0.76	120	1.07	286	2.56
Hungary	79	0.79	202	2.02	107	1.07	168	1.67	251	2.49
Ireland	18	0.40	40	0.90	49	1.10	41	0.93	29	0.67
Italy	315	0.52	655	1.09	1580	2.63	1350	2.26	1159	1.96
Latvia	49	2.20	292	12.99	2276	100.65	2798	123.21	15	0.66
Lithuania	17	0.52	10	0.30	16	0.48	20	0.59	23	0.68
Luxembourg	0	0.00	2	0.40	5	1.01	3	0.62	1	0.21
Malta	4	0.96	3	0.72	9	2.18	4	0.98	3	0.74
Netherlands	115	0.69	252	1.52	154	0.93	87	0.53	165	1.01
Poland	62	0.16	153	0.40	644	1.69	189	0.50	36	0.09
Portugal	12	0.11	10	0.09	27	0.25	21	0.20	17	0.16
Romania	2581	12.05	3493	16.28	3734	17.37	3161	14.68	4982	23.10
Slovakia	400	7.36	1449	26.71	1447	26.74	729	13.50	383	7.10
Slovenia	11	0.54	9	0.44	12	0.59	17	0.85	15	0.75
Spain	463	1.00	740	1.61	1808	3.95	1877	4.15	698	1.57
Sweden	54	0.57	85	0.91	154	1.66	78	0.85	68	0.75
United Kingdom	277	0.44	408	0.66	437	0.71	794	1.30	377	0.62
EU total	**12636**	**2.54**	**13352**	**2.70**	**17410**	**3.53**	**16741**	**3.36**	**13919**	**2.83**
Iceland	1	0.31	2	0.63	3	0.94	1	0.32	2	0.65
Liechtenstein	–	–	–	–	–	–	–	–	–	–
Norway	22	0.45	46	0.95	40	0.83	49	1.03	29	0.62
EU/EEA total	**12659**	**2.51**	**13400**	**2.68**	**17453**	**3.51**	**16791**	**3.34**	**13950**	**2.81**

Foodborne transmission of HAV has been implicated in several outbreaks in recent years. Between 2007 and 2012, EFSA and ECDC reported 14 hepatitis A outbreaks in which there was strong

evidence of food being the infection vehicle. The suspected food vehicles were fish and seafood products (crustaceans, shellfish, molluscs and products containing these), sandwiches, vegetables, juices, semi-dried tomatoes, bakery products and other foods (EFSA and ECDC, 2009, 2010, 2011, 2012, 2013, 2014). Minimally processed food products may be the origin of foodborne outbreaks. For example, Australia reported an outbreak of HAV infection involving 144 cases in which frozen semi-dried tomatoes were identified as the vehicle of infection (Gallot et al., 2011). Semi-dried tomatoes were also implicated in simultaneous outbreaks involving 59 HAV cases in France in 2010 (Donnan et al., 2012) and 14 cases in the Netherlands (Petrignani et al., 2010), and were suspected in a cluster of cases in the United Kingdom and in the Netherlands in 2011 (Carvalho et al., 2012; Fournet et al., 2012). In August and November 2012, the Netherlands reported two clusters of HAV sub-genotype IA infection associated with consumption of mussels in the ECDC Epidemic Intelligence Information System for Food- and Waterborne Diseases (EPIS-FWD). In several outbreaks associated with fresh products, food handlers involved in harvesting or preparing foods have been identified as the original source (Craven et al., 2009). For example, in 2004, an outbreak of 269 cases detected in Belgium was associated with the consumption of raw beef, contamination of which was traced back to an infected food handler in a distribution plant (Robesyn et al., 2009).

Frozen raspberries were implicated in HAV infection outbreaks in 1987, with 24 HAV cases reported in Scotland, United Kingdom (Reid and Robinson, 1987). In 1997, an outbreak affecting 153 people, associated with consumption of frozen strawberries, was reported in Michigan, USA (CDC, 1997). More recently, in 2013, two multinational foodborne outbreaks of HAV infection affected EU/EEA countries. The first was reported in Finland, Denmark, Sweden and Norway and the second was reported in travellers returning from Egypt to several European countries; each outbreak affected over 100 patients. Foodborne transmission, through frozen and fresh strawberries respectively, was suspected in both outbreaks (ECDC, 2014). In addition, in 2013, a HAV infection outbreak was investigated in eight different states of the USA; pomegranate seeds from Turkey were implicated as the vehicle of infection (CDC, 2013). These three, so far unrelated, outbreaks were found to be associated with unique outbreak strains different from the one associated with the outbreak described in this document.

According to the RASFF database, 35 notifications of HAV in food were reported between 1999 and 2013. Contamination with HAV was found in eight EU countries (Belgium, the Czech Republic, Denmark, France, Germany, Italy, the Netherlands and Spain), in the following food items: shellfish (e.g. oysters, mussels, clams and scallops), semi-dried tomatoes, dates, frozen strawberries, strawberry yoghurt cake and frozen berry mix.

The virus is very resistant in the environment as well as to several preservation methods used in the food industry, e.g. acidification or freezing (Buisson et al., 1993; John and Rose, 2005; Gerba and Kennedy, 2007; Butot et al., 2008; Webert et al., 2008; Baert et al., 2009). In particular, according to several studies, the decontamination of berries proves to be difficult as the survivability of enteric viruses on frozen berries is quite long, with marginal reduction of the infectivity even after long periods of storage time (Butot et al., 2008, 2009). Considering the long shelf-life (up to 24 months) and the wide distribution of frozen berry products, contaminated lots may result in continuous source outbreaks of national or multinational size.

1.2. Case definition

The ECDC, in consultation with the affected MS, has developed a European epidemic HAV infection case definition for the purpose of identifying cases associated with the hepatitis A outbreak occurring in Europe in 2013 and 2014 **to establish the extent of this outbreak.** Due to the long period of the outbreak the case definition has changed during the work on this project. The following definition reflects the current status of the outbreak.

According to the European epidemic HAV infection case definition, a **confirmed case** is defined as:

> *An EU/EEA resident with laboratory confirmed HAV genotype IA*
>
> *and*
>
> *date of symptom onset (or date of testing if onset date not available) on or after 01/01/2013*[7]
>
> *and*
>
> *at least one of the following conditions:*
>
> 1) *identical sequence (i.e. 100.0 %) to the 2013 HAV genotype IA outbreak strain (GenBank accession number KF182323) based on a fragment of 460 nucleotides at the region of VP1–2a*[8]
> 2) *99.8 % similarity to this sequence (i.e. one nucleotide difference in 460 nucleotides)*
> 3) *identical sequence (i.e. 100.0 %) on a shorter fragment of at least 174 nucleotides at the region of VP1–2a*

According to the European epidemic HAV infection case definition, a **probable (suspect/possible) case** is defined as:

> *An EU/EEA resident with laboratory-confirmed HAV infection*
>
> *and*
>
> *date of symptoms onset (or date of testing if onset date not available) on or after 01/01/2013*[9]
>
> *and**fulfilling, within 15–50 days before onset, at least one of the following epidemiological criteria:*
>
> 1) *Having been in a country experiencing the outbreak during the indigenous outbreak period* [10]*;*
> 2) *Person-to-person contact with a confirmed case (secondary case).*

The following **exclusion criteria** for probable cases are applied:

> 1) *HAV confirmed case which has a different sequence type to the 2013 HAV genotype IA outbreak strain*
> 2) *Existence of an epidemiological link to the previous exclusion criterion number 1;*
> 3) *History of travel out of the EU/EFTA within 15-50 days before disease onset.*

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[7] At the time of writing this report, outbreak cases were still being reported by at least one EU/EEA country; hence no end date for the outbreak case definition could be defined.

[8] For Norwegian isolates, identical sequence to GenBank number KF773842 based on a fragment of 466 nucleotides at the region VP3–VP1. Further details in section 1.4.

[9] Same as above: at the time of writing this report, outbreak cases were still being reported by at least one EU/EEA country; hence no end date for the outbreak case definition could be defined.

[10] As of 30 June 2014, these are Finland from January to June 2014; Ireland from January to October 2013; Italy from January 2013 onwards; Netherlands from August to December 2013; Norway from November 2013 to April 2014.

For the additional purpose of assisting in the food trace back exercise, any secondary confirmed or probable case (having person-to-person contact with a confirmed case) is excluded.

In addition, the definitions of a secondary case and a travel-related case are as following.

A secondary case: a person with no reported exposure to berries, who was judged to have acquired infection by secondary transmission via person-to-person or unknown route.

A travel-related case: a person with a history of travel abroad 15 to 50 days prior onset of symptoms.

1.3. Outbreak detection and descriptive epidemiology

On 8 May 2013, Germany reported in the EPIS-FWD (Gossner, 2013) and in the formal Early Warning and Response System (EWRS) (Guglielmetti et al., 2006) seven cases of HAV genotype IA infection in persons with a travel history to ski resorts in northern Italy. EPIS-FWD is an informal restricted web-based platform bringing together EU/EEA multidisciplinary experts to ensure the early detection and communication of multinational food- or waterborne outbreaks; EWRS is an EU/EEA restricted web-platform platform to ensure rapid and effective response to cross-border health threats related to communicable diseases.

Following the alert from Germany, Italy reported on EPIS-FWD an increase in the number of HAV cases at the national level and declared an outbreak. Some of the cases identified were infected with HAV OS.

Since May 2013, confirmed and probable cases (as per case definition in section 1.2) were reported in Italy on a monthly basis. Confirmed or probable cases with a travel history to Italy were also reported by Bulgaria, Denmark, Germany, Ireland, the Netherlands, Poland, Sweden and the United Kingdom. In addition, Finland, Ireland, the Netherlands and Norway reported clusters or outbreaks of confirmed cases with no travel history. France, Germany, Sweden and the United Kingdom also reported sporadic confirmed cases of hepatitis A in patients with no travel history. All confirmed cases were infected with HAV OS.

Since 1 January 2013, 1 444 cases associated with this HAV infection outbreak have been reported by 12 EU/EEA countries (Table 2). The most recent case was reported on 4 June 2014 in Finland. Of the overall 1 444 cases, 331 (22.9 %) were confirmed and 1 113 probable (77.1 %). Italy reported 90 % of all cases. Of the 144 cases reported by other EU/EEA countries, 41 were probably infected in Italy and one in Norway (reported from Germany); of the remaining 102 cases, 100 most likely acquired their infection domestically, and for two this information is not available. A total of 811 cases were reported as primary cases and 34 as secondary (for 599 cases this information is not available).

Table 2: Confirmed and probable hepatitis A cases by reporting country and travel history to an outbreak-country during the country's national outbreak period, European multinational HAV infection outbreak 2013–2014, as of 30 June 2014 (information for May and June 2014 may be incomplete)

Reporting country	Cases reported		Confirmed cases		Travel-related cases to an outbreak country [a), b)]	
	No	% overall	No	% reported	No	% reported [c)]
Bulgaria	1	0.1	0	0.0 %	1	100.0
Denmark	1	0.1	1	100.0 %	1	100.0
Finland	11	0.8	5	45.5 %	0	0.0
France	5	0.3	5	100.0 %	0	0.0
Germany	35	2.4	9	25.7 %	25	71.4
Ireland	25	1.7	21	84.0 %	4	16.0
Italy	1 300	90.0	228	17.5 %	0	0.0
The Netherlands	15	1.0	15	100.0 %	1	6.7
Norway	31	2.1	31	100.0 %	0	0.0
Poland	6	0.4	3	50.0 %	6	100.0
Sweden	10	0.7	9	90.0 %	2	20.0
United Kingdom	4	0.3	4	100. %	2	50.0
Total	**1 444**	**100.0**	**331**	**22.9 %**	**42**	**2.9**

(a): For one French and one British case, this information is not available.
(b): As of 30 June 2014, these are Finland from January to June 2014; Ireland from January to October 2013; Italy from January 2013 onwards; Netherlands from August to December 2013; Norway from November 2013 to April 2014.
(c): Not including cases in residents of the same country (e.g. Finnish cases excluded from Finland).

The highest number of cases associated with this outbreak was reported in April 2013 (Figure 1). From March to October 2013, more than 100 cases were reported each month. Since November 2013 the number of cases reported per month has decreased to below 70.

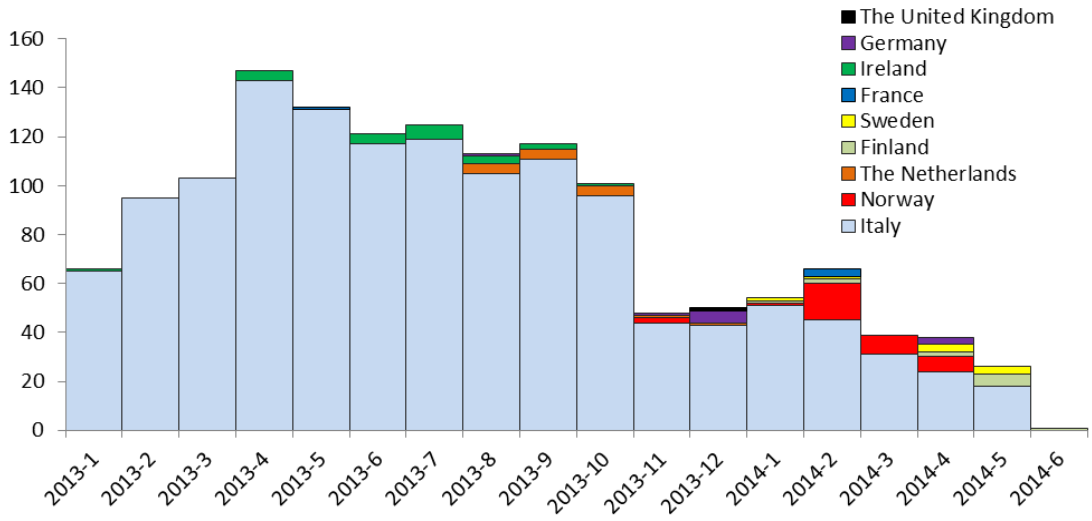


Figure 1: Distribution of total cases of hepatitis A by month of onset and by probable country of infection, European multinational HAV infection outbreak, January 2013 to June 2014, as of 30 June 2014 (n = 1 442; information for May and June 2014 may be incomplete). Information on the month of onset is not available for two cases (one British and one French)

Overall, at the EU level, the median age of confirmed or probable cases associated with this outbreak was 37 years (ranging from 1 to 92 years; 1 440 cases with available information) and 54 % were male (1 441 cases with available information) (Figure 2).

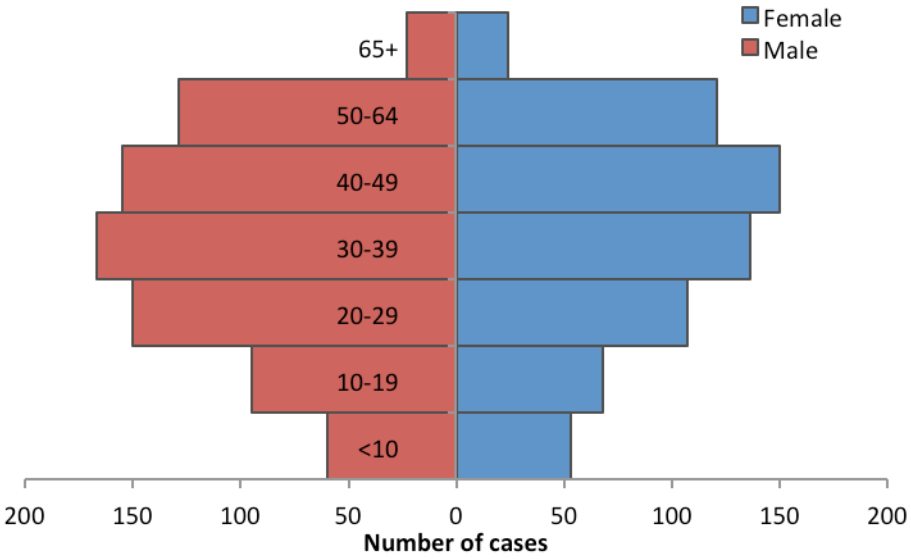


Figure 2: Age and sex distribution of confirmed and probable cases of hepatitis A, European multinational HAV infection outbreak 2013–2014, as of 30 June 2014 (n = 1 398; information on sex and/or age is missing for six cases)

Of the five EU/EEA countries that reported a hepatitis A outbreak, Italy reported most of the confirmed and probable cases for the entire duration of the outbreak (Figure 3). The highest number of cases reported in Italy is in April 2013, while confirmed cases peaked in June 2013. The large proportion of probable cases reported and the delay in the Italian peak of confirmed versus probable

cases can be explained by the fact that sequencing was performed on only a proportion of isolates, mostly from May to July 2013, after the outbreak was declared. Furthermore, 41 additional confirmed and probable cases reported by different EU countries were likely to have acquired their infection in Italy (Figure 3).

Ireland reported 21 confirmed cases with no travel history to an outbreak country and onset from April to October 2013 (Figure 4). The Netherlands reported 14 confirmed cases with no travel history and onset from August to December 2013 (Figure 5). Norway reported 31 confirmed cases with no travel history; in addition, one confirmed German case is likely to have acquired infection in Norway in March 2014 (Figure 6). Finland reported 11 confirmed and probable cases with no travel history and date of onset from January to June 2014; 5 of the 11 cases had onset in April 2014 (Figure 7).

Most cases reported in Germany had a travel history to Italy (n = 19) and one case to Norway; however, in November and December 2013, and in April 2014, Germany also reported six confirmed and four probable cases with no travel history. The United Kingdom reported four confirmed cases, of which two had a travel history to Italy, one could not be interviewed and one, with onset in December 2013, had no travel history outside the United Kingdom. Sweden reported nine confirmed cases and one probable case, two of which had a history of travel to Italy; the remaining eight cases did not have a travel history and had onset between January and May 2014. France reported five confirmed cases with no travel history, three of which had symptoms onset in February 2014 and were found to have an epidemiological link. The additional MSs involved, namely Bulgaria, Denmark and Poland, reported only cases with travel history to Italy.

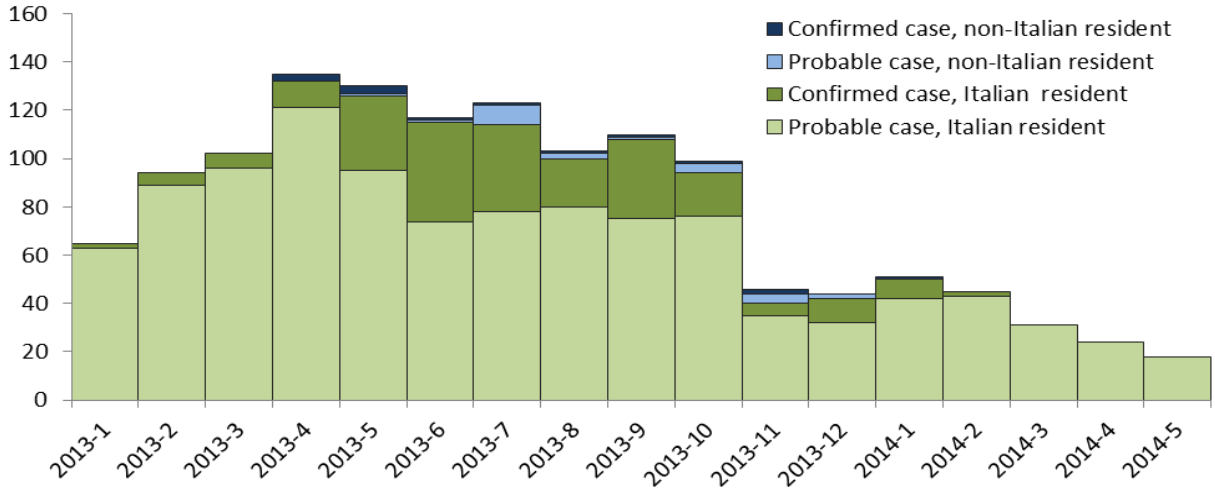


Figure 3: Confirmed and probable cases of hepatitis A probably acquired in Italy by month of onset and residency (Italian/non-Italian), European multinational HAV infection outbreak, January 2013 to May 2014, as of 30 June 2014 (n = 1 300; information for May 2014 may be incomplete)

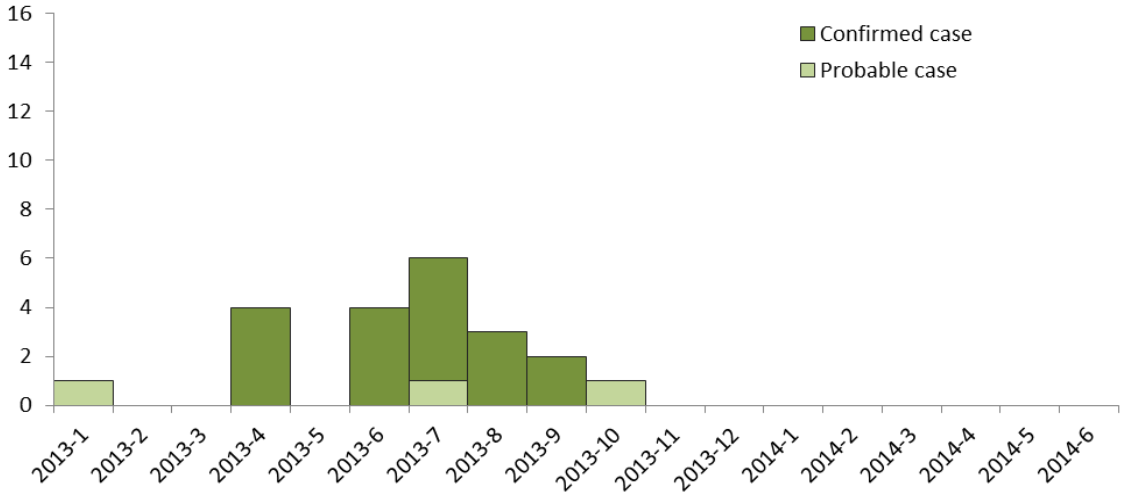


Figure 4: Confirmed and probable non-travel-related cases of hepatitis A reported by Ireland by month of onset, European multinational HAV infection outbreak, January 2013 to June 2014, as of 30 June 2014 (n = 21; information for May and June 2014 may be incomplete)

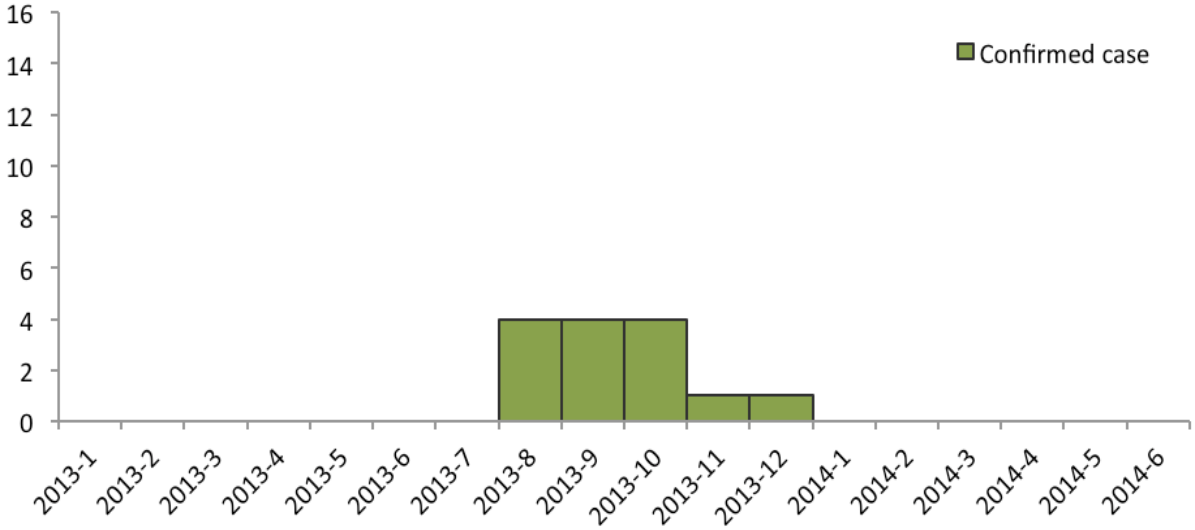


Figure 5: Confirmed and probable non-travel-related cases of hepatitis A reported by the Netherlands by month of onset, European multinational HAV infection outbreak, January 2013 to June 2014, as of 30 June 2014 (n = 14; information for May and June 2014 may be incomplete)

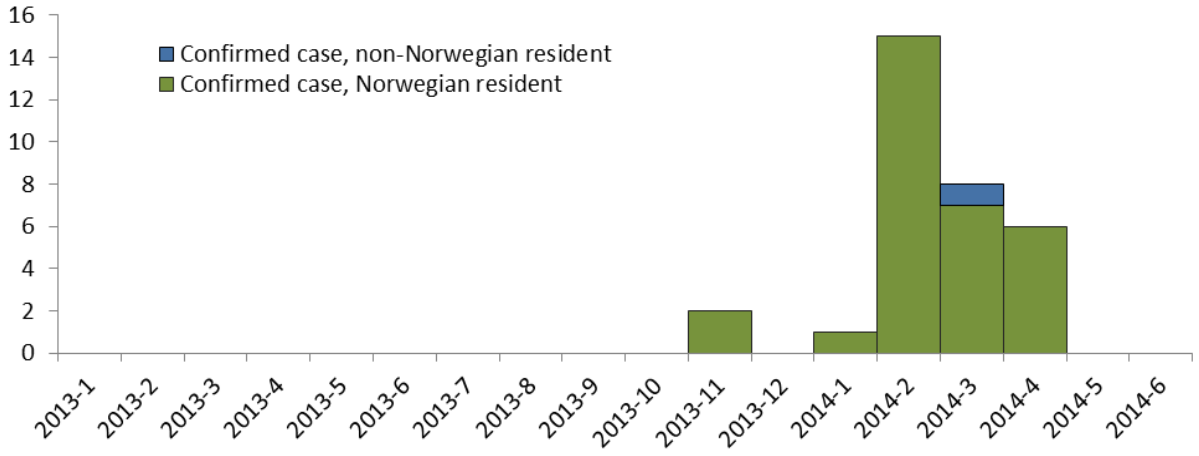


Figure 6: Confirmed and probable cases of hepatitis A probably acquired in Norway by month of onset and residency (Norwegian/non-Norwegian), European multinational HAV infection outbreak, January 2013 to June 2014, as of 30 June 2014 (n = 31; information for May and June 2014 may be incomplete)

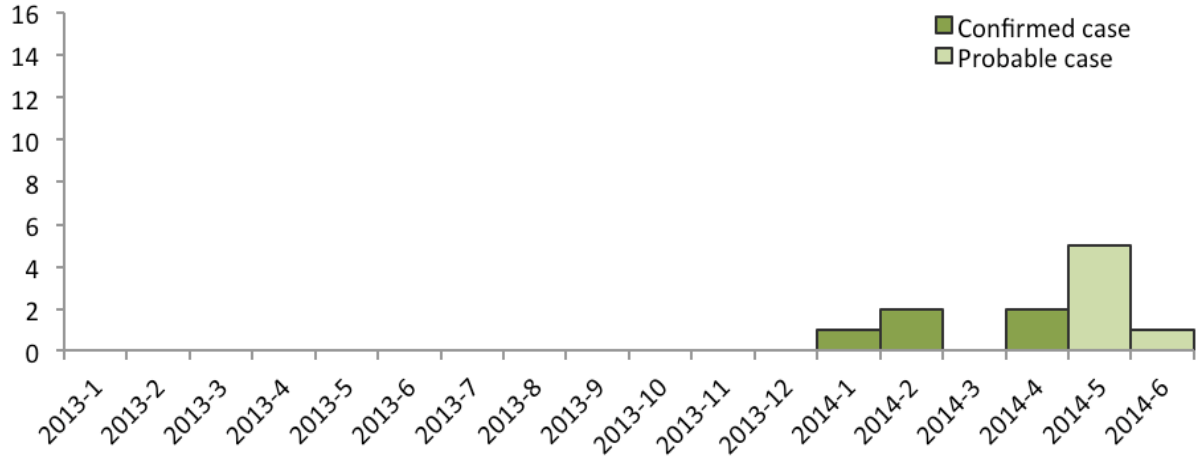


Figure 7: Confirmed and probable non-travel-related cases of hepatitis A reported by Finland by month of onset, European multinational HAV infection outbreak, November 2013 to June 2014, as of 30 June 2014 (n = 11; information for May and June 2014 may be incomplete)

Figures 3–7 depict the distributions of onset symptoms in the five EU/EEA countries experiencing national outbreaks of hepatitis A in cases with no travel history. While Italy reported cases throughout the duration of the outbreak, Finland, Ireland, the Netherlands and Norway reported cases in different time periods. It is likely that exposures to contaminated food items also occurred at different times.

Italy appears to be the country most affected by the outbreak. It must be remembered that, as only a low proportion of isolates (17.5 %) have been sequenced, the overall number of cases associated with the outbreak could be over-estimated. On the other hand, sequencing practices for HAV isolates are not standardised and only a proportion of EU/EEA countries perform HAV RNA sequencing on a routine basis. The vast majority of these countries have reported cases associated with this outbreak. Therefore, despite an increase in HAV typing since the outbreak declaration, it is likely that cases infected with HAV OS have not been identified in countries not performing HAV molecular surveillance. To date no deaths have been reported associated with this outbreak; however,

surveillance systems for HAV infections are not always able to capture this information. Information on hospitalisations, liver transplants and other critical outcomes has not been collected for this report.

1.4. Summary of microbiological investigations

Information on the molecular characterisation of isolates is available for the 331 confirmed cases. All isolates are sub-genotype IA and share an identical sequence. The outbreak sequence GenBank accession number is KF182323 and the sequence is available on EPIS-FWD or from ECDC upon request. The British and Irish reference laboratories sequenced genomic regions of approximately 400 nucleotides at the VP1–2a junction. The German reference laboratory sequenced a genomic region 349 nucleotides long at the VP1–2a junction. All other laboratories, except the Italian regional laboratories and the Norwegian reference laboratory in the initial phase, used a common protocol from the Dutch National Institute for Public Health and the Environment (available on request from HAVNET@rivm.nl) and sequenced a genomic region of 460 nucleotides in the VP1–2a region. Italian regional laboratories used different protocols for VP1–2a regions, sequencing ranging from 225 to 360 nucleotides, resulting in a 174 nucleotide region common to all sequences by countries. The Norwegian reference laboratory initially sequenced a region of 466 nucleotides of the VP3–VP1 junction of all isolates. For 14 of these, the VP1–2a region was also sequenced. All isolates proved to be identical in both regions sequenced. The Netherlands reported that the HAV OS is identical to that of an outbreak in Prague, Czech Republic, in 2008 (Castkova and Benes, 2009).

1.5. Summary of epidemiological investigations

1.5.1. Patient interviews

Since August 2013, the majority of the cases in the affected MSs have been interviewed using questionnaires adapted from the questionnaire initially developed by the HPSC, Ireland, and shared with all the affected MS through EPIS-FWD (see Appendix D). Consumption of mixed frozen berries has been implicated as a source of HAV infections since the beginning of the investigations in May 2013. Information on consumption of berries (i.e. fresh or frozen) during the relevant exposure period was available for 742 cases: of these, 477 (64.3 %) recalled having consumed berries. Restricting the analysis to confirmed cases, information is available for 245 cases (74.0 % of all confirmed cases): of these, 198 (80.1 %) reported consumption of berries during the relevant exposure period (Figure 8). Data from the EFSA Comprehensive Database, including information for 52 852 subjects, show that 24.3 % of European consumers consumed berries at least once during the outbreak period (EFSA BIOHAZ Panel, 2013).

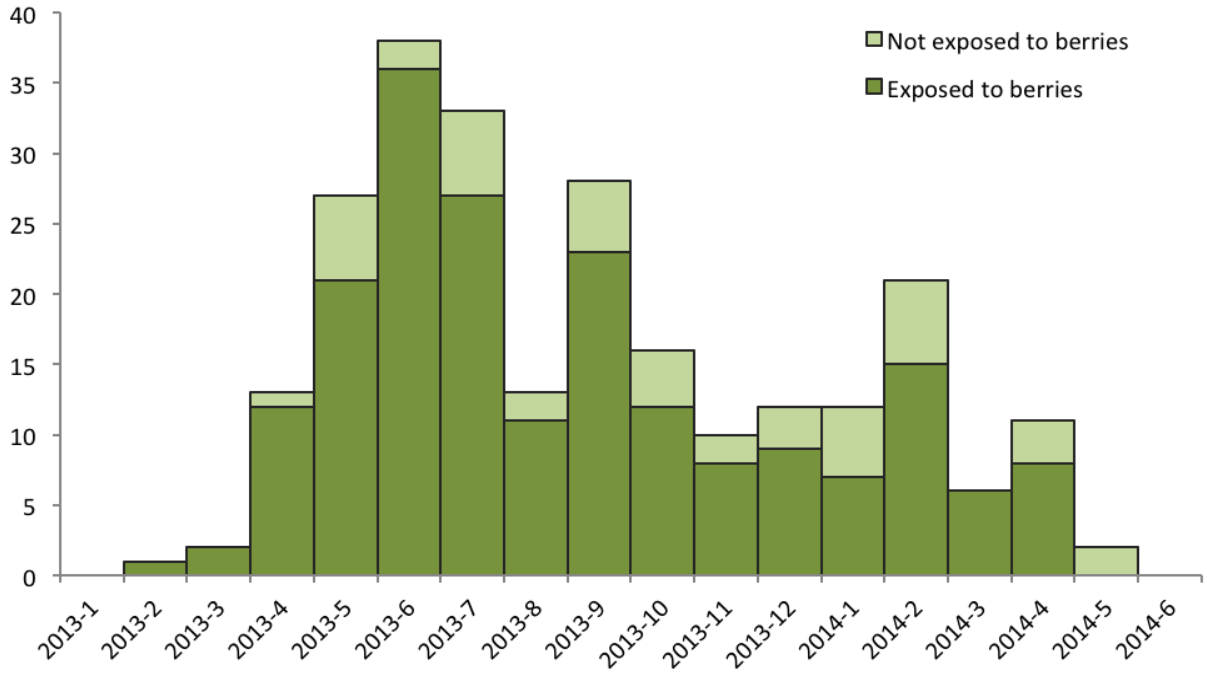


Figure 8: Confirmed cases with known status of exposure to berries by month of onset (n = 245), European multinational HAV infection outbreak 2013–2014, as of 30 June 2014 (information for May and June 2014 may be incomplete; information missing for 86 confirmed cases)

It is noteworthy that the exposure to berries may be subject to recall bias, owing to the long interval between exposure and onset of symptoms/diagnosis and the fact that berries may be a minor ingredient or used as a decoration in the food. Therefore, the proportion of confirmed cases exposed to berries might be even higher than reported, while the lack of exposure to berries might be explained by a different or a secondary route of transmission (e.g. cross-contamination, person-to-person transmission).

1.5.2. Analytical epidemiological studies

Retrospective case–control studies were carried out separately in Italy, Ireland and Norway in order to identify risk factors for HAV infection and test the hypothesis of an association between hepatitis A and consumption of frozen berries. The results are presented in section 2.

2. Investigations in related countries

This section summarises the general situation of HAV surveillance in the outbreak countries, as well as in some countries which were involved in the tracing activities. Special emphasis is given to the description of epidemiological or microbiological investigations related to the specific outbreak.

2.1. Investigations in Italy

Background

In Italy, hepatitis A is mandatorily reported to the Italian National Surveillance System (Ministerial Decree of 5/7/1975, modified on 15/12/1990). In parallel, in order to strengthen the surveillance and to promote the investigation of risk factors associated with acute viral hepatitis, a sentinel surveillance system for acute viral hepatitis (SEIEVA—Sistema Epidemiologico Integrato Epatiti Virali Acute) was implemented in 1984.

Hepatitis A in Italy is present both in sporadic and endemic–epidemic form, depending on the region. Over the last decade, the disease had declined, stabilising at less than 1 case per 100 000, in all age groups.

Following the EPIS-FWD and EWRS alerts in early May 2013 concerning HAV cases from Germany, Poland and the Netherlands, a series of actions were immediately undertaken by the Italian health authorities in order to manage and control the outbreak. In particular, the following specific recommendations were provided by the Ministry of Health (MoH): enhance surveillance and awareness of HAV, collect additional epidemiological information on associated risk factors and characterise the virus RNA by genotyping and sequencing at the VP1–2a region from a sample of new cases (as in Italy genotyping and sequencing are not normally performed on a routine basis).

Preliminary investigations were concentrated in the area in northern Italy where the German, Polish and Dutch cases had travelled: sequencing of the VP1–2a region of the virus derived from five resident cases, one Dutch case and two German cases showed 100 % sequence identity. The sequence of the outbreak strain was further characterised and the sequence submitted to GenBank (GenBank accession number KF182323). The preliminary epidemiological investigation conducted in the Autonomous Province (AP) of Trento and Bolzano showed that the only food common to the different cases was mixed frozen berries. Berries eaten by cases in another region, Veneto, tested positive for HAV. The VP1–2a region of the virus from the berries showed 100 % sequence identity to the human isolates.

On 23 May 2013, the MoH designated a multidisciplinary task force to coordinate at national level the investigation of the 2013 HAV outbreak in Italy. The task force operated in close cooperation with the regional and the local public health and food safety authorities. The members of the task force included public health and veterinary epidemiologists, virologists and food safety microbiologists as well as the national RASFF contact point and experts in trace-back activities.

For the enhanced HAV surveillance, cases were defined according to the EU case definition.

The outbreak investigation included descriptive epidemiology and a case–control study, microbiological testing of food specimens, molecular typing of positive human and food specimens and food tracing investigations.

2.1.1. Epidemiological and microbiological results

From 1 January 2013 to the end of June 2014 a total of 1 300 cases of HAV were reported according to the European epidemic HAV case definition (322 cases were excluded because they reported having

travelled out of the EU/EFTA in the period 15–50 days before disease onset). HAV notifications in 2013 were 4-, 3- and 2-fold higher than in the same period in 2012, 2011 and 2010, respectively.

The greatest increase in the number of cases was observed in northern Italian regions (Trento, Bolzano, Emilia-Romagna, Lombardy, Friuli Venezia Giulia, Piedmont, Veneto and Tuscany), which accounted for 70 % of the total cases recorded in 2013. These regions have a total population of 20 million. Another region that showed an increase in the number of cases in 2013 is Apulia (in southern Italy), which recorded an 11-fold increase in the number of cases.

The median age of cases was 34 years (range 1–92 years). The cases were equally distributed among men and women: 55 % of the cases were men and 45 % were women. As of July 2014, no acute liver failures and deaths have occurred.

Owing to the large extent of the outbreak, molecular sequencing has been conducted on only a proportion of isolates, mostly between May and July 2013. Between 1 January 2013 and July 2014, the National Reference Laboratory of the National Public Health Institute (ISS) conducted genotyping and characterisation by nested polymerase chain reaction (PCR) and sequencing of HAV isolates from anti-HAV immunoglobulin M (IgM)-positive serum samples sent from Italian hospitals nationwide and analysed VP1–2a sequences received from five regional reference laboratories (Emilia-Romagna, Lazio, Lombardy, Puglia and Veneto). Viral RNA is extracted, sequenced and genotyped at the VP1–2a region using a protocol supplied by RIVM. Up to November 2013, a total of 352 clinical samples had been analysed. The available sequences were linked to the notification database, and for 346 sequences it was possible to obtain epidemiological information (all the sequences excluded were the OS sequence). A total of 228 cases showed a sequence with 100 % nucleotide identity to the OS sequence isolated from the frozen berries sample and 118 cases were classified as non-outbreak strains and therefore excluded from the analysis.

With regard to the consumption of berries, among confirmed cases who reported the information, 78 % (127 out of 162) declared to have consumed frozen mixed berries in the six weeks before the symptom onset.

A retrospective matched case–control study was performed to identify risk factors for HAV infection acquired, from 1 January to 31 May 2013, in some of the regions where the largest increase in the number of cases was observed (Trento, Bolzano, Emilia-Romagna, Friuli Venezia-Giulia and Apulia).

A case was defined as a symptomatic person, positive for HAV IgM, with onset of symptoms (or date of testing if onset date was not available) from 1 January 2013 until 31 May 2013. For Apulia, where HAV is endemic and where molecular typing of the viruses isolated from cases is standard procedure, only cases presenting with HAV OS and sub-genotype 1A were included in the study.

Potential controls were selected from the general population resident in the five Italian regions matching each case by age (± 3 years) and place of residence (individual matching). The exclusion criteria for controls were: had been diagnosed with hepatitis A in the past, had previously presented symptoms consistent with a diagnosis of hepatitis A (i.e. jaundice + dark urine) or had been vaccinated against hepatitis A.

Moreover, we conducted a second analysis focusing only on those cases in whom HAV had been sequenced and identified as the “outbreak” sequence and their matched controls.

The potential risk factors explored were the consumption of mixed frozen berries, other food items described as potential sources of HAV infection and history of travel (Table 3).

Up to four matched controls for each case were selected (assuming 5 % exposure among controls, 80 % power to detect a minimum OR of 3, alpha error of 5 %). The minimum sample size necessary was estimated to be of 555 (444 controls and 111 cases).

The study included a total of 538 subjects, 119 cases (22.1 %) and 419 controls (77.9 %). The median age was 37.0 years (range 3–70 years) for HAV cases and 38.0 years (range 1–72 years) for controls (p = 0.6384). The majority of study participants in both groups were male. No significant difference in the sex of cases and controls was observed. As a result, a median of 3.5 controls for each case were included in the study.

In the univariate analysis, compared with the 419 controls, cases were more likely to have eaten berries (OR 4.42) or raw seafood (OR 4.65) or to have travelled (OR 2.34) (Table 3). In the multivariate analysis, the highest association with the illness was for people who consumed berries (OR_{adj}, 4.2; 95 % CI, 2.54–7.02) (Table 3).

Table 3: Consumed foods and other risk factors positively associated with hepatitis A on univariate and multivariate analysis

Consumed foods and other risk factors	Odds Ratio, crude (95 % CI)	Odds ratio, adjusted (95 % CI)	p-value
Vegetables			
Fennel	1.03 (0.66–1.62)		
Fresh salad	1.02 (0.57–1.73)		
Bag salad	0.93 (0.59–1.45)		
Radishes	0.77 (0.44–1.34)		
Carrots	0.70 (0.43–1.12)		
Celery	1.29 (0.80–2.07)		
Raw seafood	4.65 (2.70–8.00)	3.83 (2.16–6.79)	< 0.001
Milk products (non-packaged)	0.62 (0.37–1.02)		
Untreated water	0.77 (0.39–1.50)		
Berries	4.42 (2.70–7.27)	4.22 (2.54–7.02)	< 0.001
Travel	2.34 (1.45–3.77)	1.98 (1.15–3.40)	0.014
Age	1.02 (0.93–1.13)		
Sex	0.83 (0.55–1.26)		

Of the 119 cases enrolled in the study, 24 were sequenced by the time of the study. The date of onset of hepatitis of sequenced cases was from January to May 2013. The sequenced viruses had nucleotide identity of between 99.8 % and 100 % to the outbreak strain (HAV genotype 1A). A restricted statistical analysis was conducted on the 24 cases and 82 matched controls in order to confirm the above-described results. Seventeen out of the 24 cases (70.8 %) ate berries and 10 of 24 (41.7 %) ate raw seafood. No significant difference in the sex of cases and controls was observed within the restricted analysis either. The statistical analysis identified berries as the highest associated risk factor for developing the disease (OR_{adj} 4.99; 95 % CI 1.32–18.92), followed by raw seafood (OR_{adj} 4.46; 95 % CI 1.10–18.04).

As all cases from the Apulia region reported having eaten raw seafood, an analysis excluding cases from this region was undertaken and resulted in berries being the unique risk factor for the disease with an OR of 7.29 (95 % CI 1.56–34.02).

Table 4: Summary of case–control study in Italy

Case definition	Symptomatic person (EU case definition 2012) Positive for HAV IgM Onset of symptoms from 1 January to 31 May 2013 After the identification of the "outbreak" sequence, only HAV OS was included in the study
Identification of cases	Hepatitis A is a notifiable disease in Italy. Clinicians are obliged to notify all cases identified. On 23 May the Ministry of Health published a note for regional health authorities in order to enhance surveillance and awareness of HAV, recommending that any new HAV cases be reported within 24 hours, that additional epidemiological information on associated risk factors be collected and that virus genotyping and sequencing be performed in new cases
Selection of controls	Potential controls were selected from the general population from GP and/or regional (if available) registry lists in participating Italian regions
Definition of controls (e.g. no history of travel)	Controls were excluded if they had been diagnosed with hepatitis A in the past, had previously presented symptoms consistent with a diagnosis of hepatitis A (i.e. jaundice + dark urine) or had been vaccinated against hepatitis A
Number of cases	A total of 127 cases were enrolled, but only 119 were included after applying the exclusion criteria
Number of controls	A total of 461 controls were enrolled, but only 419 were included after applying the exclusion criteria
Matching of controls (e.g. age and sex)	Age (± 3 years) and place of residence
Ascertainment of exposure (e.g. interview, self-report)	Telephone interview
Response rate	
Exposures assessed in the study (e.g. food items, travel)	History of travel For each of the following foods, respondent was asked to specify frequency, place of consumption (if at home specifying place of purchase and brand and if at a restaurant/bar specifying where): Raw vegetables, specifying type of vegetables (fennel, fresh salad, bag salad, radishes, carrots, celery) Raw seafood, specifying type Milk products (non-packaged), such as mozzarella, ricotta, fresh cheese History of drinking any untreated water (from a pond, stream, spring or lake) Berries, specifying type of berry and if frozen, fresh or dried
Results (list risk factors, OR and CIs)	In the multivariate analysis, berries were the risk factor most strongly associated with the disease (OR_{adj} 4.22; 95 % CI 2.54–7.02), followed by two well-known risk factors in Italy: consumption of raw seafood (OR_{adj} 3.83; 95 % CI 2.16–6.79) and travel to an endemic area (OR_{adj} 1.98; 95 % CI 1.15–3.40) Genotyping results were available for 24/119 cases sequences, all with 100 % nucleotide homology with the VP1–2a a region (identical to the sequence isolated from the frozen berries). When restricting the analysis to cases for which sequencing data were available, the statistical analysis identified berries as the risk factor most strongly associated with developing the disease (OR 4.99; 95 % CI 1.32–18.92), followed by raw seafood (OR 4.46; 95 % CI 1.10–18.04)

Starting from November 2013, at national level, a progressive reduction in the number of cases has been observed, and in May 2014 the numbers of notifications were similar to those observed in the previous three years (2010–-2012). However, when analysing the data by region, in the first quarter of 2014 (January to March 2014), in two regions (Central Italy) the number of reported cases was similar

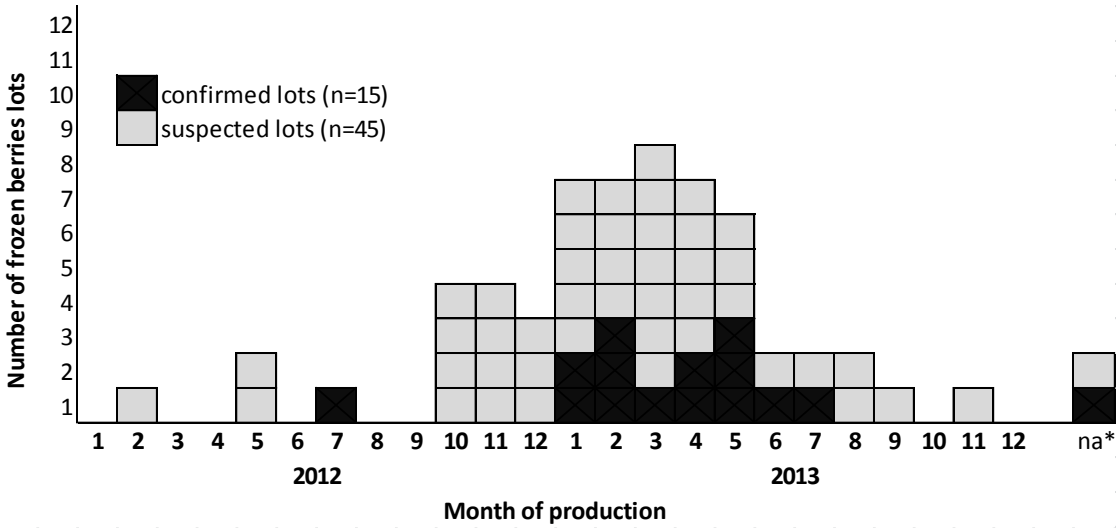
to the number of cases reported in the same period of 2013 (January to March 2013) and 10-fold higher than in the same period of previous three years (2010–2012).

2.1.2. Tracing-back data collection and microbiological investigation on frozen berries

Frozen berry lots possibly linked to the HAV outbreak were identified in Italy by sampling frozen berry products and testing for the presence of HAV and by back-tracing the products that possible and confirmed cases had consumed in the 50-day period before the onset of symptoms. Frozen berry lots were classified as follows:

- Confirmed lot: any batch of frozen berries (brand + lot number) with a positive analytical result for the presence of HAV.
- Suspect lot: any batch of frozen berries (brand + lot number) consumed by at least one patient affected by hepatitis A after 1 January 2013.
- Possible product: any brand of frozen berries consumed by at least one patient affected by hepatitis A after 1 January 2013 in Italy, before the onset of symptoms, for which the lot number could not be identified.

Overall, 15 confirmed and 45 suspected lots manufactured by 11 frozen berry packing companies (9 Italian and 4 in other EU MSs) have been identified. Moreover, two possible products have also been reported. The last confirmed and suspected lots were identified on 1 October 2013 and 6 December 2013, respectively. Dates of production of the identified confirmed ad suspected frozen berry lots ranged between 7 February 2012 and 7 November 2013 (Figure 9).



*na, information not available

Figure 9: Distribution of confirmed and suspected lots of frozen berries identified in Italy, by month and year of production.

During the outbreak, a large number of frozen berries samples were collected from all over the country and tested for HAV contamination. Samples were taken either as part of the official control activities or from companies within Hazard Analysis and Critical Control Point (HACCP) plans. Most of the analytical assays were carried out by the Istituto Zooprofilattico Sperimentale della Lombardia ed Emilia Romagna (IZSLER)—National Reference Centre for Emerging Risks in Food Safety, using an

accredited in-house developed method[11], based on nested PCR. The laboratory of the Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta (IZSPLV), also performed laboratory investigation on frozen berries samples using the same method. A total of 15 samples of mixed frozen berries were tested positive (see Table 44). As a preliminary result, the VP1–2a sequence could be obtained from one of the positive frozen berry samples and showed 100 % similarity to the outbreak sequence obtained from human epidemic cases. HAV whole-genome sequences from this sample and from another frozen berry sample that was taken from an open bag at a patient's home were obtained. The two genomes were 99.9 % similar and their VP1–2a a sequences were 100 % similar to the outbreak sequence (Chiapponi et al., 2014). However, because of the circumstances of sampling, this second sample was neither back-traced nor considered among the positive contaminated lots. The total number of frozen berry samples that have been examined in Italy since the onset of the epidemic outbreak, by reasons for sampling and by type of berry, is summarised in Table 5.

Table 5: Frozen berry samples examined in 2013 and 2014 by the laboratories of the IZSLER and the IZSLPV for HAV contamination, since the beginning of the HAV epidemic outbreak in Italy

Type of frozen berry	Reason for sampling	
	Official control	HACCP/other reasons
Mixed berries	251	683
Strawberry	5	74
Raspberry	30	113
Bilberry/blueberry	17	38
Cranberry	1	9
Redcurrant	14	68
Blackberry	2	3
Other	2	
Total samples tested	**322**	**988**

Contaminated lots were withdrawn from the market and promptly recalled after the detection of HAV contamination. RASFF alert notifications and news were published after the identification of positive lots (RASFF/2013 694, 756, 757, 880, 1087, 1091, 1229, 1334, 1350, 1403, 1602).

Soon after a positive HAV contaminated lot had been detected, the production site of the Italian packing companies that had manufactured the lots was inspected. Data were collected on berry ingredients used in the mix products as well as on any suppliers of frozen foodstuffs manufactured by the company in 2012 and 2013 to facilitate trace-back investigation. A national database for storing and analysing trace-back and trace-forward data on frozen berry transactions and frozen food suppliers was implemented.

Publicly accessible information on HAV-positive lots was published on the website of the MoH[12] to alert consumers. This was part of a broader risk communication campaign on HAV outbreak, aimed at providing advice and recommendations to consumers on the correct practices when preparing and consuming frozen berries to mitigate the risk of HAV.

Guidelines for frozen berry sampling and testing were developed and distributed by the MoH to Competent Authorities at regional level and to food business operators and published on the MoH

[11] http://www.accredia.it/UploadDocs/4307_Nota_Ministero_della_Salute_allerta_alimentare_HAV_frutti_di_bosco_surgelati__03_10_2013.pdf
[12] http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=menu_principale&p=dalministero&id=1176

website[13]. Moreover, soon after the publication in May 2013 of ISO/TS 15216:2013 (ISO, 2013), the ISS undertook validation of the method on frozen berries and green vegetables. Accreditation was achieved by ISS on 14 October 2013 and validation parameters have been made available to public laboratories involved in official control of food through the ISS website[14]. Three practical training sessions on the application of the ISO/TS 15216:2013 method were organised by ISS in June 2014. In each session technicians from the Regional Veterinary and Food Safety Laboratories were trained in the application of ISO/TS 15126:2013 for the detection of HAV and norovirus geno-group I and II RNA in soft fruits.

2.2. Investigations in Ireland

Background

HAV infections have been notifiable in Ireland by clinicians since 1981. Since 2004, laboratories have also been required to notify HAV infections. The incidence of HAV in Ireland has fallen substantially from a peak of 16/100,000 population (564 cases) in 1989 to 0.7/100 000 population (30 cases) in 2012. From 2004 (when outbreaks of infectious diseases became notifiable) to the end of 2012, no foodborne outbreaks due to HAV were reported in Ireland. Prior to 2013, molecular investigation of HAV cases was not routinely available in Ireland.

Following the EPIS-FWD and EWRS alerts in April and May 2013, a decision was taken in Ireland to retrospectively and prospectively genotype and sequence all available samples from serologically confirmed cases of HAV infection since the beginning of 2013. In June 2013, three HAV cases from Ireland were identified as HAV OS. None had a history of travel to Italy. An outbreak investigation commenced and a multidisciplinary outbreak control team was established. The outbreak investigation included descriptive epidemiology and a case–control study, microbiological testing of human and food specimens, molecular typing of positive specimens and food tracing investigations.

The case definition was as follows:

- **Suspected/possible case:** A person with laboratory-confirmed HAV where the sequence result is pending or no specimen is available for sequencing and not having the exclusion criteria listed below.
- **Confirmed case:** A person with laboratory-confirmed HAV genotype IA and identical sequence to the Italian outbreak strain (GenBank accession number KF182323) and a date of symptom onset on or after 1 January 2013.

Exclusion criteria:

1. HAV confirmed to have a different sequence type to the Italian outbreak strain.
2. An epidemiological link to exclusion criterion 1.
3. Travel outside Europe to a country of high HAV endemicity during the exposure period

2.2.1. Epidemiological and microbiological results

A total of 23 cases of HAV infection meeting the outbreak case definition were notified from 1 January 2013 to 24/10/2013 (Figure 10). Of these, 15 were confirmed primary cases, 3 were possible primary cases, 4 were confirmed secondary cases and 1 was a possible secondary case. Cases were distributed nationally, occurring in five of the eight health regions. Cases ranged in age from 25 to 64 years (median age 35 years) and 57 % were female.

[13] http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=menu_principale&p=dalministero&id=1176

[14] http://www.iss.it/spva/index.php?lang=1&id=341&tipo=18

The outbreak was declared over on 24 October 2013. Subsequently, two further confirmed cases were notified, with onset dates in October and November 2013, both of which had travelled to Italy.

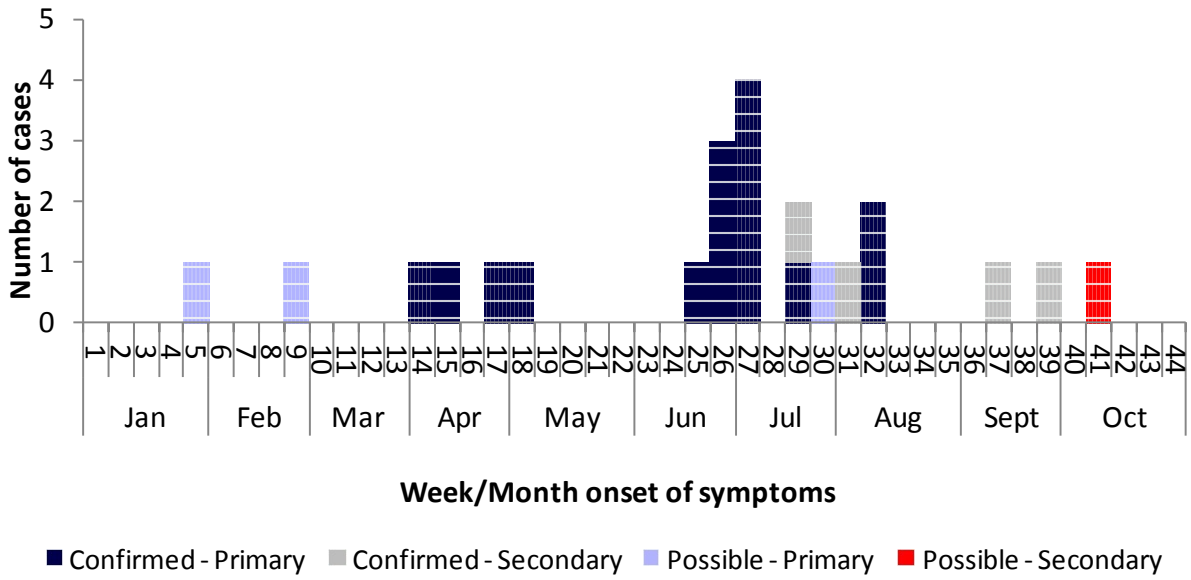


Figure 10: Hepatitis A outbreak cases by week of symptom onset, Ireland, 1 January to 24 October 2014 (n = 23)

A matched case–control study was conducted. Only confirmed primary cases without a history of travel to Italy were eligible for inclusion in the study. Controls were matched to cases on age, sex and county of residence. In total, 11 cases and 42 controls were included. The primary hypothesis tested was that illness was associated with the consumption of frozen berries. Other hypotheses were also tested. Products containing frozen berries were found to be associated with the outbreak. Amongst cases, 91 % had consumed at least one of four products containing frozen berries, compared with 39 % of controls (matched OR 12, 95 % CI 1.5–94). See Table 6 for a summary of the case–control study.

Table 6: Summary of case–control study in Ireland

Case definition	Only confirmed primary cases without a history of travel to Italy were eligible for inclusion in the study
Identification of cases	Hepatitis A is a notifiable disease in Ireland. Clinicians and laboratories are obliged to notify all cases identified. Since June 2013 the majority of laboratory-confirmed cases of hepatitis A have been genotyped and sequenced. Active case finding was also carried out by alerting clinicians about the outbreak in July 2013 and asking them to test jaundiced patients for hepatitis A and to notify positive cases
Selection of controls	Controls were selected from the general population by random digit dialling
Definition of controls	Potential controls were excluded if they had a history of hepatitis A infection, or had received hepatitis A vaccine, or were a household contact of a case of hepatitis A
Number of cases	There were 14 confirmed primary cases without a history of travel to Italy.
Number of controls	42
Matching of controls	Age (±5 years), sex, area of residence
Ascertainment of exposure	Telephone interview using a questionnaire
Response rate	Of the 14 cases who were invited to participate in the study, 11 participated
Exposures assessed in the study	• Travel abroad For each of the following foods, respondent was asked to specify frequency, place of purchase and brand: • Fresh berries, specifying type of berry • Berry-flavoured smoothies, specifying type of berry • Berry-flavoured juices, specifying type of berry • Berry-flavoured cheesecake, specifying type of berry • Yoghurt with berry layer, specifying type of berry • Berry-flavoured ice cream, specifying type of berry • Berry-flavoured sauce/coulis/purée, specifying type of berry • Frozen berries, specifying type of berry • Pomegranate • Uncooked dried fruit • Raw/uncooked vegetables • Seafood and shellfish
Results	Combined variable of frozen berries or products containing frozen berries: 91 % of cases and 39 % of controls were exposed (matched OR 12, 95 % CI 1.5–94)

Selected food samples from food companies and cases' freezers were taken as part of official control activities. The samples were sent to IZSLER in Brescia, Italy, for analysis, because no laboratory in Ireland was accredited for testing berries for HAV. The samples were analysed using a nested PCR method described in section 2.1.2. In total, 16 food items, which included frozen berries, products containing frozen berries and fresh berries, were tested. HAV was not detected in any of these food samples.

RASFF NEWS 13-706 was initially used to trace suspected food items during the Irish investigation. RASFF NEWS 13-722 was used for the standardised tracing in the multinational investigation.

2.3. Investigations in France

Background

In France, hepatitis A surveillance is monitored by mandatory notification carried out by physicians or microbiologists and by the National Reference Centre (NRC) for microbiological investigation (typing and sequencing).

The notification criterion is the presence of HAV IgM antibodies in serum. Laboratories send HAV-positive serum samples to the NRC on a voluntary basis, but the NRC requests samples when a cluster of cases or an outbreak is identified. In the last five years, HAV incidence in France has ranged from 1.6 to 2.0/100 000 population.

In 2013, two sporadic cases of HAV OS were identified by the NRC for the first time in France, one in May and one in September. The cases, one woman and one man, 39 and 19 years old respectively, resided in two different French regions and had not travelled to Italy. Only one could be interviewed using the "Italian" questionnaire. She regularly consumed frozen mixed berries or frozen strawberries but did not remember if consumption occurred during the estimated period of exposure (mid-April to mid-May).

2.3.1. Epidemiological and microbiological results

In February 2014, a cluster of three HAV cases were notified in Picardie (northern region of France, Aisne district). The cases were two women, 24 and 44 years old, and one man, aged 69. Symptom onset occurred from 8 to 13 February and all were hospitalised in the same hospital. No cases travelled outside France and no other HAV risk exposures were identified.

All three cases were HAV OS and were thus investigated using the "Irish" questionnaire on berry consumption.

Initial investigation revealed an epidemiological link with a catering service: one case was an employee, the second was a nurse's aide in a residential home that received deliveries from the caterer and the third was a resident in another residential home for handicapped adults, also client of the caterer. The resident exclusively consumed meals prepared by the caterer, the employee of the catering service and the nurse's aide regularly consumed meals prepared by the caterer on work days.

In the list of menus delivered by the caterer to the two group homes, fruit tarts with berries were identified. The tarts were consumed by the nurse's aide and the resident of the group home. The employee of the catering service did not recall having eaten the tart.

2.3.2. Results of microbiological investigations

Based on the results of the epidemiological investigation, the lot of the suspected fruits tarts consumed by the two cases was identified and on 14 March 2014. Food trace back investigations were initiated by the French General Directorate for Competition Policy, Consumers affairs and Fraud Control (DGCCRF).

The tarts were produced in France and distributed to the caterer by a French wholesaler. The lot of mixed frozen berries (blackberries, bilberries and redcurrants) in the suspected lot of fruit tarts was imported from Poland via Belgium. The frozen berries used for the preparation of the suspected frozen mixed berries in Poland were from Bulgaria for blackberries, from Germany for bilberries and from Poland for redcurrants.

In order to trace the suspected lots of berries linked to the French outbreak, SANCO RASFF initiated the notification RASFF News 14-737 (3 April).

2.3.2.1. Results of HAV analysis in the suspected food items

Official sampling of leftovers of the suspected lot of frozen mixed berries used in producing the tarts and of the suspected lot of tarts were tested for HAV by the Service Commun des Laboratoires—Etablissement de Montpellier (3 April, 17 April). Samples were HAV positive and a RASFF alert notification was initiated by France (RASFF 2014.0465#124186, 4 April). Both HAV samples were positive, but sequencing was not possible owing to the low level of viral contamination.

2.3.2.2. Measures taken in France on the HAV-positive lots of fruit tarts and frozen berries

Having identified the tarts as the most likely source of contamination in the three cases, the French wholesaler, on 3 April, stopped distribution of the products, informed his clients and destroyed the remainder of the lot. Following the identification of HAV in the lot of frozen mixed berries, the French company producing the tarts returned the remainder of the lot to the Belgian wholesaler.

2.4. Investigations in Norway

Background

Over the past 10 years one or two domestic cases of hepatitis A have been notified monthly in Norway, with the exception of 2013, when a Nordic outbreak led to an increase in notified cases.

Between February and March 2014, more than 20 cases of hepatitis A were notified, most of them with no travel history. The first typing results showed that 16 domestic cases out of 21 had an identical outbreak strain (NOR-2014-V1) of genotype IA based on a 466-bp sequence in the VP3–VP1 region of the HAV genome. To confirm the association with the European hepatitis A outbreak ongoing since January 2013, the reference laboratory repeated the sequencing using the region used in the case definition for the European outbreak (VP1–2a region, 460 bp). Results from 1 April confirmed that the Norwegian isolates were HAV OS.

As HAV is generally genotyped only during outbreak investigations in Norway, the onset of the outbreak is difficult to determine because HAV samples are stored for only a limited time. All samples collected since November 2013 for which serum was still available at local and regional laboratories, have been typed and the following outbreak case definition has been developed:

- **Probable case:** A person living in Norway with clinical illness compatible with HAV infection and serum-positive for HAV IgM antibodies, with onset of symptoms since November 2013 and no travel history to endemic areas two to six weeks before onset of symptoms.
- **Confirmed case:** A probable case from whom the HAV outbreak strain is identified.

2.4.1. Epidemiological and microbiological results

As of 19 June 2014, a total of 31 confirmed cases of HAV infection meeting the Norwegian outbreak case definition had been notified since November 2013 (Figure 11). Of these, 29 were confirmed primary cases and 2 were confirmed secondary cases. Cases were distributed nationally across the country. Cases ranged in age from 24 to 71 years (median age 44 years) and 52 % (n = 16) were male.

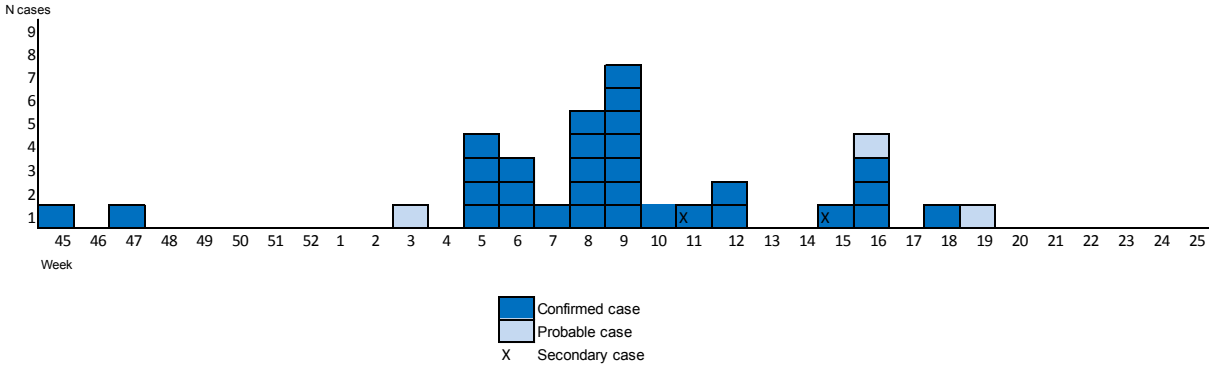


Figure 11: Hepatitis A outbreak cases by week of symptom onset, Norway, November 2013 to June2014

Table 7: Summary of the two case–control studies in Norway

	Case–control study 1	**Case–control study 2**
Case definition	Probable case: a person living in Norway with clinical illness compatible with HAV infection and serum positive for HAV IgM antibodies, with onset of symptoms since November 2013 and no travel history to endemic areas two to six weeks before onset of symptoms. Confirmed case: a probable case from which the HAV outbreak strain is identified	
Identification of cases	Cases notified to the Norwegian Surveillance System for Communicable Diseases (MSIS)	
Selection of controls	Controls were randomly selected from population registry	
Definition of controls	Excluded if they were vaccinated, had had HAV or had travelled to endemic countries two to six weeks before the onset of symptoms of their matched case	
Number of cases	15	15
Number of controls	38	20
Matching of controls	Controls were individually matched with cases by sex, year of birth and municipality	Controls were individually matched with cases by sex, year of birth and municipality
Ascertainment of exposure	Telephone interview both cases and controls	Telephone interview by telephone or email to cases and controls
Response rate	Of the 15 cases invited to participated 15 accepted Of the 45 controls we aimed to include (rate 1:3) we obtained 38 (84.4 %)	Of the 15 cases invited to participated 15 accepted Of the 45 controls we aimed to include (rate 1:3) we obtained 20 (44.4 %)
Exposures assessed in the study	• Having eaten outside of home (Y/N) and place • Seven different types of fresh and frozen berries, also in smoothies, cake and sauce • Other fruits • Spices • Salads	Having eaten the specific cake suspected
Results	None of the exposures was significantly associated with the disease	Exposure the cake: matched OR 13 (95 % CI 1.7_110); A total of 13 cases (77 %) had eaten the cake

All primary cases have been interviewed. We used trawling questionnaires for the first 13 cases. Different types of berries, salads, vegetables and fruits were the most commonly mentioned food items by the cases. A first matched (1:3) case–control study was performed to test the hypotheses generated from the trawling questionnaires. The study included 15 cases. No exposure was significantly associated with the disease.

When interviewed, several cases reported eating cakes containing berries during the incubation period. Two cases stated that they had eaten a specific type of berry-mix buttermilk cake from the same shopping centre in Oslo. The trace-back investigation showed that the berry-mix buttermilk cake was imported frozen and distributed to several locations in Norway. Further trace-back investigation and correspondence with the patients showed that the same type of berry-mix buttermilk cake had been consumed by several more cases. A second matched (1:3) case–control was performed with the specific berry cake as the hypothesised source. The results of this study pointed to the cake (see Table 7).

The cake was recalled from the Norwegian market on 11 April, and a rapid alert notification (RASFF no 2014.0502#125707) was sent to all EU Member States.

The berry-mix buttermilk cake was sampled and the HAV outbreak strain NOR-2014-V1 was identified in RNA extract from berries on top of the cake. NOR-2014-V1 is identical to HAV OS.

2.5. Investigations in Sweden

Background

In Sweden, hepatitis A has been a legally notifiable disease since 1969, and suspected and laboratory-confirmed cases are reported by clinicians and diagnostic laboratories to the County Medical Officer and the Public Health Agency of Sweden. Hepatitis A is subject to mandatory contact tracing and patients must provide information regarding possible modes of transmission.

During the past 10 years the total number of hepatitis A cases notified annually in Sweden has varied between 54 and 154 (incidence 0.6–1.6/100 000 population). The number of domestic cases has also increased, and the number of cases notified in 2013 (55) was the highest since 2009. Outbreaks in which frozen berries were the suspected source of infection have been reported previously in Sweden, and in 2013 a Nordic outbreak caused by frozen strawberries involved 17 Swedish cases.

2.5.1. Epidemiological and microbiological results

The majority of the domestic cases with an unknown source were typed and sequenced in the VP1–2a and the VP3–VP1 region. Following the EPIS-FWD and EWRS alerts in May 2013 concerning the Italian outbreak, cases with a travel history to Italy or other European countries were also included. Between January 2013 and May 2014, 56 cases were analysed, of which 9 were confirmed as having HAV OS. Of these, seven were primary cases and two were secondary cases.

The confirmed cases had date of onset between 10 July 2013 and 28 May 2014, with all cases except one infected in 2014. Cases ranged in age from 20–62 years (median age 47 years) and 56 % were females. A questionnaire developed for the Nordic outbreak was used for interviewing the cases. All cases except the case in 2013 and the secondary cases reported consumption of frozen berries (mixed berries, strawberries) and/or smoothies. No other possible modes of transmission were identified. Two of the cases had a travel history to Italy and one to Germany. The latter case (date of onset in April) also reported consumption of smoothies at a resort in Sweden during the incubation period. Another two of the four domestic cases (date of onset in January and February) also consumed smoothies at the same resort. One case in April had consumed smoothies at two different hotels in Sweden before onset of disease. In addition to the nine confirmed cases, a probable secondary case was notified in May 2014.

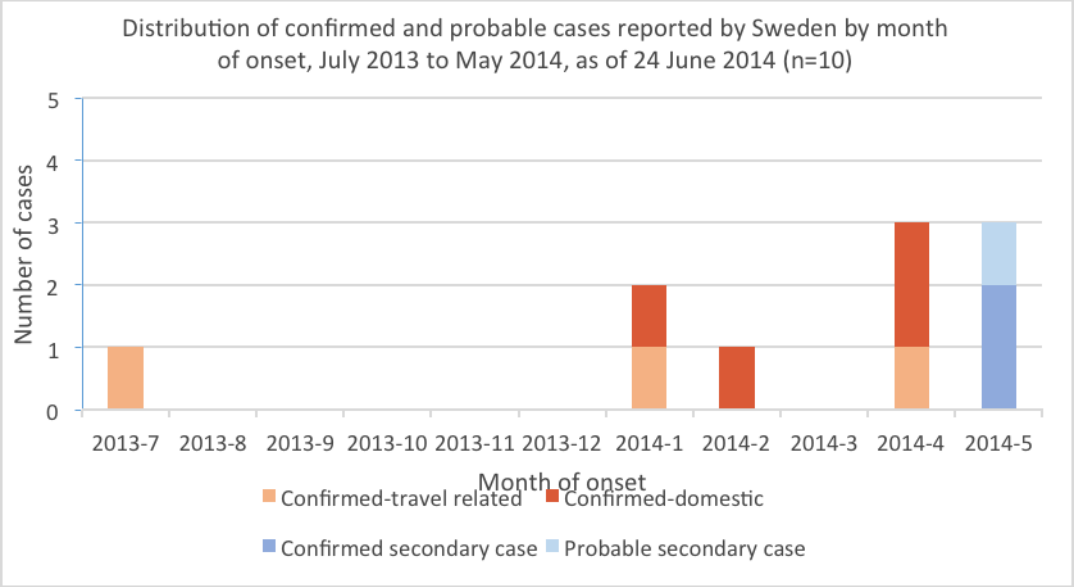


Figure 12: Distribution of confirmed and probable cases of hepatitis A reported by Sweden

2.6. Investigations in the Netherlands

Background on surveillance in the Netherlands

Hepatitis A is notifiable in the Netherlands, and notification is done by physicians to regional health services (MHS), which subsequently report to a national surveillance database (OSIRIS), hosted by RIVM. The national notification criteria are the presence of a clinical signs of hepatitis combined with HAV IgM antibodies in serum. The regional health services are in contact with patients and routine demographic and epidemiological data are collected, including age, sex, country of birth, onset of disease, related cases, travel history, homosexual contacts (MSM) and other possible modes of transmission. In the cases of patients without a reported travel history to an endemic country, MSM contact or known contact with an infected person, additional information on food consumption history and potential point source exposures is collected. For these patients with an unknown source within the Netherlands, regional health services and diagnostic laboratories send diagnostic serum samples to the RIVM for typing and sequencing of a 460-nucleotide (nt) fragment of the VP1–2a region.

Background on the outbreak and the involved sequence

In April 2013, one Dutch case was found to be possibly linked to an outbreak in Italy comprising cases in Italy, but also cases in Germany and Poland with a travel history to Italy, as reported in the EPIS system of ECDC. At that time, the outbreak sequence was not yet known. The Dutch case was the first patient for which a sequence was obtained. Later, sequences identical to KF182323 were also detected in samples of German and Italian cases, and consequently this sequence should be considered the outbreak sequence. This outbreak sequence was compared with sequences in the HAVNET database (www.havnet.nl), which includes 4 500 sequences and their country of origin, and molecular characterisation showed that the sequences were identical to a previous reported strain, genotype IA, involved in the 2008 outbreak in the Czech Republic.

2.6.1. Epidemiological and microbiological results

All cases notified between April 1st and December 31st, 2013 reported with an unknown source within the Netherlands or Italy was considered to be potentially linked to this outbreak. The case definitions used are presented in Table 8. In total, there were 15 confirmed cases, of which 1 was presumed to have been infected in Italy. Of the remaining 14 confirmed cases with an unknown source reported in the Netherlands, 10 were presumed to be confirmed primary cases and 4 were confirmed secondary cases. For these 15 confirmed cases, a sequence was available matching the outbreak strain definition and those considered primary cases were included in our food questionnaire analysis. For the 10 confirmed primary cases with unknown source in the Netherlands and 1 confirmed primary case which was presumed to be infected in Italy, we compiled data from 4 types of questionnaires: the Dutch general questionnaire, the NVWA questionnaire, the Irish questionnaire and the Italian questionnaire.

2.6.2. Tracking and tracing suspected food vehicles in the HAV outbreak

The epidemiological investigation of the HAV cases with unknown source in the Netherlands pointed in the direction of a possible relation to the consumption of fresh soft fruit and not, as expected, frozen soft fruit, as in the Italian and Irish outbreaks. At least 9 out of 10 primary confirmed cases purchased their fresh soft fruit at 2 national supermarket chains.

Although fresh soft fruit is a widely consumed food item in the Netherlands during summertime, it was the only food item that was identified in the food questionnaires. The estimated period of consumption of contaminated food by cases starts 50 days before the onset of symptoms in the first patient with unknown source (1 July 2013) to 2 weeks before symptom onset of the last patient with unknown source (4 December 2013). The two supermarket chains identified in the epidemiological investigation have a national market share of 40–50 %. Realising that the leads to start the tracing investigation were restricted for the first eight primary cases, it was decided to focus the trace-back investigation on various fresh soft fruit (strawberries, raspberries, blackberries and blueberries), with priority given to fresh strawberries supplied by these two supermarkets between 1 July 2013 and 1 September 2013.

Table 8: Summary of the descriptive epidemiological study in the Netherlands

Case definition	Suspected case: unknown source in the Netherlands or Italy and no serum available at RIVM for sequencing, or serum test was negative Confirmed case: unknown source in the Netherlands or Italy and sequence identical or maximum ≤ 0.3 % (1 nt out of 460 nt) different to the Italian berry strain (KF182323) Unrelated case: Unknown source in the Netherlands or Italy and nucleotide sequence > 0.3 % different from the Italian berry- strain (KF182323) Primary or secondary case: a primary case was considered one of the above that had no known contact with hepatitis A-diagnosed patients. A secondary case was considered one of the above but with known contact with a primary case
Identification of cases	National notification system and laboratory diagnosis and typing
Number of cases	40 cases with an unknown source in the Netherlands or Italy between 1 April and 31 December 2013: • 17 unrelated cases • 8 suspected cases infected in the Netherlands (n = 7) or Italy (n = 1) • 11 confirmed primary cases infected in the Netherlands (n = 10) or Italy (n = 1) • 4 confirmed secondary cases infected in the Netherlands
Ascertainment of exposure (e.g. interview, self-report)	11 primary confirmed cases, of which 10 infected in the Netherlands and 1 confirmed primary case presumed to be infected in Italy were questioned using structured questionnaires, including one harmonised with the Irish study
Response rate	Dutch general food questionnaire: 11/11 (100 %) Additional NVWA questionnaire: 3/10 (30 %) Additional Irish questionnaire: 7/10 (70 %) Additional Italian questionnaire: 1/1 (100 %) Any questionnaire: 11/11 (100 %)
Exposures assessed in the study (e.g. food items, travel)	A broad range of food items at risk for HAV contamination (~80), supermarket chains where shopping is done, restaurant visits, events visited, travelling abroad, travelling within the country, MSM contact

The epidemic curve for the 11 confirmed primary cases and 4 secondary cases is presented in Figure 5.

2.7. Surveillance in Poland (producing country)

Background

Hepatitis A is a notifiable disease in Poland. Physicians report cases on a standardised form to district sanitary epidemiological stations (PSSE, Powiatowa Stacja Sanitarno-Epidemiologiczne). Epidemiologists from the PSSEs review reported cases based on the EU case definition. Subsequently, the PSSE forwards the report to regional sanitary epidemiological stations and then to the Department of Epidemiology at the National Institute of Public Health—National Institute of Hygiene. Laboratory confirmation of HAV infection is based on the presence of specific IgM antibodies. Molecular characterisation of hepatitis A is not carried out in Poland. Therefore, data on HAV genotypes are not available. The surveillance system in Poland also includes reporting of other and unspecified cases of hepatitis (ICD-10: B17.0,2-8; B18.8-9;B19), a low proportion of which are hepatitis A cases.

2.7.1. Epidemiological situation of hepatitis A in Poland in 2011–2013

Hepatitis A endemicity in Poland has been low since 2000. In 2010–2013, the number of hepatitis A cases observed in Poland decreased. Incidence remains at a relatively steady level and constitutes less than 0.4/100,000 population. During 2011 - 2013 the incidence was 0.17/100,000 (65 cases), 0.18/100,000 (71 cases) and 0.12/100,000 (48 cases) respectively. In 2011 and 2012, the reported incidence was highest among the 20–39 years age group. In comparison to previous years, incidence among population aged 20-39 decreased. Between 2011 and 2013, 9 outbreaks of hepatitis A involving 26 cases were reported. Four of nine outbreaks involved cases with a history of travel to an endemic country. In recent years the proportion of imported cases of hepatitis A has remained relatively steady at approximately 50 %.

The incidence of hepatitis A varies between provinces in Poland. Differences in incidence between the provinces are related to the occurrence of local outbreaks of hepatitis A (Figure 13).

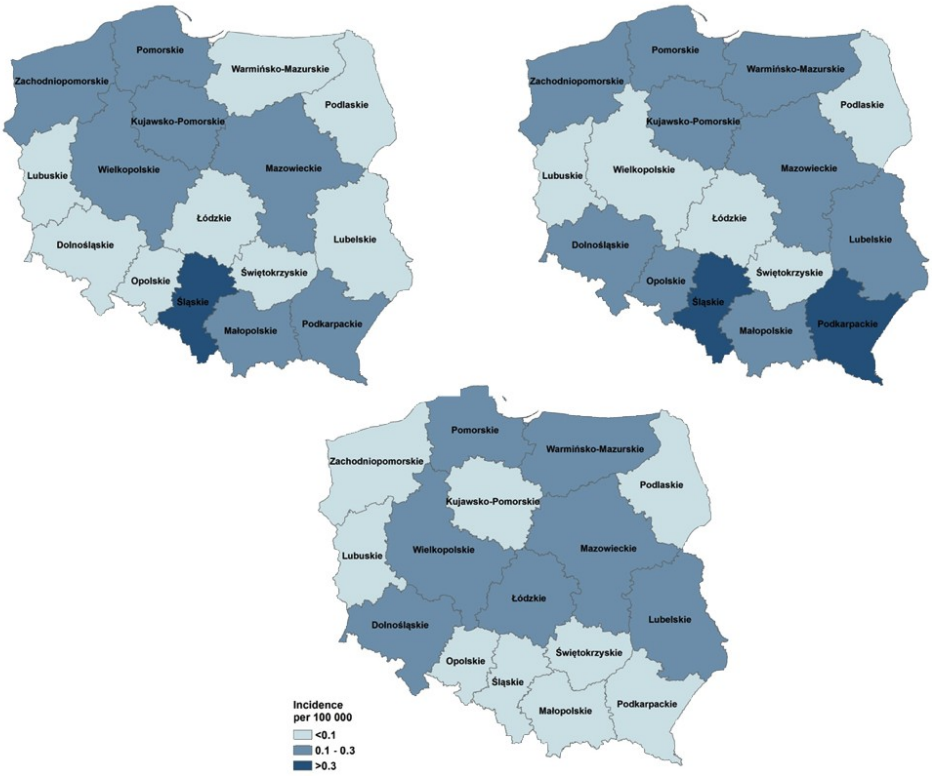


Figure 13: Hepatitis A in Poland in 2011(upper left), 2012 (upper right) and 2013 (lower), incidence per 100 000 population

The results of the trace-back analysis (Section 5) showed that suspected suppliers of redcurrants were located in the districts of Lublin, Opole Lubelskie, Kraśnik (Lubelskie province) and Lipsk (Mazowieckie province). During 2011–2013, three cases of hepatitis A were registered in Lublin and one in Kraśnik, both in Lubelskie province. No cases of hepatitis A were registered in the district of Lipsk (Mazowieckie province).

The incidence of hepatitis A in Lubelskie province was 0/100 000 in 2011, 0.14/100 000 in 2012 and 0.14/100 000 in 2013. In 2012, all cases were travellers returning from Egypt. Onset of the disease was in July, November and December. Two of the cases lived in Lublin (city) and one in Świdnik (city). No case was employed in picking, processing or selling of berries. In 2013, one case was imported from Thailand, with symptom onset was in mid-June. The further two cases occurred in January and November. The cases lived in Lublin (city), Kraśnik (city) and Łuków.

The incidence in Mazowieckie province was 0.21/100 000 (11 cases) in 2011, 0.13/100 000 (7 cases) in 2012 and 0.15/100 000 (8 cases) in 2013. Nearly 50 % of all hepatitis A cases were imported (seven cases in 2011, five cases in 2012, three cases in 2013). Most cases lived in Warsaw, but two cases lived in rural areas. Like the cases from Lublin province, none of the infected individuals were employed in processing berries.

No natural phenomenon that could lead to contamination of berries at the level of primary production was observed in Lubelskie and Mazowieckie provinces during the period 2011–2013. Extensive flooding occurred in Poland in 2009 and 2010. In 2009 the most affected regions were Podkarpackie, Dolnośląskie and Podlaskie provinces, and in 2010 the southern and central parts of Poland (the Vistula and Odra River Valleys).

2.7.2. Results of microbiological investigations

Due to the fact that there were many suppliers originating from Poland involved in traced food chains and no evidence that frozen berries originating from Poland and distributed to outbreak countries were contaminated with HAV, the authorities in Poland focused on tracing back the berries up to the primary production level. Following RASFF alerts from Italy some archival samples on suspected products were tested on request of Polish food business operators (Table 9).

In relation to notification 2013.1229, the manufacturer of the suspect frozen berry mix (PL#281) provided the results of tests of samples taken from the batch in question (1.2.3.10.18.04 A3, best before date: 06/2014), the raw materials (fruits) used to make the berry mix and the water used in production. Hepatitis A virus was not detected (see the reports in notifications 2013.1229-add01, 2013.1229-add03 and 2013.1229-add04). The tests were carried out by the laboratories EUROFINS and CEERAM in France. The French authorities also reported that two Italian laboratories carried out tests on the products of the batch in question, sampled in France, Italy and Belgium. The results showed compliance. Furthermore, 13 tests were performed on various lots of the reference product, organic red fruit cocktail, stocked in France at the time. All test results were negative.

In relation to NEWS 13-706, the manufacturer of product under suspicion, “red fruit mix” (mieszanka owocowa), PL#273, provided the results of laboratory analysis of the product that was sent by PL#206 to IE#238 on 7 January 2013. HAV was not detected in the sample. The analytical report is available in NEWS 13-706 #91948. The product was sampled in Ireland and tested by laboratory Eurofins Food Ireland.

Table 9: Summary of laboratory analysis for HAV in food items

Sample country	Sample location	Sample date	Product sampled	Product identifiers (lot no)	Sample storage	Analysis date	Laboratory	Laboratory country	Analytical method	Result
Poland	Producer		Redcurrant	Frozen fruits from Season 2013		7 October 2013	J.S. Hamilton Poland S.A., ul. Chwaszczyńska 180, 81-571 Gdynia	Poland	PB-202 wyd.II z dn. 15.06.2013	Negative (2013.0694-add22)
Poland	Producer		Redcurrant	Frozen fruits from season 2013		7 October 2013	J.S. Hamilton Poland S.A., ul. Chwaszczyńska 180, 81-571 Gdyniad	Poland	PB-202 wyd.II z dn. 15.06.2013	Negative (2013.0694-add22)
Poland	Producer		Redcurrant	Lot 12312		11 June 2013	CONGEN Biotechnologie GmbH, Robert-Rossle-Str.10, 13125 Berlin	Germany	RT-PCR-assay	Negative (2013.0756-add05)
Poland	Producer		Redcurrant	Lot 13030		3 July 2013	CONGEN Biotechnologie GmbH, Robert-Rossle-Str.10, 13125 Berlin	Germany	RT-PCR-assay	Negative (2013.0880-add05)

2.8. Surveillance in Bulgaria (producing country)

Background

Bulgarian legislation requires medical doctors to report cases of acute hepatitis to Regional Healthcare Inspectorates (RHIs) by means of a Rapid Notification Form (GPs and outpatient services) or a list of hospitalised patients (infectious diseases wards and hospitals). Every person with symptoms of acute hepatitis is hospitalised and laboratory tested for hepatitis A, B and C. Epidemiologists from the RHIs conduct epidemiological investigation and classify each case using the EU case definition. Hepatitis A is included in a list of notifiable infectious diseases in Bulgaria, as are hepatitis B, hepatitis C and unspecified hepatitis.

Every day, the RHIs report aggregate data to the National Centre of Public Health and Analyses, which collates and reports aggregate national data to the Ministry of Health, National Centre of Infectious and Parasitic Diseases and PHIs on a weekly basis.

Only serological testing for HAV infection is performed in Bulgaria.

2.8.1. Epidemiological situation of hepatitis A in Bulgaria in 2011–2013

Bulgaria is a country with intermediate endemicity of hepatitis A. Since 2000, the annual incidence has varied between 25 and 94 cases per 100 000 population, reflecting non-epidemic periods or epidemic peaks. In 2011 and 2012, the incidence was relatively high—75.88/100 000 (5 588 cases) and 67.13/100 000 (4 919 cases) respectively. In 2013, the incidence fell to 25.05/100 000 (1 825 cases). In 2011–2013, the most affected population group was children aged 5–9 years, followed by the 10–14 years and 1–4 years age groups, which are the main risk groups for the disease in Bulgaria in general. From 2011 to 2013, 28 outbreaks of hepatitis A were detected in different Bulgarian districts, most of them in minority Roma neighbourhoods. The communicable disease surveillance system in Bulgaria is unable to provide data concerning travel history of hepatitis A cases at national level.

3. Tracing of suspect food

3.1. Definition of the tracing

At the beginning of the tracing activities to investigate the possible source of contamination with HAV, a clear definition of the extent of the task was agreed. Case or lots were classified according to specific criteria and the **starting points in the food chain** (stations/food operators) that supplied the lots or food items to cases were identified. Furthermore, the **food items** (ingredients for the tracing activities, e.g. types of berries) were agreed.

3.1.1. Classification of evidence regarding suspected products or lots

Summary

The strength of evidence (microbiological and epidemiological) of the association between food vehicle (berries) and the HAV outbreak resulted in the classification of the starting points (Table 10). The tracing activities were focused on the cases/lots with a very high, high and medium level of evidence.

For the classification of lots of berries and berry products, a risk-based approach was adopted, using the following definitions:

- **Confirmed lot:** any batch of fresh or frozen berries or berry products with a positive analytical result for the presence of HAV.

- **Suspected lot:** any batch of fresh or frozen berries or berry products consumed by at least one confirmed or probable epidemic case of infection affected with hepatitis A after 1 January 2013, where the exact lot and brand could be identified from the food history.
- **Possible product:** any brand of fresh or frozen berries consumed before the onset of symptoms by at least one case affected with hepatitis A after 1 January 2013, considering products present in the premises under investigation during the incubation period for HAV (15–50 days).
- **Connected lot:** any batch of fresh or frozen mixed berries or mixed berry products that shares with a confirmed batch at least one component of the mix.

Combining the levels of epidemiological and microbiological evidence with the classification of lots, the classification list (1–4) in Table 10 was defined.

Table 10: Classification based on strength evidence of the association between food vehicle (berries) and the HAV outbreak

Classification	Level of evidence for connection to outbreak	Lot	Consumption	Case [(a)]	Country: number of starting points
1	Very high	Confirmed lot (HAV 1A, OS detected)			Italy: 1 lot Norway: 1 lot
2A	Very high	Confirmed lot (HAV detected)	Consumed by at least one confirmed case	Confirmed case (HAV 1A, OS)	France: 1 (+1) lot Italy: 5 lots
2B	High	Suspected lot	Consumed by at least one confirmed case	Confirmed case (HAV 1A, OS)	Italy: 5 lots Norway: 1 lot
2C	High	Confirmed lot (HAV detected)			Italy: 8 lots
3A	Medium	possible lot	Produced in reasonable time before infection of at least one confirmed case	Confirmed case (HAV 1A, OS)	Ireland: 11 cases Sweden: 2 cases Netherlands: 8 cases
3B	Low	Suspected lot	Consumed by at least one non-genotyped case	Probable case	Not traced
4	Low	Possible lot	Produced in reasonable time[2] before infection of a tested case	Probable case	Not traced
Total					**43 lots or cases**

OS = HAV whose nucleotide sequence differs from that of the outbreak strain by fewer than two nucleotides.
(a): For case definition, see section 1.2.
(b): Reasonable time before onset is set to the incubation time of HAV, i.e. 15–50 days.

In total, 8 starting points were classified as having very high evidence, 14 as having high evidence and a further 21 as having medium evidence.

Reasoning

The starting points for tracing were classified based on the strength of evidence (microbiological and epidemiological) of the association between food vehicle (berries) and the HAV outbreak. Thus, the strength of the evidence was rated as very high when food was confirmed to be contaminated with HAV OS or if HAV-contaminated food items were known to have been consumed by confirmed cases. Evidence was rated high strength when a suspect lot was consumed by at least one confirmed case and the exact lot and brand could be identified from the food history or when a lot had a positive analytical result without further genotyping. Possible lots, identified by estimating the lot or lots that confirmed cases may have consumed during their exposure period (i.e. 15 to 50 days before onset of illness), were rated as providing evidence of medium strength. Finally, the strength of the evidence is rated as low when the contamination of HAV of the outbreak strain is probable, but specific indications are missing. Starting points rated as having low-strength evidence were not traced.

These rules result in a classification of starting points in the food chain with the highest evidence for tested lots that were confirmed to be contaminated by the HAV 1A outbreak strain (OS), and lowest evidence for possible lots linked to probable cases.

Uncertainties

- Inclusion of starting points with a lower class of evidence may erroneously lead the analysis towards stations or products without contamination.
- Exclusion of starting points with a lower class of evidence may exclude additional evidence.

3.2. Restriction of tracing to specific food items

In Ireland and Italy, many of the confirmed or suspect food items contained mixes of different combinations of frozen berries, and in the Netherlands fresh berries were suspected (Table 11). At the beginning of the tracing activities, using data from Italy, Ireland, and the Netherlands, tracing was restricted to berries which were common ingredients. Blackberries, raspberries, blueberries/bilberries and redcurrants were traced. Blueberries and bilberries were not differentiated owing to the possibility of misclassification during data collection. Frozen blackcurrants, lingonberries, strawberries and cranberries were excluded from tracing activities. At the Swedish starting point other fruits were identified (including passion fruit, buckthorn and pomegranate) but these were not traced. In addition, fresh strawberries were traced in the Netherlands, as they were identified by the descriptive epidemiological study as a possible source of the infection.

3.3. Classification of risk for stations in the supply chain

Classification of food operators (stations) according to the risk of HAV contamination allows the tracing dataset to be analysed considering different hypotheses for mechanisms of contamination. Contamination due to either a primary source or a cross-contamination was considered. Cross-contamination is the process by which microorganisms are unintentionally transferred from one substance (food) or object (food contact surface) to another, with harmful effect, either by mixing contaminated food with uncontaminated objects or by transferring microorganisms via contaminated surfaces to uncontaminated food. As a consequence, there are many places in the production chain where cross-contamination could occur, in particular at stations which perform freezing, mixing, packaging or re-packaging activities (Table 12). However there are stations with functions of trade, transport and storage of frozen, packed berries where direct handling does not occur and cross contamination at these stations is not possible. These stations are categorised as “Frozen berry trader”. Table 12 outlines the different type of stations along the food chain for frozen berries.

Table 11: Ingredients of products/lots at starting points by country

Country	Fresh or frozen	Blackberries	Raspberries	Blueberries/ bilberries	Redcurrants	Blackcurrants	Lingonberries	Cranberries	Strawberries
Italy	**Frozen**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	
Ireland	**Frozen**	**Y**	**Y**	**Y**	**Y**	**Y**			
France	Frozen	Y		Y	Y				
Norway	Frozen	Y	Y		Y				Y
Sweden	Frozen	Y	Y	Y	Y	Y			Y
Netherlands	**Fresh**	**Y**	**Y**	**Y**					**Y**

Y = ingredients in starting points of that country.
Bold type= country involved at the beginning of the project.

Uncertainties

The exact nature of the activities performed by stations in the food chain may not be known, and some stations may perform different activities depending on the availability of products in the supply chain.

Table 12: Classification of stations in the food chain and risk for contamination or cross-contamination (EFSA BIOHAZ Panel, 2014)

Characteristics of station	Risk of contamination and/or spread of contamination within a station
Primary producer	
Horticultural farm or wild area with berry plants Berry picking or collecting of wild berries Storage and transport of fresh berries	Contamination via irrigation, water used to dilute pesticides or flooding of the area with natural water Contamination via infected workers during picking or handling For berries picked mechanically, contamination via contaminated machinery Cross-contamination of berries via contaminated facilities for collecting, storage or transport Contamination from part of the crop to the whole production season Spread of contaminated berries to several customers
Fresh berry trader	
Collecting fresh berries from primary production Cleaning, sorting and/or re-packing of fresh berries Storage and transport of fresh berries Distribution of fresh berries	Contamination of the production by infected workers during handling (cleaning, sorting, re-packing and/or distribution) Cross-contamination of the production by contaminated ingredients Cross-contamination of the production via contaminated facilities for cleaning (e.g. water), sorting (e.g. sorting line), re-packing (e.g. packing line) and/or transporting (e.g. trays) Cross-contamination of berries via contaminated facilities for storage or transport Spread of contaminated products to several customers
Freezing processor	
Freezing of fresh berries Sorting and packing of frozen berries Storage and distribution of frozen berries	Contamination of the production by infected workers in handling (sorting and/or packing) Cross-contamination of the production by contaminated fresh or frozen ingredients Cross-contamination of the production via contaminated facilities for sorting (e.g. sorting line) and/or packing (e.g. packing line) Spread of contaminated products to several customers
Frozen berry processor, e.g. packager	
Mixing or re-packing of frozen berries Storage and distribution of frozen berries	Contamination of the production by infected workers in handling (sorting and/or packing) Cross-contamination of the production by contaminated ingredients Cross-contamination of the production via contaminated facilities for sorting (e.g. sorting line) and/or packing (e.g. packing line) Spread of contaminated products to several customers

Frozen berry trader, e.g. supplier	
Storage and distribution of frozen berries	Frequently frozen berries will be traded without any handling or transport
Berry product producer, e.g. manufacturer	
Use of frozen berries in preparation of products such as fruit yoghurts, cheesecakes, smoothies, fruit juices etc., fresh or frozen	Cross-contamination of the production by contaminated ingredients, when these are not heated or exposed to other methods of inactivation of HAV Contamination of the production by infected workers in handling (processing and/or packing) Cross-contamination of the production via contaminated facilities for sorting (e.g. production line), packing (e.g. packing line), storage and/or transport Spread of contaminated products to several customers and/or consumers
Berry product retailer, e.g. local retailers, supermarkets	
Sell of berry products to consumers Preparation of berry products for direct consumption (e.g. de-freezing) Preparation of food for consumer using berry products (e.g. restaurants)	Cross-contamination of the food by contaminated ingredients, when these are not heated or exposed to other methods of inactivation of HAV Contamination of the production by infected workers in handling (processing, and/or handling) Cross-contamination of the production via contaminated facilities for preparation, handling and/or storage Spread of contaminated products to consumers
Berry product consumer, e.g. cases	
Use and consumption of berry products	Cross-contamination of the food by contaminated ingredients, when these are not heated or exposed to other methods of inactivation of HAV Contamination of the food by infected persons in the same household Cross-contamination of the food via contaminated facilities for preparation, handling and/or storage

3.4. General production and trade pattern

Summary

Production of fresh redcurrants, blackberries and raspberries is concentrated in a few EU countries. Only some of the berries produced will be frozen or further processed. Berry import data are available only for general trade categories and do not distinguish between frozen berries and those subjected to other forms of processing, such as drying. In addition, the exporting country may be not the country of origin. The balance between countries' export and import figures takes into account non-agricultural production, e.g. picking in public forests.

Reasoning

The following tables focus on redcurrants, raspberries, blackberries, blueberries/bilberries, and strawberries. Similar information can be found for the other berries from Eurostat or national statistical institutes.

Uncertainties

Owing to the long shelf life of frozen berries (up to 24 months) and the production of more complex food items from frozen berries, the trade patterns might not be directly linked to the countries of origins or the years of production.

The balance of yearly export and import does not take into account long storage of berries, or transformation into other product categories.

3.4.1. Redcurrant production and trade (fresh or processed)

Redcurrant production is concentrated to Poland. Poland exports a large excess of redcurrants. Import of redcurrants from outside the EU is negligible.

Table 13: Fresh redcurrant production in the EU in metric tons (source: Eurostat: apro_cpp_crop / C2275)

Country	Fresh redcurrant production in the EU					
	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	45 400	88	45 900	95	47 100	97
Czech Republic	2 800	5	1 800	4		
Denmark	3 300	6				
Others [(a)]	0	0	500	1	1 700	3
Total	**51 500**	**100**	**48 200**	**100**	**48 800**	**100**

(a): Others include Lithuania, Austria, Belgium, Bulgaria, Estonia, Finland, Croatia, Portugal, Romania, Slovakia and Slovenia; for details see Appendix C.

Table 14: Redcurrant trade balance in the EU in metric tons
(Source: Eurostat: CN 8103030/8112051)

EU Member State	Fresh or processed redcurrant trade balance (export – import) in the EU [a]: positive numbers = excess of export, negative numbers = excess of import					
	Fresh			Processed, unsweetened		
	2011[b]	2012	2013	2011	2012	2013
	Tonnes	Tonnes	Tonnes	Tonnes	Tonnes	Tonnes
Poland		580.7	412.7	12 735	12 841.4	13 111.2
Denmark		54.9	719.1	1 124	702.9	1 341.2
Hungary		11.3	–388.8	1 646	699.5	7 48.2
Netherlands		1 133.9	1 058.8	369.7	469.7	501.4
Czech Republic		1 255.5	488.2	190.3	147.6	156.8
Greece		84.8	251.9	–9.0	–36.4	129.4
Lithuania		–22.3	–48.5	111.1	38.9	69.2
Portugal		1.9	–130.1	–8.2	–4.5	38.8
Spain		34.3	148.1	–71.0	–29.9	21.7
Slovakia		–7.4	–17.8		7.1	0.5
Italy		59.1	544.1	–1 052.4	–987.8	–1 267.0
France		–373.3	–391.1	–676.3	–1 158.5	–1 514.2
Germany		–2 007.2	–1 104.2	–9 312.8	–8 276.6	–7 590.3

(a): Selected Member States; for the complete table, see Appendix C. (b): No data available

Table 15: Fresh or processed redcurrant import into the EU in metric tons
(Source: Eurostat: CN 8103030/8112051)

Exporting country	Fresh or processed redcurrant import into the EU											
	Fresh						Processed, unsweetened					
	2011[b]		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Chile			244	100	169	98						
Serbia			0	0			44	92	51	59	120	90
Ukraine							0	0	30	35		
Ecuador											9	7
Macedonia									5	6		
Turkey											5	4
Others [a]			0	0	3	2	4	8	0	0	0	0
Total			244	100	172	100	48	100	86	100	134	100

(a): For details, see Appendix C. (b): No data available

3.4.2. Raspberry production and trade (fresh or processed)

Poland is also the biggest producer of raspberries in Europe, but the import of processed raspberries (including frozen raspberries) is of the same magnitude. The separated data on frozen raspberries show that freezing is the major method of processing. Biggest exporter to the EU is Serbia, with about half amount of the production in Poland.

Table 16: Fresh raspberry production in the EU in metric tons
(Source: Eurostat: apro_cpp_crop / C2278)

Country	Fresh raspberry production in the EU					
	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	118 000	71	127 100	72	121 500	71
UK	16 000	10	14 000	8	14 000	8
Spain	9 600	6	12 900	7	11 700	7
Bulgaria	7 600	5	4 900	3	5 400	3
Germany	4 800	3	4 700	3	5 100	3
France	3 700	2	3 200	2	4 000	2
Portugal	0	0	3 100	2	2 700	2
Others [(a)]	7 400	4	6 300	4	7 900	5
Total	**167 100**	**100**	**176 200**	**100**	**172 300**	**100**

(a): Others include Lithuania, Hungary, Italy, Belgium, Austria, Finland, Croatia, Denmark, Latvia, Czech Republic, Estonia, Ireland, Greece, Luxembourg, Netherlands, Romania, Slovenia, Slovakia Sweden and Iceland; for details, see Appendix C.

Table 17: Raspberry trade balance in the EU in metric tons
(Source: Eurostat: CN 8102010/8112031)

EU Member State	Fresh or processed raspberry trade balance (export – import) in the EU [(a)]: positive numbers = excess of export, negative numbers = excess of import					
	Fresh			Processed, unsweetened		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Poland	18 441.9	13 931.3	13 360.3	32 934.0	5 4631.1	60 416.0
Bulgaria	90.8	108.0	61.3	1 943.9	2 924.4	2 707.4
Cyprus	19.7	–1.1	22.7	1 964.4	1 951.1	2 287.3
Netherlands	–1 743.9	1 634.3	6 288.4	76.3	1 655.6	567.9
Spain	16 354.1	16 803.4	18 106.9	–623.6	–292.7	490.8
Romania	–2.7	–6.0	77.7	109.6	256.2	23.9
UK	–85 77.1	–9 130.2	–9 754.9	–5 924.8	–8 504.6	–11 026.7
France	–65 94.7	–6 793.4	–6 408.9	–3 0819.9	–31 704.9	–32 987.0
Germany	–14 401.0	–12 108.8	–14 216.0	–52 765.6	–54 046.9	–52 078.2

(a): Selected Member States; for complete table, see Appendix C.

Table 18: Fresh or processed raspberry import into the EU in metric tons (Source: Eurostat: CN 8102010/8112031)

Exporting country	Fresh or processed raspberry import into the EU											
	Fresh						Processed, unsweetened					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Serbia	3 883	41	389	6	471	6	67 686	71	59 570	78	55 666	72
Chile	12	0	21	0	2	0	21 628	23	11 382	15	12 589	16
China							2 696	3	2 392	3	5 014	7
Morocco	1 989	21	2 361	36	3 375	46	298	0	251	0	331	0
Bosnia and Herzegovina	21	0	77	1	121	2	2 586	3	2 525	3	2 180	3
Mexico	968	10	1 520	23	1 602	22	20	0	6	0	30	0
USA	741	8	1 150	18	852	12	2	0	49	0	136	0
South Africa	655	7	805	12	684	9					0	0
Turkey							119	0	151	0	723	1
Others [(a)]	1 089	12	170	3	237	3	204	0	244	0	422	1
Total	**9 358**	**100**	**6 493**	**100**	**7 344**	**100**	**95 239**	**100**	**76 570**	**100**	**77 091**	**100**

(a): For details, see Appendix C.

Table 19: Frozen raspberry imports into EU in metric tons

Exporting Country	Frozen raspberries				
	2005	2009	2010	2011	2012
	Tonnes				
Serbia	28 754	54 225	57 036	67 734	57 897
Chile	13 523	12 913	19 485	21 628	11 382
Bosnia and Herzegovina	1 429	1 678	2 143	2 633	2 575
China	279	1 713	3 636	2 701	2 334
Morocco	2	567	241	298	251
Norway	96	130	155	161	122
Turkey	74	183	105	119	151
USA	45	106	153	2	49
Canada	23	NR	NR	NR	49
FYROM [(a)]	82	1	4	14	20
Mexico	NR	NR	NR	20	6
Switzerland	19	38	9	4	11
Ukraine	141	4	17	2	10
Egypt	NR	NR	0	NR	NR
Peru	NR	NR	NR	NR	NR
Tunisia	NR	NR	NR	NR	NR
Argentina	52	14	NR	NR	NR
Other	1	101	68	2	0
Total	**44 518**	**71 673**	**83 052**	**95 317**	**74 856**

NR, not reported at the time of production of the table.
(a): FYROM: Former Yugoslav Republic of Macedonia.

3.4.3. Blackberry production and trade (fresh or processed)

Specific data on blackberry production in the EU are missing. Instead the production category "other berries" comprises all fresh berries except strawberries, currants, raspberries and gooseberries. Again, Poland is the biggest producer of other berries in Europe, but import is equally important (see section 3.4.4 on blueberries).

It should be noted that only production for agricultural holdings is counted and picking in public forests is not included. Here the export-import balance shows that Bulgaria is exporting more than importing or producing on farms, this difference can be explained by blackberry picking in public forests. One exception occurred in 2012 when Bulgaria export–import balance showed a huge excess of import of fresh blackberries.

Nevertheless, Serbia is biggest exporter of blackberries to the EU.

Table 20: Other fresh berry (excluding strawberries, currants, raspberries, and gooseberries) production in EU in metric tons (Source: EUROSTAT: apro_cpp_crop / C2290)

Country	Other fresh berry production in the EU					
	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	5 7500	93	64 600	92	67 900	93
Portugal	3 500	6	3 900	6	4 000	5
Others [a]	1 000	2	1 700	2	1 100	2
Total	**62 000**	**100**	**70 200**	**100**	**73 000**	**100**

(a): Others include Austria, Lithuania, Romania, Denmark, Bulgaria, Czech Republic, Estonia, Ireland, Latvia, Slovakia, Finland and Sweden; for details, see Appendix C.

Table 21: Blackberry trade balance in the EU in metric tons (Source: Eurostat: CN 8102090/8112059)

EU Member State	Fresh or processed blackberry trade balance (export – import) in the EU [a]: positive numbers = excess of export, negative numbers = excess of import					
	Fresh [b]			Processed, unsweetened [c]		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Bulgaria	–18.8	–683.2	–29.8	831.3	885.4	1 359.5
Cyprus	–24.1	–7.8	–2.2	233.7	583.5	211.9
Romania	–21.8	–7.1	–49.2	108.1	287.8	197.3
Luxembourg	–22.8	–20.4	–22.2	–1.6		39.0
Slovakia	–35.3	–32.8	–47.3	0.9	13.4	9.8
Estonia	16.0	13.3	0.4	–10.8	4.5	4.4
Italy	–1 712.6	–3 548.8	–3 308.5	–2 185.5	–2 988.9	–2 779.4
France	–661.8	–510.3	–711.6	–3 368.5	–4 090.1	–4 301.4
Germany	–1 789.2	–1 385.6	–1 587.6	–11 235.2	–12 989.5	–8 981.3

(a): Selected Member States; for complete table, see Appendix C.
(b): Fresh berries: Blackberries, mulberries and loganberries (CN 8102090).
(c): Processed berries: blackberries, mulberries (CN 8112059).

Table 22: Fresh or processed blackberry import into the EU in metric tons (Source: Eurostat: CN 8102090/8112059)

Exporting country	Fresh or processed blackberry import into the EU											
	Fresh [a]						Processed, unsweetened [b]					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Serbia	1 485	28	1503	29	2 505	37	22 542	74	19269	64	15 760	62
Chile	16	0			6	0	5 031	17	6387	21	6 760	27
Mexico	2 950	55	2 749	52	2 856	42	33	0	83	0	390	2
China	14	0	17	0	18	0	1 548	5	2531	8	1 126	4
Guatemala	263	5	670	13	792	12	19	0	43	0	56	0
Bosnia and Herzegovina	0	0	0	0	1	0	513	2	478	2	650	3
Ukraine							179	1	764	3	499	2
Macedonia	489	9	70	1	100	1	116	0	137	0	38	0
Turkey	2	0			1	0	73	0	335	1	140	1
Kosovo			74	1	252	4						
Others [c]	109	2	163	3	214	3	206	1	110	0	62	0
Total	**5 328**	**100**	**5 246**	**100**	**6 745**	**100**	**30 260**	**100**	**30 137**	**100**	**25 481**	**100**

(a): Fresh berries: blackberries, mulberries and loganberries (CN 8102090).
(b): Processed berries: blackberries, mulberries (CN 8112059).
(c): For details, see Appendix C.

3.4.4. Blueberry/bilberry production and trade (fresh or processed)

Fresh blueberry/bilberry production is included in the category "other fresh berry production" (see section 3.4.3).

Table 23: Blueberry/bilberry trade balance in the EU in metric tons (Source: EUROSTAT: CN 8104030/8104050/8104090/8119050/8119070)

EU Member State	Fresh or processed blueberry/bilberry trade balance (export – import) in the EU [a]: positive numbers = excess of export, negative numbers = excess of import					
	Fresh [b]			Processed, unsweetened [c]		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Sweden	353.8	1043.4	1 160.1	2 375.9	4 366.4	6 346.8
Latvia	41.0	506.7	212.6	2 896.9	3 819.9	3 542.2
Romania	372.5	346.5	595.8	2 425.6	2 620.0	3 118.7
Estonia	–26.4	–22.4	321.2	–209.0	–855.4	873.3
Cyprus		36.1		354.0	946.0	517.6
Finland	–135.6	–530.4	–1269.3	–1 038.3	–1575.2	435.5
Netherlands	–9 839.3	–133.6	1 520.8	–1 265.0	–1 117.4	166.6
Spain	12 210.9	11 848.7	13 684.0	248.1	–102.1	23.3
Greece	–40.7	–142.7	–20.4	31.6	42.9	19.8
Malta	–1.9	–3.8				
Italy	–774.9	–1 084.0	–2 443.8	–9 466.5	–9 219.2	–8 697.8
France	–898.4	–1 480.0	–164.7	–5 091.0	–6 777.8	–8 750.5
Germany	2 349.7	–5 283.5	–6 679.1	–20 112.3	–20 368.9	–20 821.0

(a): Selected Member States; for complete table, see Appendix C.
(b): Fresh berries: species *Vaccinium myrtillus*, *V. macrocarpum*, *V. corymbosum* and others (CN 8104030/8104050/8104090)..
(c): Processed berries: *Vaccinium myrtillus*, *V. mirtilloides* and *V. angustifolium* (CN 8119050/8119070).

Table 24: Fresh or processed blueberry/bilberry import into the EU in metric tons (Source: Eurostat: CN 8104030/8104050/8104090/8119050/8119070)

Exporting country	Fresh or processed blueberry/bilberry import into the EU											
	Fresh [a]						Processed, unsweetened [b]					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Canada	630	3	359	1	634	2	24 061	40	2 3877	40	21 066	37
Russia	1 102	5	411	2	268	1	14 768	25	1 4941	25	16 969	30
Chile	8 897	40	11 894	47	13 611	49	2 793	5	3 146	5	4 117	7
Ukraine	615	3	774	3	403	1	13 174	22	12 837	22	11 455	20
Argentina	4 851	22	4 476	18	3 943	14	753	1	874	1	631	1
USA	1 159	5	1 248	5	1 368	5	26 58	4	1 831	3	1 503	3
Morocco	1 866	8	2 928	12	3 415	12	123	0	376	1	112	0
Uruguay	1 433	6	1 265	5	1 043	4			220	0	63	0
South Africa	983	4	1 180	5	1 377	5						
Serbia	71	0	204	1	257	1	1 026	2	688	1	1052	2
Others [c]	712	3	495	2	1 273	5	872	1	296	1	549	1
Total	**22 319**	**100**	**25 234**	**100**	**27 592**	**100**	**602 28**	**100**	**59 086**	**100**	**57 517**	**100**

(a): Fresh berries: species *Vaccinium myrtillus*, V. *macrocarpum*, *V. corymbosum* and others (CN 8104030/8104050/8104090).
(b): Processed berries: *Vaccinium myrtillus*, *V. mirtilloides* and *V. angustifolium* (CN 8119050/8119070).
(c): For details, see Appendix C.

3.4.5. Strawberry production and trade (fresh or processed)

Production of fresh strawberries is more important than import of fresh or processed strawberries. The main producer is Spain, producing nearly twice as much as Poland, Germany or Italy.

Table 25: Fresh strawberry production in EU in metric tons
(Source: Eurostat: apro_cpp_crop / C2260)

Country	Fresh strawberry production in the EU					
	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Spain	262 700	26	290 800	28	312 500	28
Poland	175 100	17	170 800		165 900	15
Germany	154 400	15	155 800	15	149 700	14
Italy	46 000	4	40 900	4	120 200	11
UK	102 000	10	96 000	9	94 000	9
France	49 300	5	53 100	5	55 700	5
Netherlands	47 000	5	50 000	5	51 000	5
Greece	43 700	4	42 900	4		
Belgium	37 500	4	40 500	4	35 900	3
Romania	18 800	2	15 600	1	22 000	2
Austria	14 200	1	9 900	1	14 900	1
Sweden	12 900	1	16 300	2	13 800	1
Finland	12 800	1	14 200	1	13 200	1
Others [(a)]	49 700	5	50 700	5	50 200	5
Total	**1 026 100**	**100**	**1 047 500**	**100**	**1 099 000**	**100**

(a): Others include Portugal, Ireland, Denmark, Hungary, Belgium, Croatia, Lithuania, Slovakia, Czech Republic, Cyprus, Estonia, Latvia, Malta, Luxembourg Slovenia and Iceland; for details, see Appendix C,

Table 26: Strawberry trade balance in the EU in metric tons
(Source: Eurostat: CN 8101000/8110090)

EU Member State	Fresh or processed strawberry trade balance (export – import) in the EU [(a)]: positive numbers = excess of export, negative numbers = excess of import					
	Fresh			Processed, unsweetened		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Poland	8 443.2	45.8	–18.5	68 098.2	50 694.9	64 408.3
Spain	231 970.0	295 252.4	276 724.8	14 864.6	1 7439.0	18 925.0
Bulgaria	–688.5	–1 951.8	–1 588.2	1 135.2	595.3	786.7
Cyprus	–132.6	198.0	–103.9	160.9	311.9	96.0
Malta	462.4	359.2	–2.8			
Belgium	10 002.5	9 152.8	6 579.0	–12 541.8	–15 408.6	–14 583.1
France	–74 641.6	–85 264.6	–77 717.5	–37 557.7	–48 217.8	–39 295.7
Germany	–81 143.0	–88 100.5	–86 733.9	–81 479.3	–76 025.8	–75 156.6

(a): Selected Member States; for the complete table, see Appendix C,

Table 27: Fresh or processed strawberry import into the EU in metric tons (Source: EUROSTAT: CN 8101000/8110090)

Exporting country	Fresh or processed strawberry import into the EU											
	Fresh						Processed, unsweetened					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Morocco	24 228	59	22 632	59	17 749	58	42 720	32	59 660	45	56 006	45
China			49	0			67 553	50	46 300	35	40 317	32
Egypt	5 866	14	6 800	18	6 130	20	9 671	7	15 840	12	16 391	13
Turkey	5 531	13	5 197	13	3 554	12	6 982	5	5 537	4	5 743	5
Peru	336	1	313	1	255	1	2 891	2	3 050	2	3 233	3
USA	3 412	8	2 411	6	1783	6	45	0	123	0	57	0
Chile	3	0			1	0	1 772	1	1 269	1	1 194	1
Serbia	249	1	78	0	304	1	1 860	1	804	1	743	1
Others [(a)]	1 379	3	1 074	3	797	3	1 718	1	1 399	1	1551	1
Total	**41 004**	**100**	**38 554**	**100**	**30 573**	**100**	**135 212**	**100**	**133 982**	**100**	**125 235**	**100**

(a): For details, see Appendix C.

3.5. Tracing starting points by country

Summary

The tracing activities were started with 38 lots/cases in Italy, Ireland and the Netherlands. In spring 2014, an additional five lots/cases were added from France, Norway and Sweden (Table 28).

Table 28: Classification of products/lots at starting points by country

Country	Number of cases or lots traced Classification								
	1 Lots	2A Lots	2B Lots	2C Lots	3A [(a)] Cases	3B [(b)] Lots	4 [(b)] Lots	Total traced	
Italy	1	5	5 [(c)]	8[3]		0	0	**19**	44 %
Ireland					11			**11**	26 %
France		1 [(e)]						1	2 %
Norway	1		1					2	5 %
Sweden					2 [(d)]			2	5 %
Netherlands					8			**8**	19 %
Total	**2**	**6**	**6**	**8**	**21**	**0**	**0**	**43**	100 %
Traced	5 %	14 %	14 %	19 %	49 %	0 %	0 %	100 %	

For the definition of classes see Table 10

(a): Class 3A was traced only in Ireland, the Netherlands and Sweden.

(b): Classes 3B (n = 32) and 4 (n = 2) were not traced.

(d): Eight additional Italian lots of class 2B were not traced as they were lots connected with higher-priority lots. One additional Italian lot of class 2C was not traced because the positive sample had been taken from an open package in the house of a suspected case that was subsequently considered "not a case".

(d): One additional Swedish case was not traced owing to time constraints.

(e): One additional French lot was not traced as it was an ingredient of the traced lot.

The individual lots or cases and the associated starting points in the food chain are described in Tables 29 (lots) and 30 (cases). Detailed information is given in Appendix A.

Table 29: Relation between traced lots and starting points in the food chain (by country: Italy, France and Norway)

	Lot: product	Country	Class (up to 3A)	Starting point	Type of station
1	Confirmed lot IT#01: frozen berries	Italy	1	IT#17	Frozen berry processor (packager)
2	Confirmed lot IT#02: frozen berries	Italy	2A	IT#1214	Frozen berry processor (packager)
3	Confirmed lot IT#04: frozen berries	Italy	2A		
4	Suspect lot IT#20: frozen berries	Italy	2B		
5	Confirmed lot IT#06: frozen berries	Italy	2A	IT#22	Frozen berry processor (packager)
6	Confirmed lot IT#07: frozen berries	Italy	2A		
7	Suspect lot IT#016: frozen berries	Italy	2B		
8	Suspect lot IT#017: frozen berries	Italy	2B		
9	Suspect lot IT#018: frozen berries	Italy	2B		
10	Suspect lot IT#019: frozen berries	Italy	2B		
11	Confirmed lot IT#05: frozen berries	Italy	2C		
12	Confirmed lot IT#08: frozen berries	Italy	2C		
13	Confirmed lot IT#09: frozen berries	Italy	2C		
14	Confirmed lot IT#15: frozen berries	Italy	2A	IT#21	Frozen berry processor (packager)
15	Confirmed lot IT#13: frozen berries	Italy	2C		
16	Confirmed lot IT#14: frozen berries	Italy	2C		
17	Confirmed lot IT#03: frozen berries	Italy	2C	IT#19	Frozen berry processor (packager)
18	Confirmed lot IT#11: frozen berries	Italy	2C	IT#234	Frozen berry processor
19	Confirmed lot IT#12: frozen berries	Italy	2C	IT#236	Frozen berry product retailer
20	Confirmed lot FR#1: pastry	France	2A	FR#1793	Berry product producer (pastry manufacturer)
21	Confirmed lot NO#1: cake	Norway	1	NO#1787	Berry product retailer
22	Suspect lot NO#2: cake	Norway	2B		

Table 30: Relation between cases and starting points (class 3A) in the food chain (by country: Ireland, Sweden and the Netherlands)

Ireland

Type of station			Starting point by product consumed								
			Yoghurt		Cake	Frozen berries		Smoothies with frozen berries			
			RB	MB	MB	MB	BB	MB1	MB2	MB3	MB4
Frozen berry trader (supplier)			(IE#238)			IE#229	(IE#238)	(IE#238)			
Berry product producer (manufacturer)			IE#1215								
Berry product retailer (local retailer)							IE#235	IE#1211	IE#1207	IE#1208	IE#1209
23	Case IE#433765	3A	X		X						
24	Case IE#440019	3A	X		X						
25	Case IE#441254	3A	X		X						
26	Case IE#434360	3A	X	X	X						
27	Case IE#439499	3A	X	X	X	X					
28	Case IE#439125	3A		X	X						
29	Case IE#440889	3A		X	X						
30	Case IE#439110	3A					X				
31	Case IE#438998	3A						X			
32	Case IE#431742	3A							X	X	
33	Case IE#433732	3A									X

Sweden

Type of station			Starting point by product consumed	
			Mixed berries	Berry purée
Berry product retailer (restaurant)			SE#1536	
34	Case SE#1	3A	X	X
35	Case SE#2	3A	X	X

Netherlands

Type of station			Starting point by product consumed						
			Fresh berries						
			FSB1	FRB1	FBL1	FBB	FSB2	FRB2	FBL2
Berry product retailer (supermarket)			NL#1301				NL#1314/#1315		
36	Case NL#1090587 /NL-pt3	3A	X						
37	Case NL#1090481 /NL-pt6	3A	X						
38	Case NL#1095205 /NL-pt7	3A	X	X					
39	Case NL#1106187 /NL-pt12	3A	X	X	X				
40	Case NL#1093061 /NL-pt8	3A	X	X	X	X			
41	Case NL#1090269 /NL-pt2	3A					X		
42	Case NL#1093507 /NL-pt9	3A					X	X	
43	Case NL#1091445 /NL-pt4	3A					X	X	X

X = Product was consumed by the case. RB, raspberries; MB, mixed berries; BB, blackberries; FSB, fresh strawberries; FRB, fresh raspberries, FBL, fresh blueberries.

4. Data sources and analysis tool

4.1. Background

Beginning with the outbreak caused by Shiga toxin-producing *Escherichia coli* O104:H4, the BfR in Germany started to develop a GPL-licensed open-source software tool called "FoodChain-Lab", which supports tracing back and forward analysis of suspicious food items along food supply chains. Starting at the locations identified as the most probable sites of infection, the tool allows trace-back of supply chain connections between different starting points of the multinational outbreak. Such trace-back and trace-forward analyses led in the case of the enterohaemorrhagic *E. coli* (EHEC) outbreak to the identification of sprouts as the vehicle for the EHEC pathogen and of a specific lot of fenugreek seeds imported from Egypt as the most likely source of contamination (Weiser et al., 2013).

4.2. Methodology: tracing back and forward strategies

Usually, the aim of tracing back is to document the full distribution and production chain of a product being suspected as the vehicle (food item) of a foodborne disease outbreak. This should allow the source of contamination to be identified. As a starting point, food commodities or components of a complex meal which have been consumed by cases meeting a case definition are selected. For this, epidemiological or microbiological evidence helps to identify the most suspicious food items to be selected as a starting point for tracing back analysis. If a common supplier can be identified by tracing back analysis, linking supply chains to several cases/contaminated food commodities, it becomes possible to inspect and investigate the potential entry site and source of contamination (Figure 14).

Starting a tracing forward strategy from an identified or suspicious common point (node) in the direction of the customer might be used to identify additional, as yet unknown, clusters or cases or critical nodes where contaminated food commodities might still be available. It can also be used to validate the hypothesis derived from backward tracing.

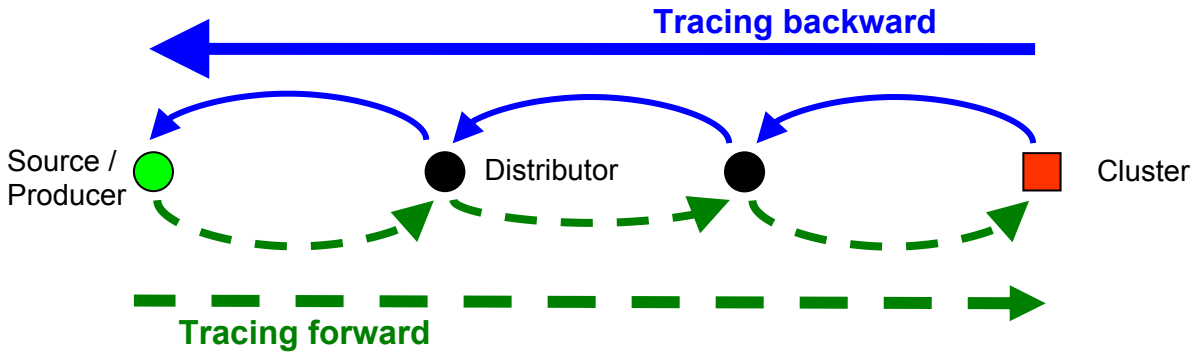


Figure 14: Schematic overview of the tracing back and tracing forward strategy

4.3. FoodChain-Lab data structure

The software tool FoodChain-Lab uses a data structure containing entities: station, product, lot and delivery. Within the software all kind of receivers and deliverers are called station. The data structure is shown in Figure 16. In order to comply with the requirements of the FoodChain-Lab tool, the supply chain data need to be structured in such a way that it is clear which delivery of a station (deliverer) goes into which product of a different station (recipient), e.g. Station A delivers 10 kg of frozen strawberries on 6 September to Station B, which on 8 September includes 100 g in its product "dessert". The red arrows in Figure 15 illustrate this concept.

As a consequence, it is *not* sufficient to provide only the following information: Station A delivers 10 kg of frozen strawberries to Station B. Information from Station B on the target product is missing and is urgently needed.

In order to be able to finally assemble all information, it is recommended that as much information as possible is provided for each entity (e.g. address, VAT number, product description, etc.). The data model applied in FoodChain-Lab allows detailed information to be recorded for each of the entities (Figure 16). In Figure 16 the most important attributes are marked green. In addition, this data model allows tracing of supply chains of indefinite length, with varying length and with a different number of intermediate steps for the same food commodity. This is necessary if, for example, a part of a batch is handled by several intermediate distributors or is re-packed.

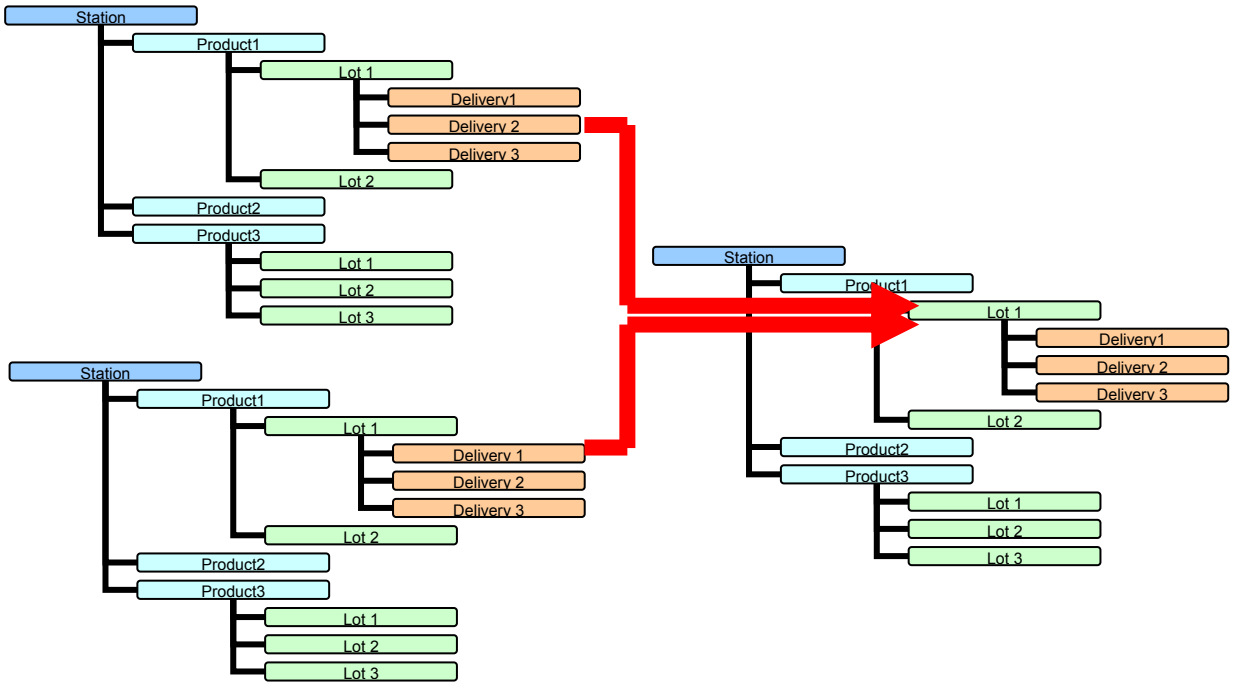


Figure 15: General principle of food supply chain reconstruction as performed by FoodChain-Lab

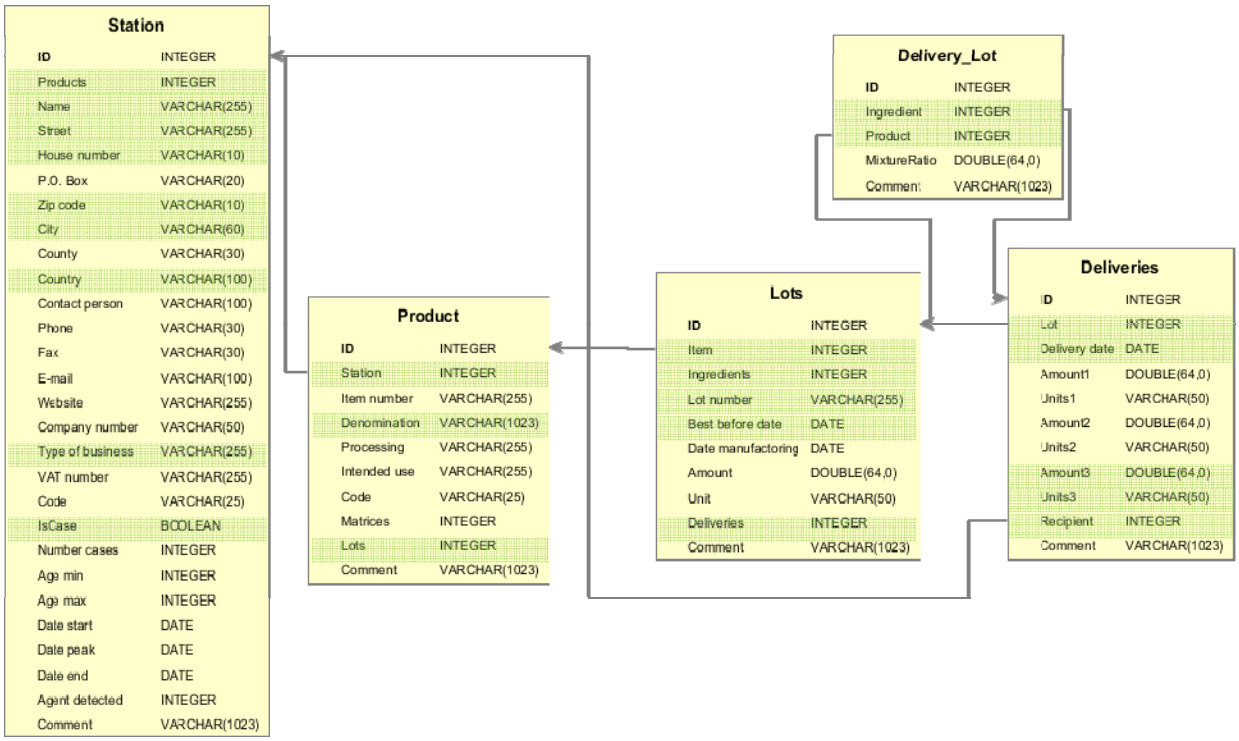


Figure 16: Detailed data structure used by FoodChain-Lab for analysing the food supply chain. The most important attributes are marked in green

The collection of data from suppliers and distributors on food commodities which are traced back in relation to the HAV outbreak is done by the responsible EU Member States via predefined Excel sheets which can be attached to any RASFF notification. The FoodChain-Lab software is able to import all information from these Excel files (section 4.2).

4.4. Data quality and data validation

During data import, the FoodChain-Lab software performs plausibility checks in order to ensure that information is consistently imported from the Excel files, e.g. that each food business operator is given a unique identifier or that changes in batch or lot numbers at the different stations of the food distribution chain are documented. Moreover, the software verifies that one delivery step follows the other in the correct sequence (i.e. the chronology within the supply chain is correct) and that the amounts handled are plausible. To ensure this, FoodChain-Lab checks that the following are true:

- outgoing deliveries within the same lot occur after the incoming deliveries;
- quantities of each product get smaller along the supply chain and incoming and outgoing deliveries or storage at each company are of the same order of magnitude.

Figure 17 highlights the similarity search implemented to overcome typing errors and other differences in data entries. The aim is to allocate the same identifier to information which belongs together.

Another objective of FoodChain-Lab is to support geographical visualisation. To collect information on the geographical localisation of the stations, an internal installation of Gisgraphy (http://www.gisgraphy.com/) is used. Gisgraphy is an open-source geocoding service which uses data

from the OpenStreetMap project (http://www.openstreetmap.org). This tool can be used for validation of the correctness of the data collected.

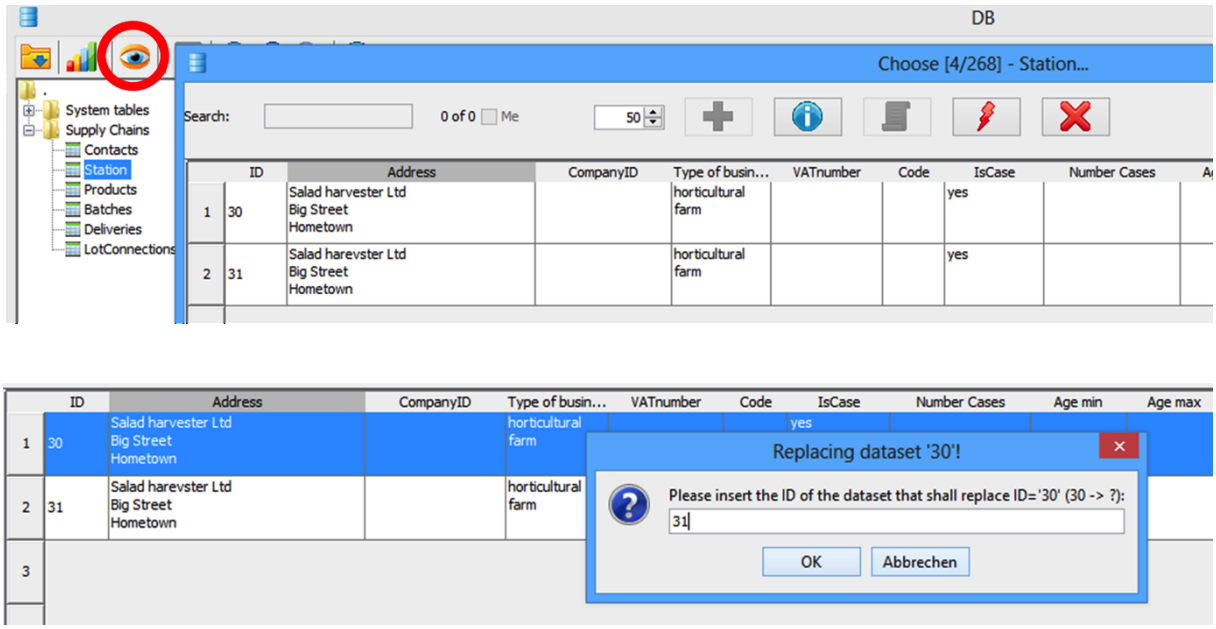


Figure 17: Screenshot of the FoodChain-Lab DB graphical–user interface that allows for searching for similarities within stations, products, lots and deliveries in order to merge things that should be merged

4.5. Data analysis

A core application area of FoodChain-Lab is the visualisation and analysis of collected food chain data. This is accomplished by constructing and visualising interactive network graphs. A network consists of nodes and connections (edges) between the nodes. In case of the trade of food commodities to and from stations (food enterprises, retailers and kitchens), the stations will be represented by nodes and the movement of food commodities between the stations is represented by edges. An edge always connects two nodes.

The principle of network analysis is depicted in Figures 18 and 19.

In the context of a tracing back task, the identification of probable sources of foodborne infections is supported by features integrated into FoodChain-Lab. The tool can be used to link the information collected on the food supply chain back (via several edges and nodes) to find a common node.

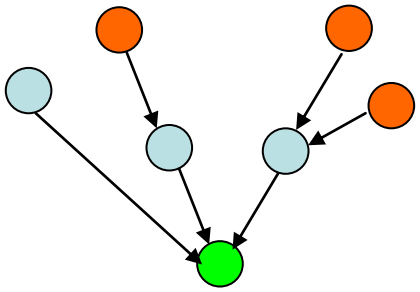


Figure 18: Principle of network graphs: the circles are the nodes (e.g. companies trading a product) and the lines are the edges (e.g. representing the movement from one company to another)

The possible common point of contamination of several food products can then be further explored by microbiological examinations and/or by tracing forward analysis. Tracing forward analyses should verify whether, for all or most of the cases meeting the case definition, a vehicle can be identified which can be linked to the identified source. Furthermore, it can be assessed whether additional cases can be shown to be caused by the same food commodity. This task is also supported by FoodChain-Lab. In addition to the specific software features that are required to enable trace-back and tracing forward analysis (and which are described in the following sections), the following general features distinguish FoodProcess-Lab:

- All data processing steps are applicable interactively, i.e. visualisations refresh immediately based on user defined selection criteria or configuration settings (predefined colours, sizes of nodes/edges). This enables application of FoodChain-Lab in brainstorming-type sessions.
- Data, calculation results and graphical visualisations can easily be exported as data tables or images for use in other tools or in reports.
- Data can be anonymised immediately and consistent coding can be used for presentation of results.

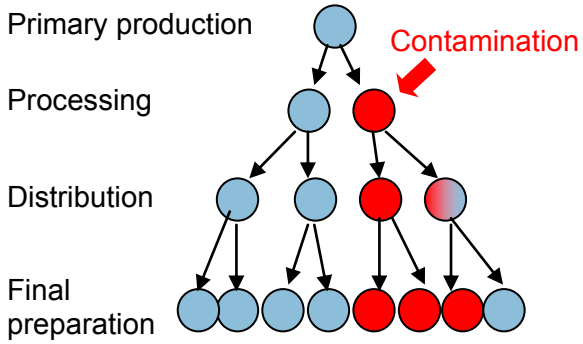


Figure 19: Contamination of a food item during processing and spread along the supply chain to different final products, visualised as a network graph

4.5.1. Filters

On the basis of a supply chain network, the use of filters allows specific categories related to the products or specific companies to be analysed. For example, if one suspicious ingredient is selected, any link common to several human cases who consumed food items containing this ingredient can be visualised, regardless of the number of nodes that have to be connected along the supply chain and the renaming/varying of products therein. Selecting a suspect node ("hotspot") in the network results in a list of nodes and their connections. For example, in the EHEC outbreak, selection of disease clusters and a specific lot from fenugreek sprouts resulted in a list of common nodes and their connections with each other within the network (Weiser et al., 2013).

FoodChain-Lab provides an interface to interactively and visually analyse the whole network or parts the network. If a certain station looks suspicious, the user can interactively select it and the software shows all station/deliveries that are connected to this station, as shown in Figure 20.

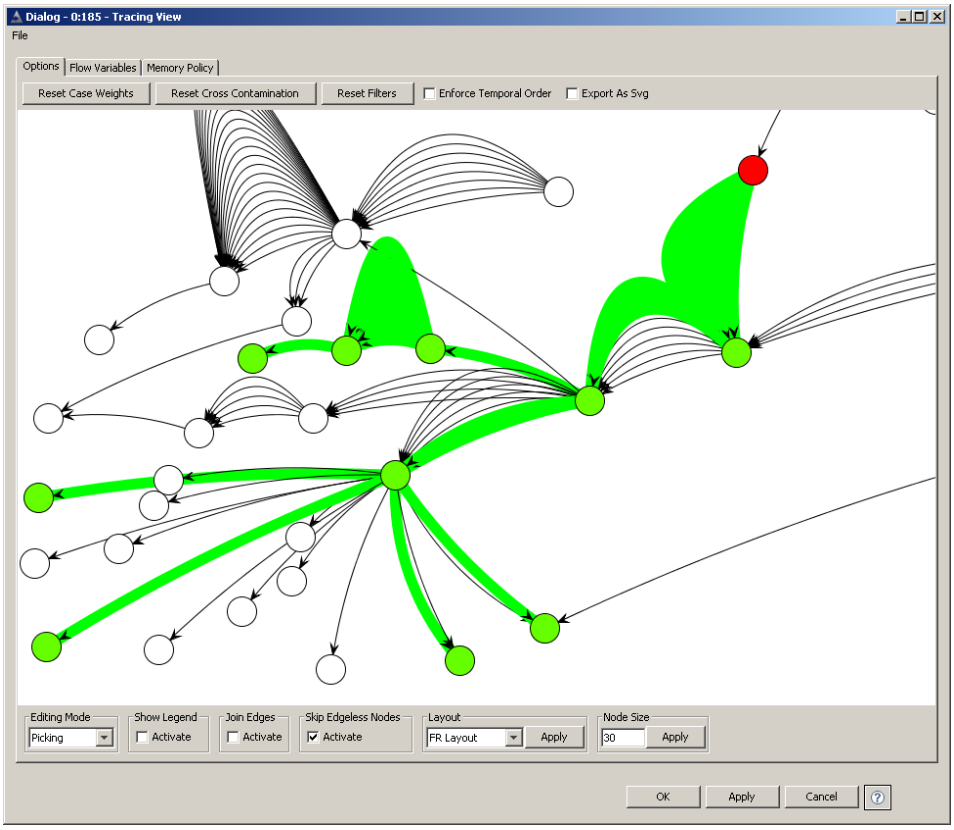


Figure 20: Interactive network visualisation and tracing. The green edges mark all direct and indirect deliveries from one company. The green nodes mark all stations that received these deliveries

4.5.2. Cross-contamination

Consideration of cross-contamination, which may occur between lots or products, can be switched on and off for each station separately. For stations where cross-contamination should be taken into account (switched on), it is assumed that all deliveries from all suppliers are connected to all deliveries to all recipients. Taking cross-contamination into account still requires correct temporal order of the deliveries, i.e. a delivery from a supplier may not be connected to an older delivery to a recipient.

Considering cross-contamination is often helpful in situations in which there is no obvious common source. Using the cross-contamination mode does not necessarily mean that this really happened, but it gives data analysts the opportunity to compensate for missing information (e.g. on individual lots) by simulating different scenarios for selected stations.

4.5.3. Scoring

FoodChain-Lab provides the user with a scoring feature. The standard scoring analysis can be adjusted by the user by assigning weights (priorities) to cases or contaminated lots. FoodChain-Lab computes scores taking into account the user-defined weights for all stations and also for the deliveries. The higher the score, the more likely it is that a contamination of a commodity at the specific station can explain the weighted cases or contaminated lots. The calculation of the score is depicted in Figure 21.

Besides calculating scores, FoodChain-Lab also allows to visualise the scores. To achieve this, usually the node sizes are adjusted according to their score, i.e. bigger nodes are more likely to be relevant in the outbreak investigation than small nodes. This immediate visual representation helps to speed up investigations.

$$\text{Score}(S_j) = \frac{\sum_{i=1}^{n} cp_i \cdot R(S_j, c_i)}{\sum_{i=1}^{n} cp_i}$$

$$R(S_j, c_i) = \begin{cases} 1, & \text{if } S_j \rightarrow c_i \\ 0, & \text{if } S_j \not\rightarrow c_i \end{cases}$$

S_j : station j

c_i : case i

with: cp_i : priority of case i

n : number of cases

$\text{Score}(S_j) \in [0, 1]$

Figure 21: Scoring scheme implemented in FoodChain-Lab

4.5.4. Regional analysis

If geographical information is available, this can be used for GIS-based visualisations, as shown in Figure 22. If geographical information (latitude and longitude data) is not available, FoodChain-Lab is able to generate that information based on address information associated with the stations. This is done by using Gisgraphy (www.gisgraphy.com), as already explained in section 4.4. Gisgraphy allows in-house geo-referencing, which guarantees confidential data handling.

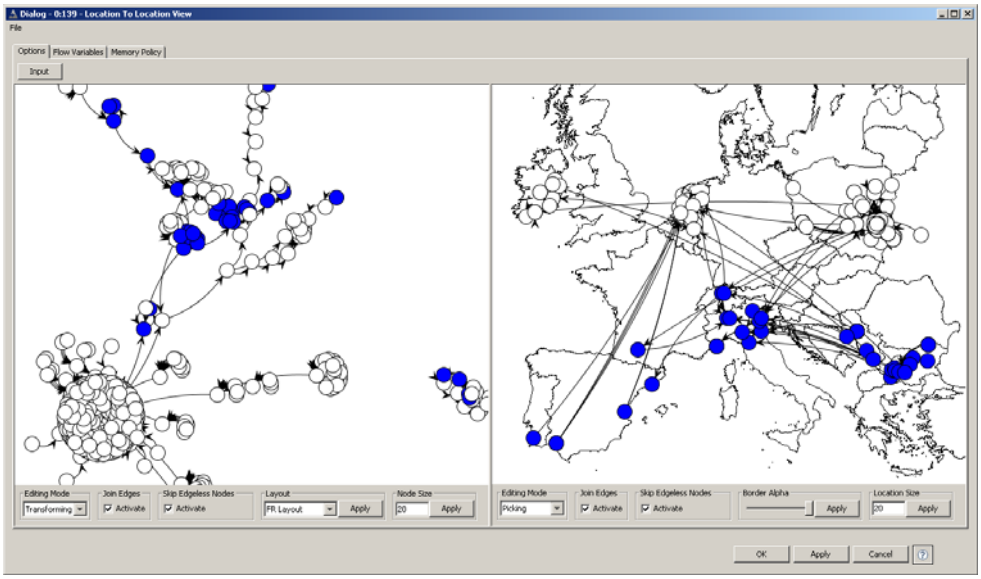


Figure 22: Interactive graphical (left) and geographical (right) network visualisation. Blue nodes on the left and on the right represent the same entities

FoodChain-Lab is also able to score regions. To accomplish this, the user has to define a region of interest by selecting the desired nodes. This can be done within the interactive GIS map viewer which is part of FoodChain-Lab. This feature is of high relevance:

- for regions where tracing information is missing;
- when scenarios should be evaluated that should consider the possibility of environmental contamination, e.g. that primary producers use the same (probably contaminated) water sources on their farms.

The process of finding regions can also be automated with FoodChain-Lab; this saves time in the case of large datasets and means that the analysis is performed in a more objective way. To do this the DBSCAN algorithm (http://en.wikipedia.org/wiki/DBSCAN) is used on the latitude/longitude coordinates of the stations. This algorithm assigns stations to a cluster if they are within a certain distance of at least one node of the cluster. A maximum distance of 10 km between stations was used in the analysis.

4.6. Data sources

All data used in this report were collected, using a standard data format and template, by the national and regional authorities via the European RASFF system. The data can be found in iRASFF-News listed in Table 31.

Table 31: iRASFF News used to exchange information

iRASFF-News	Exchange of
iRASFF 13-721	Tracing data and data requests concerning starting points in Italy
iRASFF 13-722	Tracing data and data requests concerning starting points in Ireland
iRASFF 14-737	Tracing data and data requests concerning starting points in France
iRASFF 14-736	Tracing data and data requests concerning starting points in Norway
iRASFF 14-738	Tracing data and data requests concerning starting points in Sweden
iRASFF 13-723	Tracing data and data requests concerning starting points in the Netherlands

The lots of berries linked to HAV epidemic outbreak cases that could be identified and traced back in Italy, Ireland, France, Norway, Sweden and the Netherlands are shown in Tables 29 and 30.

The tracing dataset comprises 6 227 transactions from 1 974 stations in 39 countries (from primary producer to cases/lots). It covers back-tracing of the starting points described in section 3.5, as well as forward-tracing for some companies in Italy and Poland.

To simplify the data collection in third countries (outside EU or cooperating countries in the RASFF system), questions were developed to ensure that the primary production is located in the third country and, thus, that the food production chain ended there.

Missing data exists where tracing information could not be obtained beyond the company exporting berries into Europe or at the level of primary production in countries when a large number of small scale producers contributed to a single lot of berries.

5. Analysis and results

5.1. Descriptive analysis of the tracing results

Summary

Analysis of the berry ingredients of the traced lots showed that all lots classified with very high or high strength of evidence contained blackberries, and the majority contained redcurrants (Table 32).

Analysis of the country of origin of berry ingredients of the lots showed that Poland and Bulgaria were the most frequently identified countries origin of berries in all evidence classes (Table 33). This is indicative of the fact that these two countries are major producers and exporters of frozen berries; Poland is the largest producer of redcurrants in Europe.

When berry type and country of origin were combined, it was observed that only two lots (both 2C) with a classification of very high- or high-strength evidence did not contain Polish redcurrants (Table 34). Overall, 63 % of starting points traced contained redcurrants, of which 96 % were from Poland. In the case of blackberries, Bulgaria was the most frequently identified country of origin, but Bulgarian blackberries were not found in all lots within any of the evidence classes. Overall, 74 % of the starting points traced contained blackberries, of which 59 % were from Bulgaria. When interpreting these results it is important to note that complete tracing data were available for a high proportion of products of Polish origin (either to the primary producer or to a freezing processor), but for other

countries final end points were missing and, therefore, the country of origin may not be correctly identified.

Other ingredients, for example raspberries, blueberries and strawberries, do not occur in the majority of lots or were sourced from a variety of countries.

In conclusion, the largest number of the starting points could be connected to either:

- redcurrants with tracing end point in Poland;
- blackberries with tracing end point in Bulgaria.

Analysis

A comprehensive descriptive analysis of the tracing dataset was performed with regard to the type of berry included in the back-traced lots, country of primary origin (harvesting) of the berries and, whenever available, geographical origin of the primary producers within a country. Frequency distributions and proportions of lots including the different types of berries and their origin were calculated, according to the classification of the lots. This approach allows an exploration of possible links between outbreak human cases and the berries taking into account the strength of evidence.

5.1.1. Types of berries involved in the starting points

Among the lots with very high-strength evidence, only blackberries and redcurrants appear consistently (Table 32).

Raspberries and strawberries are more frequent in the case-related starting points of class 3A. This might be related to the general market share of these types of berries (Appendix C). The exclusion of lingonberries and blackcurrants from tracing is still justified after including the newer outbreaks in France, Norway and Sweden. These types of berries appear in only a few lots (or cases) and in the lower evidence classes (2C, 3A).

Table 32: Occurrence of different types of berries in lots/products at the starting points of tracing

Type of berries	Classification of lots/cases											
	1		2A		2B		2C		3A		Total	
	Very high-strength evidence				High-strength evidence				Medium-strength evidence			
	No	%	No	%	No	%	No	%	No [(a)]	%	No	%
Blackberries	2	100	6	100	6	100	8	100	10	48	32	74
Redcurrants	2	100	6	100	6	100	6	75	7	33	27	63
Raspberries	2	100	5	83	5	83	7	88	17	81	36	84
Blueberries, bilberries	1	50	6	100	5	83	7	88	7	33	26	60
Strawberries	1	50	0	0	1	17	0	0	16	76	18	42
Lingonberries [(b), (c)]	0	0	1	17	0	0	2	25	0	0	3	5
Blackcurrants [(b)]	0	0	0	0	0	0	1	13	7	33	8	19
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**21**	**100**	**43**	**100**

(a): No of related cases.
(c): Lingonberries and blackcurrants were not traced.
(c): Lingonberries, cranberries.

5.1.2. Origin of berries involved in the starting points

Regarding the origin of the berries involved in the starting points, Poland and Bulgaria are frequently the tracing end points of ingredients for the confirmed lots with HAV and HAV OS contamination (Table 33). Poland is the tracing end point of all lots with very high-strength evidence, while Bulgaria is the end point for only 88 % of lots with very high-strength evidence (100 % of class 1 and 83 % of class 2A).

The results are lower for all other countries. It should be noted, however, that Poland is the biggest producer of redcurrants, raspberries and other berries (including blackberries) in Europe, and the second largest producer of strawberries (Appendix C).

Table 33: Origin (most important countries) of all type of berries in lots/products at the starting points of tracing

Country of origin	Classification of lots/cases											
	1		2A		2B		2C		3A		Total	
	Very high-strength evidence				High-strength evidence				Medium-strength evidence			
	No	%	No	%	No	%	No	%	No [(a)]	%	No	%
Poland	2	100	6	100	6	100	7	88	13	62	34	79
Bulgaria	2	100	5	83	4	67	3	38	6	29	19	44
Serbia	1	50	4	67	3	17	3	38	4	19	15	35
Chile	1	50	1	17	1	50	2	25	2	10	7	16
Canada	1	50	3	50	3	17	3	38	2	10	12	28
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**21**	**100**	**43**	**100**

(a): No of related cases

Table 34 shows differences between Poland and Bulgaria when further differentiated by berry type. While 96 % of the traced redcurrants from starting points originated from Poland, only one lot (class 2C) of blackberries originated from Poland. The blackberries are predominantly (50 % of class 1, 83 % of class 2A 67 % of class 2B, 25 % of class 2C) from Bulgaria. Raspberries were linked to several countries of origin.

Table 34: Origin (most important countries) of different types of berries in lots/products at the starting points of tracing

Country of origin	Classification of lots/cases											
	1 Very high-strength evidence		2A		2B High-strength evidence		2C		3A Medium-strength evidence		Total containing these berries	
	No	%	No	%	No	%	No	%	No [(a)]	%	No	%
Total no of lots or cases	**2**		**6**		**6**		**8**		**21**		**43**	
Blackberries												
Bulgaria	1	50	5	83	6	67	2	25	6	60	19	59
Serbia	1	50	0	0	1	17	0	0	2	20	4	13
Chile	0	0	1	17	0	0	1	13	2	20	4	13
Poland	0	0	0	0	0	0	1	13	0	0	1	3
No of lots or cases with blackberries	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**10**	**100**	**32**	**100**
Redcurrants												
Poland	2	100	6	100	6	100	6	100	6	86	26	96
No of lots or cases with redcurrants	**2**	**100**	**6**	**100**	**6**	**100**	**6**	**100**	**7**	**100**	**27**	**100**
Raspberries												
Bulgaria	1	50	1	20	2	40	1	14	0	0	5	14
Chile	1	50	0	0	1	20	0	0	1	6	3	8
Serbia	0	0	4	80	2	40	3	43	3	18	12	33
Poland	0	0	0	0	0	0	3	43	11	65	14	39
No of lots or cases with raspberries	**2**	**100**	**5**	**100**	**5**	**100**	**7**	**100**	**17**	**100**	**36**	**100**
Strawberries												
Morocco	1	100	0		1	100	0		0		2	25
Poland	0	0	0		0	0	0		8	50	8	44
No of lots or cases with strawberries	**1**	**100**	**0**		**1**	**100**	**0**		**16**	**100**	**18**	**100**
Blueberries, bilberries												
Canada	1	100	3	50	3	60	3	42	2	29	12	46
Chile	0	0	1	17	0	0	0	0	0	0	1	4
Poland	0	0	0	0	0	0	1	14	2	29	3	12
No of lots or cases with blueberries	**1**	**100**	**6**	**100**	**5**	**100**	**7**	**100**	**7**	**100**	**26**	**100**

(a): No of related cases

More details can be found in Table 43.

5.1.3. Completeness of tracing

Trace-back was considered to be complete when the place of primary production of an ingredient was identified. Table 35 shows that more than 80 % of the tracing end points were primary producers and that less than 5 % stopped at the level of freezing processors or frozen berry traders, but for 10 % or less the status of the end point was unknown.

Table 35: Types of stations at the end points of tracing

Type of the tracing end point	Class of lots/cases as starting points of tracing											
	1 Very high-strength evidence		2A		2B High-strength evidence		2C		3A Medium-strength evidence		Total	
	No	%	No	%	No	%	No	%	No	%	No	%
Unknown	8	10	20	8	8	6	10	5	11	1	57	3
Primary producer	69	87	202	85	120	90	169	90	816	82	1376	84
Fresh berry trader	1	1	5	2	2	1	2	1	147	15	157	10
Freezing processor	0	0	1	0	1	1	2	1	1	0	5	0
Frozen berry trader	1	1	11	5	3	2	5	3	17	2	37	2
No of end points of tracing	79	100	239	100	134	100	188	100	992	100	1 632	100

Within the EU countries, 98 % of the end points traced to Poland were to the level of primary production (Table 36). In 98 % of end points traced to the Netherlands and 94 % traced to Belgium, the end point was at the level of primary production or fresh berry trader. For Bulgaria and Romania, only about 50 % of the end points of tracing could be considered complete. For Serbia, 96 % of the end points were operators of unknown type.

For the non-EU/EFTA countries, the tracing activities stopped at the level of freezing processors, frozen berry traders or status unknown (Table 36). This was because we applied a simplified data collection for those countries. If a non-EU/EFTA country (excluding Serbia) was reached, the national contact points were asked only to confirm that the tracing information was correct and the fruits were produced in their countries. Serbia was excluded from this simplification because one "hotspot" (section 5.2.1) was found to be located in Serbia.

In summary, data collection is mostly complete. An exception is the tracing of blackberries, which is incomplete in one third of the end points (Table 37), and does not reach the level of primary production or fresh berry supplier.

One consequence of incomplete data is that the information on the year of harvest is also missing. The database contains berries harvested from 2011 to 2013.

Table 36: Types of stations at the end points of tracing per country

Country of end station	Types of end points of tracing											
	Primary producer		Fresh trader		Freezing processor		Frozen berry trader		Unknown		Total	
	No	%	No	%	No	%	No	%	No	%	No	%
EU/EFTA Member States												
Poland	1 362	98	18	1			8	1	5		1393	100
Netherlands			121	98			1	1	1	1	123	100
Bulgaria	10	48					9	43	2	10	21	100
Belgium	1	6	14	88			1	6			16	100
Romania	2	50							2	50	4	100
Spain			1	25			3	75			4	100
Sweden									4	100	4	100
Non-EU/EFTA countries												
Serbia							1	4	23	96	24	100
Chile							1	11	8	89	9	100
Belarus							6	86	1	14	7	100
Canada	1	20			4	80					5	100
Morocco									4	100	4	100
Ukraine							1	33	2	67	3	100
Total												
Others [(a)]			3	20	1	7	6	40	5	33	15	100
No of end stations of tracing	**1 376**	**84**	**157**	**10**	**5**	**0**	**37**	**2**	**57**	**3**	**1632**	**100**

(a): Another12 EU and non-EU countries with one or two end points of tracing.

Table 37: Types of stations at the end points of transactions by berries

Type of berries	Types of end points of tracing											
	Primary producer		Fresh trader		Freezing processor		Frozen berry trader		Unknown		Total	
	No	%	No	%	No	%	No	%	No	%	No	%
Raspberries	1 063	72	371	25		0	13	1	31	2	1478	100
Redcurrants	775	98	10	1		0	6	1	1	0	792	100
Strawberries	45	6	645	92		0	2	0	8	1	700	100
Blueberries /bilberries	11	6	141	79	3	2	13	7	10	6	178	100
Blackberries	2	2	65	65	3	3	13	13	17	17	100	100
Blackcurrants	24	86	1	4		0	3	11		0	28	100
Others		0		0		0	4	44	5	56	9	100
No of transaction at end stations	**1 920**	**58**	**1 233**	**38**	**6**	**0**	**54**	**2**	**72**	**2**	**3 285**	**100**

5.2. Network analysis

The network analysis was used to identify possible "hotspots". "Hotspots" are stations (nodes) in the tracing net that are connected to a large number of starting points by deliveries of berries (edges) (as defined in section 3) and are therefore able to explain a large number of contaminated lots or HAV cases. A contamination event could occur at a "hotspot" or at a point prior to the "hotspot" in the supply chain. Investigations by local authorities of the supply chain at or before the "hotspot" would be required to fully characterise the source of contamination.

Owing to differences in the investigations and identification of starting points of Italy, Ireland and the Netherlands, the analysis was done separately for each Member State. The starting points in Italy were HAV-contaminated lots based on laboratory testing and suspect lots linked to confirmed cases, whereas in Ireland and the Netherlands the starting points were the products identified from food histories of the confirmed cases.

In Italy the identification of possible "hotspots" was based on the evaluation of numbers of lots as well as numbers of starting points (frozen berry processors performing packaging) to account for the sampling intensity of products from some processors, whereas in Ireland and the Netherlands the numbers of cases were used.

For some countries of origin, the identification of all primary producers or fresh berry suppliers was not possible (section 5.1.3). In addition, even in countries where the tracing information included all primary producers, a "hotspot" could be overlooked. This would occur when the connection between the stations is not a transaction of goods. Several factors, such as the exchange of temporary workers, the shared use of equipment (e.g. machinery for harvest) or a common water reservoir, could link several stations. In both cases a "hotspot" may be overlooked because the exchange of material between stations is unknown. One strategy to identify hidden "hotspots" is to combine all stations within a region (e.g. country or local administrative region) into a single virtual station. The combined score of the region will be higher than or equal to the score of each of the elements. When applying a geographical clustering to detect hidden "hotspots" it is assumed that stations within the geographical region can be linked to a common source of contamination even if, for some stations, no tangible link exists. The FoodChain-Lab software is able to identify stations separated by a predefined maximum limit (section 4.5.5). The 10 km distance between stations used in the analysis may be too large for common water reservoirs, but too narrow for the exchange of temporary workers.

To avoid redundancy of data, the "hotspots" closest to the starting points were mainly considered. As a consequence the stations supplying a "hotspot" station were not necessarily considered "hotspots". In the intermediate analysis, seven possible "hotspots" were identified: four for Italy, two for Ireland and two for the Netherlands (one "hotspot" common to Italy and Ireland was identified). These possible "hotspots" were re-evaluated with the additional data from France, Norway and Sweden. The following sections describe the final findings. More detailed information can be found in Appendix B.

5.2.1. Identification of suspected common sources of contamination with HAV

Summary

No single point source of contamination ("hotspot") linking all cases and contaminated lots (starting points) identified during the multinational outbreak could be determined. The transaction data indicate that source of the outbreak may be either:

- redcurrants produced in Poland

or

- blackberries produced in Bulgaria.

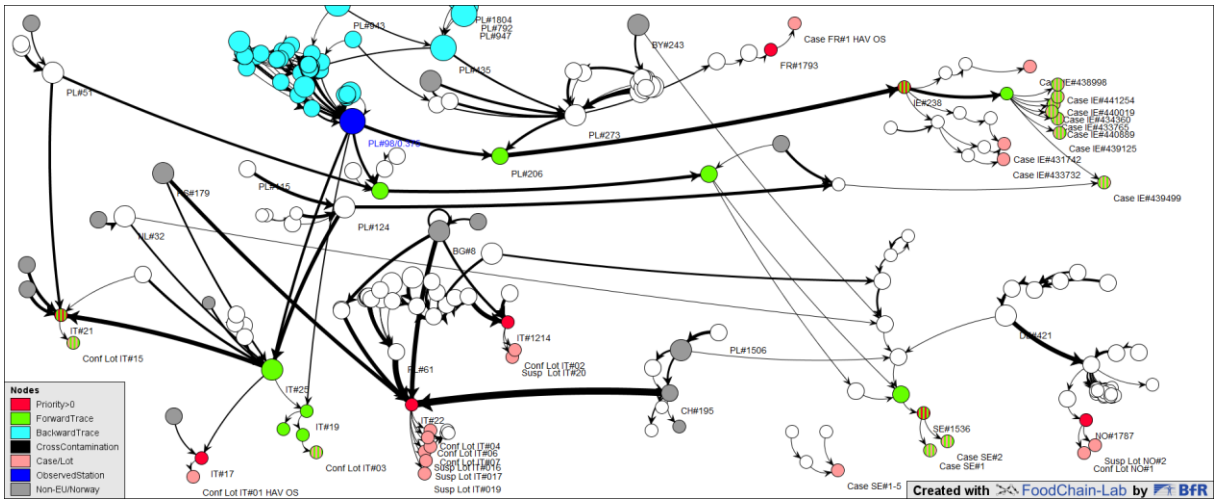
Blackberries: "Hotspot" BG#8 plus two additional Bulgarian frozen berry suppliers (BG#1222 and BG#1260) are linked to Italian lots. The French lot and Irish cases are linked to the Bulgarian frozen supplier BG#1884 and the Norwegian lot is linked to Bulgarian company BG#1808. Five Bulgarian suppliers of blackberries are linked to a total of 22 cases or lots.

Redcurrants: One or more of three "hotspots" (PL#273, PL#98 and PL#115) are linked to Italian and French lots plus the Irish cases. Four common primary producers of redcurrants were identified linking these hotspots. A further two Polish freezing processors are linked to Italian lots (PL#61 and PL#1237). The Norwegian lots are linked to Polish freezing processor PL#1810 and the Swedish cases to Polish freezing processor PL#260. Possible cross-contamination at stations further down the food chain (e.g. at IT#25) could link additional cases and lots to these freezing processors Seven Polish freezing processors are linked to a total of 31 cases or lots.

Involvement of other berries, under the hypothesis of a primary source of contamination, is unlikely because the places of origin are very heterogeneous. A special situation is the Dutch outbreak where contaminated fresh strawberries were able to explain a major part of the Dutch cases. However, no single "hotspot" could be identified in the Dutch outbreak. In the tracing network, the Dutch outbreak is isolated from the other countries. This suggests either a solitary viral contamination event in the fresh strawberry production chain or an overlooked and unidentified food item that was not recalled by the Dutch cases. For this reason, a separate analysis was carried out, as shown in Appendix B, section B.3.

5.2.1.1. "Hotspots" identified with the Italian outbreak data

"Hotspot" PL#98



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 23: Network visualisation of connections between identified "hotspot" PL#98 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

"Hotspot" PL#98 is a freezing processor and connects many starting points in Italy, Ireland and Sweden. Raspberries were supplied by 38 fresh berry suppliers and 680 primary producers. Redcurrants came from 75 primary producers.

Freezing processor PL#98 has been identified in the supply chain for raspberries in a RASFF alert notification for norovirus contamination.

Italy: Contamination of raspberries (harvested in 2012) at PL#98 could explain one starting point (IT#19) and one related confirmed lot (lot IT#03) of class 2C. Contamination of redcurrants (harvested in 2011) at PL#98 could explain one starting point (IT#21) and one confirmed lot (lot IT#15) of class 2A. Cross-contamination at PL#98 is needed to link these different lots.

Assuming cross-contamination from the redcurrants during the supply chain (packager IT#25 and packager IT#21) one additional starting point (IT#17) with three related lots could be explained: lot IT#01 of class 1, lot IT#13 and lot IT#14 of class 2C.

However freezing processor PL#117 also supplied redcurrants used in lot IT#15 and freezing processor PL#1527 supplied the redcurrants used in lots IT#13 and IT#14.

Ireland: Contamination of raspberry crumb (harvested in 2012) at PL#98 could explain seven Irish cases (all class 3A) who consumed one or more of three of the suspected Irish products (raspberry yoghurt, mixed berry yoghurt and cake) produced at starting point IE#1215.

Sweden: Contamination of raspberries (harvested in 2013) at PL#98 could also explain the Swedish starting point SE#1536 with two connected cases (case SE#1, SE#2 class 3A).

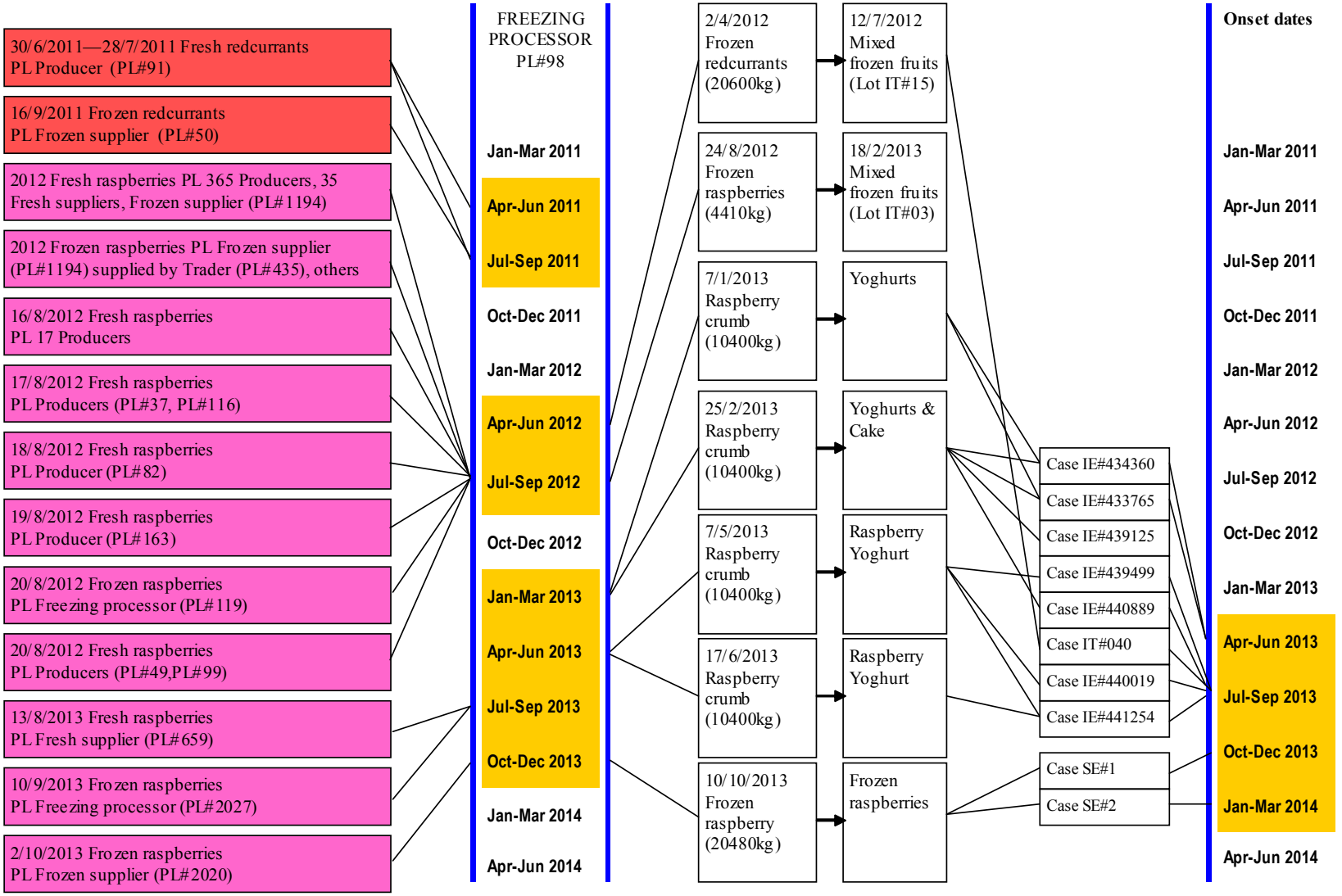
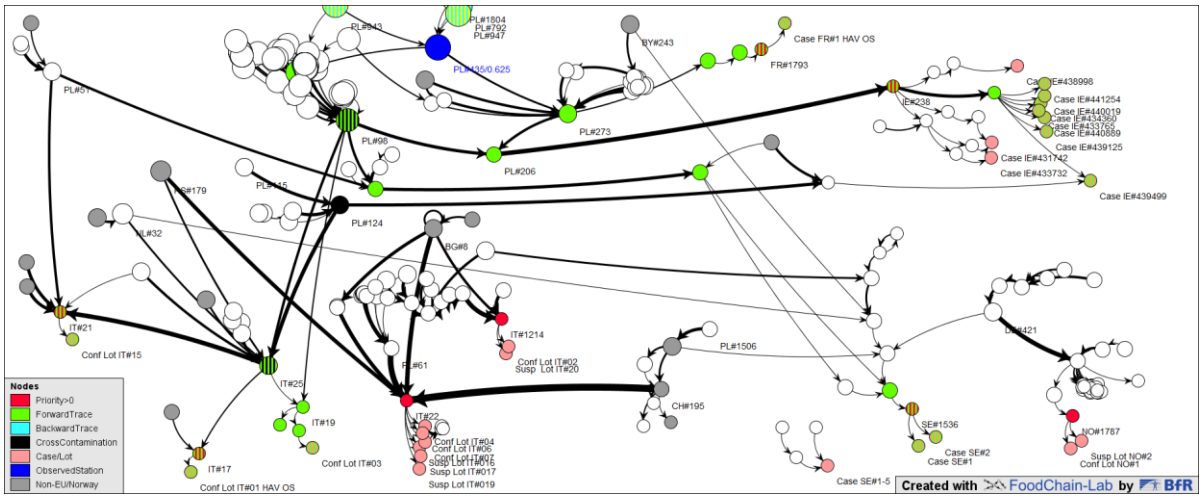


Figure 24: Time line of deliveries from "hotspot" PL#98 to lots and cases in Italy, Ireland and Sweden (only confirmed cases are represented)

Table 38: Cases/lots explained by "hotspot" PL#98

"Hotspot" PL#98	Class											
	1 Very high-strength evidence		2A Very high-strength evidence		2B High-strength evidence		2C High-strength evidence		3A Medium-strength evidence		Total	
	No	%	No	%	No	%	No	%	No	%	No	%
Raspberries							1	13	9	69	10	29
Redcurrants			1	17							1	3
Cross-contamination at hotspot			1	17			1	13	9	69	11	31
Cross-contamination in the chain	1	50	1	17			3	38	9	69	14	40
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**13**	**100**	**35**	**100**

Fresh berry trader PL#435, which supplied some redcurrants for lot IT#15, also supplied redcurrants to the freezing processor PL#273 ("hotspot" PL#273 in section 5.2.1.2), which produced the mixed berries used in the French 2A HAV-contaminated lots and the mixed berries linked to Irish 3A cases. Common primary producers of redcurrants PL#943, PL#947, PL#792 and PL#1804 can be linked to contaminated lots and outbreak cases in France, Ireland and Italy via fresh berry trader PL#435, although the redcurrants supplied to Italy were harvested in 2011 and those supplied to France and Ireland were harvested in 2012.



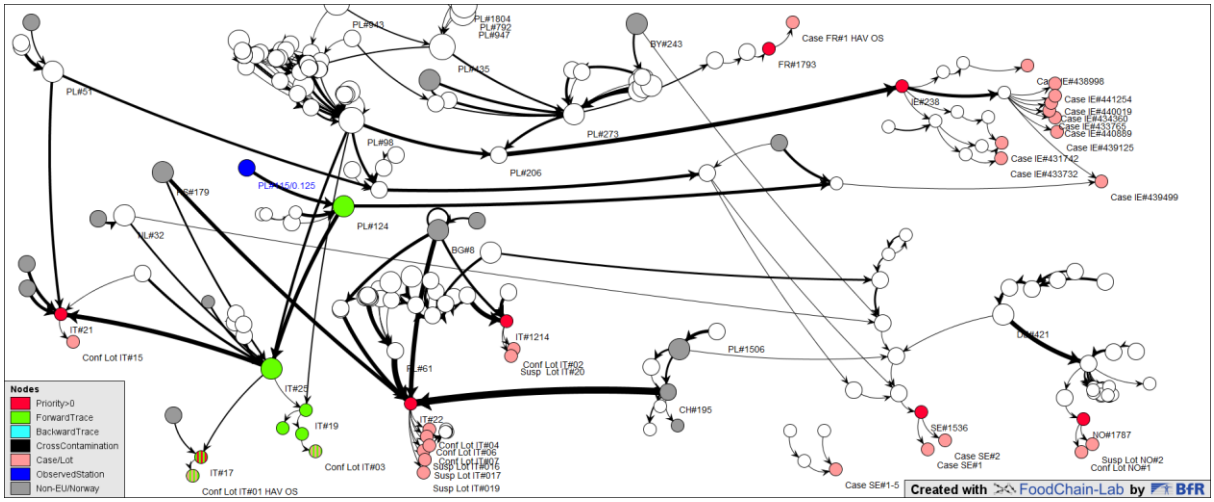
The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 25: Network visualisation of connections between fresh berry trader PL#435 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands), including cross-contamination at PL#435, PL#98, PL#124[15], IT#25 and IT#21

In summary, at this "hotspot" two different types of berries produced from harvests over three consecutive years are required to link the outbreak cases in three different countries. "Hotspot" PL#98 does not explain the French or the Norwegian outbreak, and in Italy is connected to only three of seven starting points.

[15] PL#124 is a frozen berry trader. Cross-contamination is less likely at this station.

"Hotspot" PL#115



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 26: Network visualisation of connections between identified "hotspot" PL#115 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

"Hotspot" PL#115 is a freezing processor with connections within the Italian starting points, especially with a direct link to Lot IT#01 of class 1. Redcurrants came from three primary producers.

Italy: Contamination of redcurrants (harvested in 2011) at PL#115 could explain two starting points (IT#17 and IT#19) and two related lots (lot IT#01 of class 1 and lot IT#03) of class 2C). Cross-contamination at IT#25 and then at IT#21could have contaminated lot IT#15 of class 2A. The class 2C lots IT#13 and IT#14 were also produced by packager IT#21 but the production dates were one year later than that of lot IT#15.

Table 39: Cases/lots explained by "hotspot" PL#115

"Hotspot" PL#115	**Class**											
	1		**2A**		**2B**		**2C**		**3A**		**Total**	
	Very high-strength evidence				**High-strength evidence**				**Medium-strength evidence**			
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Redcurrants	1	50					1	13			2	6
Cross-contamination in the chain	1	50	1	17			3	37	1	8	5	4
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**13**	**100**	**35**	**100**

"Hotspot" PL#115 has no direct connections with other countries and connects to only three of seven Italian starting points. Redcurrant of class 1 (lot IT#01) passed through frozen berry trader PL#124 in May 2012; prior to this transaction redcurrants from class 2A (lot IT#15) had also passed through the same frozen berry trader in January 2012, and later that year, in August, redcurrants linked to one Irish case (IE#439499) were delivered by this trader.

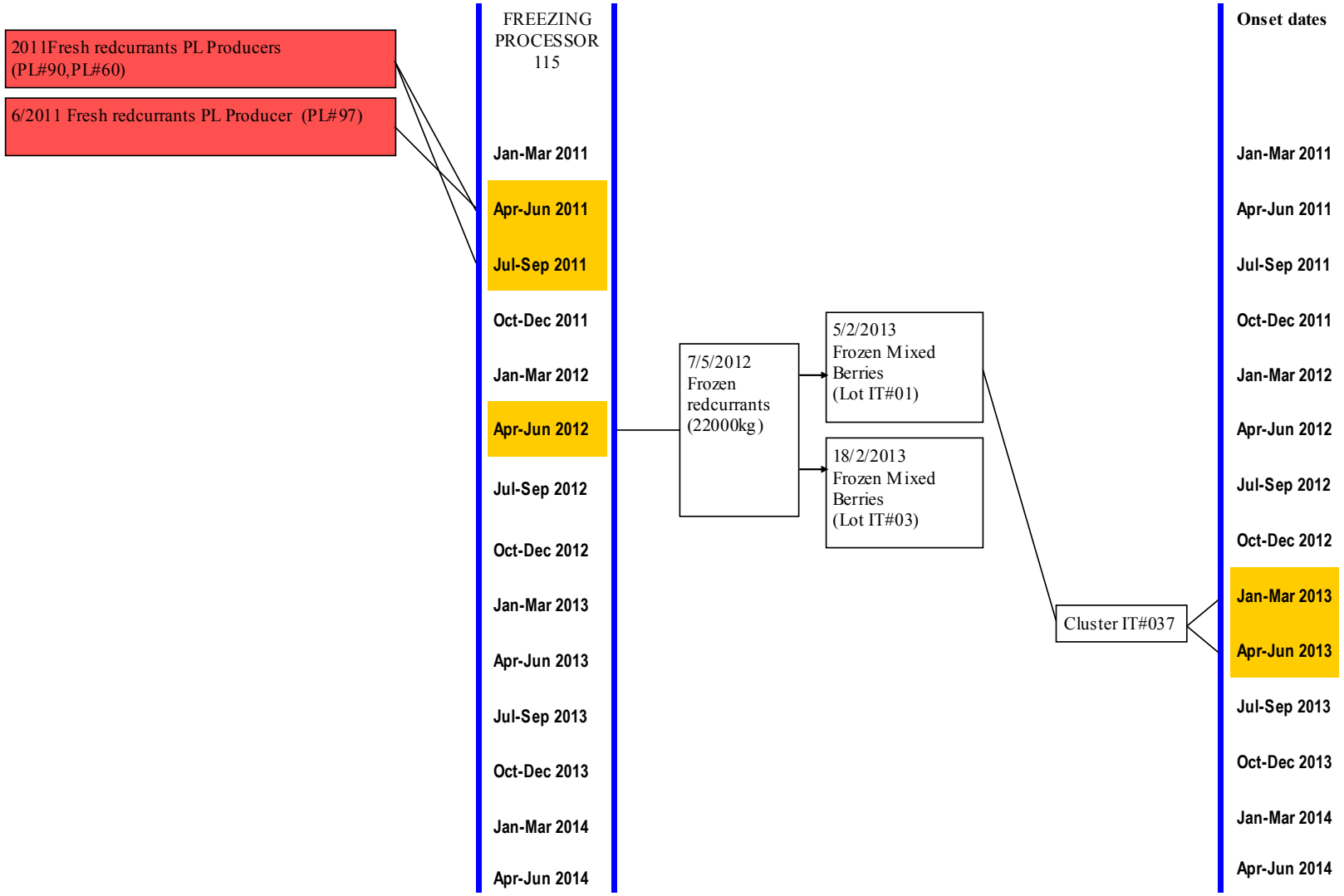
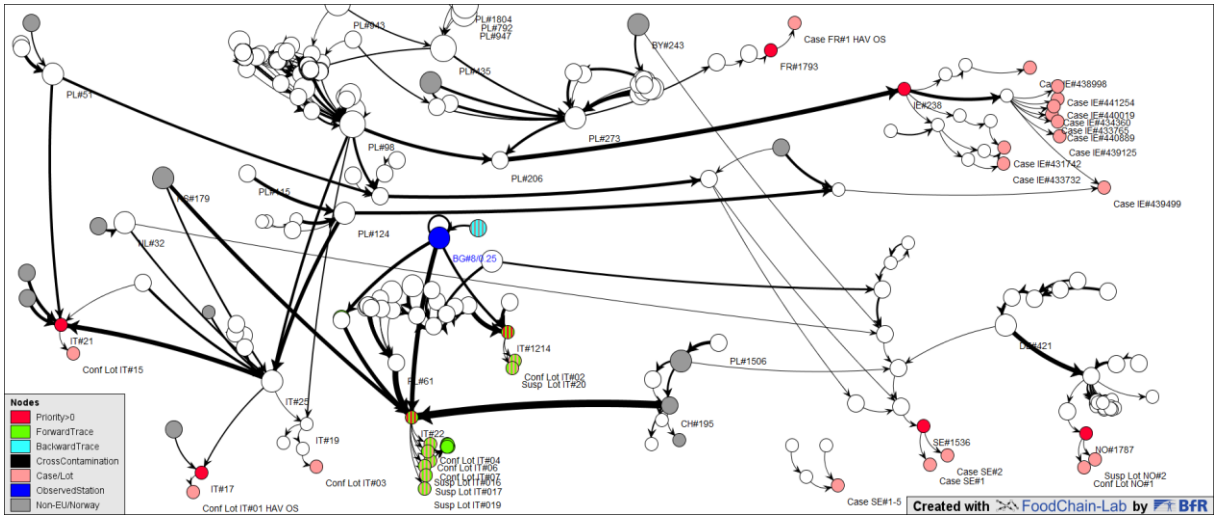


Figure 27: Time line of deliveries from "hotspot" PL#115 to lots in Italy (only confirmed cases are represented)

"Hotspot" BG#8



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 28: Network visualisation of connections between identified "hotspot" BG#8 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

"Hotspot" BG#8 is a freezing processor in Bulgaria with connections to the Italian starting points. This operator produces blackberries and also uses berries harvested by local pickers.

Italy: Contamination of blackberries at BG#8 could explain one starting point (IT#22) with eight connected lots: three confirmed lots (lots IT#04, IT#06 and IT#07) of class 2A, four suspected lots (lots IT#16, IT#17, IT#18, IT#19) of class 2B and one confirmed lot (lot IT#05) of class 2C. The same operator provided raspberries that went into lot IT#16. Contamination of raspberries at BG#8 could explain one additional starting point (IT#1214) with two related lots: one confirmed lot (lot IT#02) of class 2A and one suspected lot (lot IT#20) of class 2B.

Assuming cross-contamination at packager (IT#22) level, two more confirmed lots (lots IT#08 and IT#09) of class 2C could be contaminated because they have a production date after the direct contaminations.

Table 40: Cases/lots explained by "hotspot" BG#8

"Hotspot" BG#8	**Class**											
	1		**2A**		**2B**		**2C**		**3A**		**Total**	
	Very high-strength evidence				**High-strength evidence**				**Medium-strength evidence**			
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
BG#8 blackberries			3	50	4	67	1	13			8	23
BG#8 raspberries			1	17	2	33					3	9
Cross-contamination at BG#8			4	67	5	83	1	13			10	29
Cross-contamination in the chain			4	67	5	83	3	38			12	34
Total no of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**13**	**100**	**35**	**100**

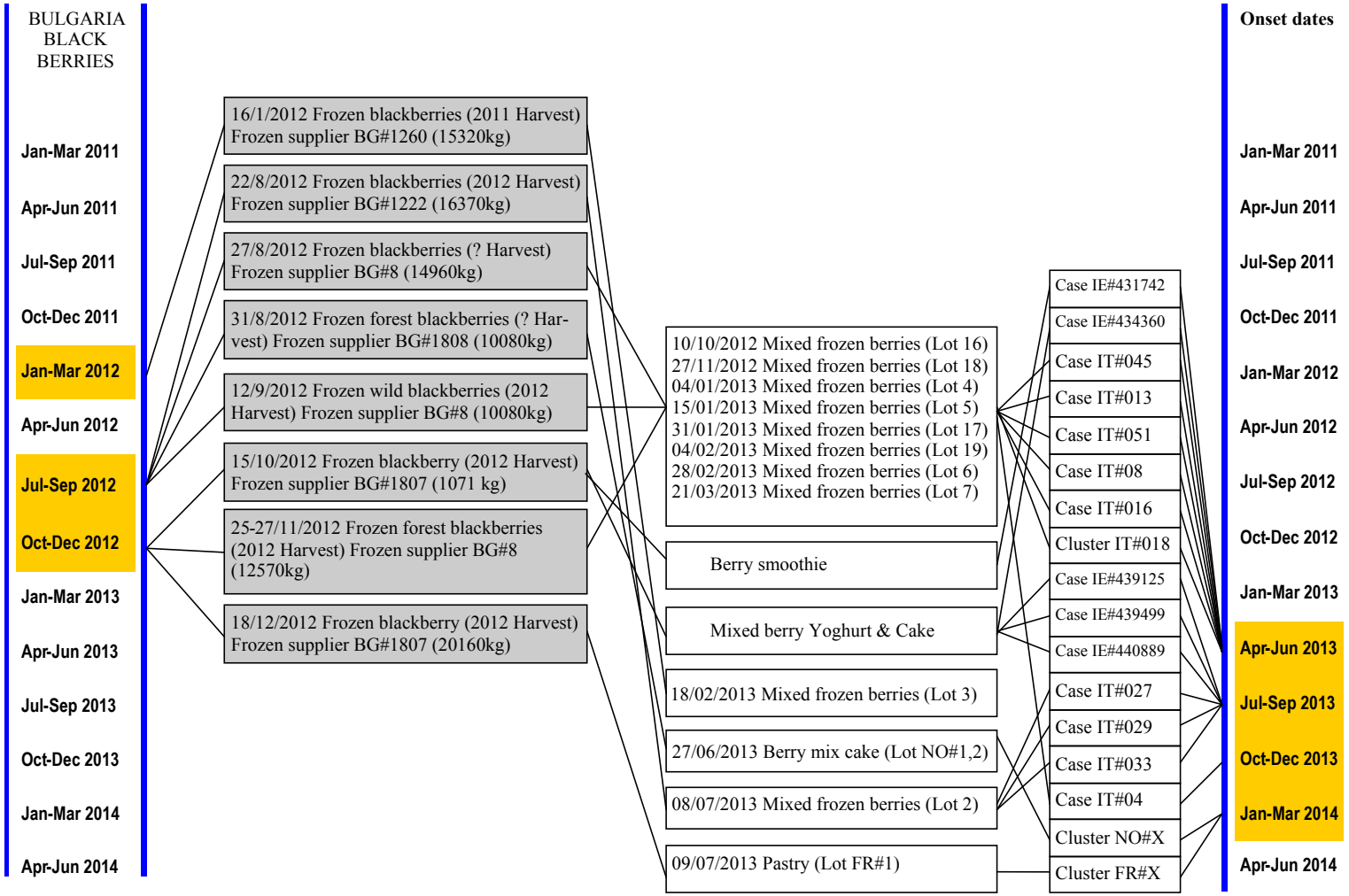


Figure 29: Time line of deliveries of blackberries from Bulgaria to lots in Italy, Ireland, France and Norway (only confirmed cases are represented)

Owing to sparse data for primary production in Bulgaria, additional connections to Bulgarian stations are under consideration (Figure 29). A possible common source cannot be excluded with the existing data, since for some lots the freezing processors and/or the primary producers could not be identified. In the case of some lots of Bulgarian blackberries, the fruit was collected from public areas and forests by local pickers, and therefore these represent the end points for tracing.

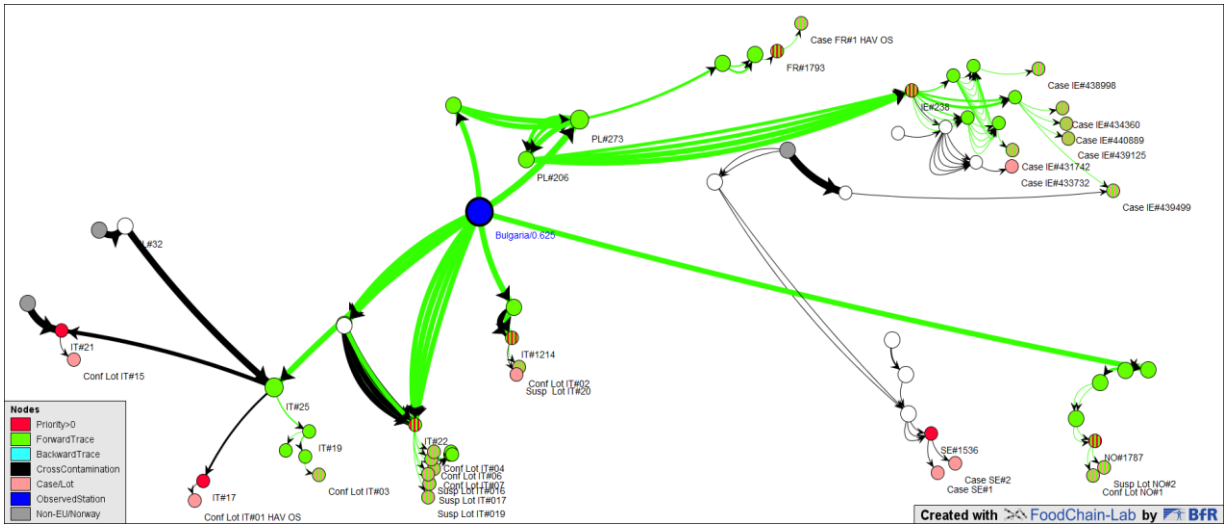
Italy: Contamination of blackberries (harvested in 2011) at Bulgarian frozen supplier BG#1260 could explain confirmed lot IT#03 of class 2C. Contaminated blackberries (harvested in 2012) at Bulgarian frozen supplier BG#1222 could also explain confirmed lot IT#02 of class 2A.

Ireland: Bulgarian blackberries from frozen supplier BG#1884 via frozen berry trader BG#1807 and the Polish processor PL#273 were used to produce the lots of mixed berries used in the manufacture of yoghurt, cake and fruit smoothies consumed by six Irish cases (all class 3A).

France: Bulgarian blackberries from the same supply chain went into the French lot (lot FR#1) of class 2A.

Norway: Bulgarian blackberries from operator BG#1808 went into the Norwegian lots: lot NO#1 of class 1 and lot NO#2 of class 2B.

Sweden: Bulgarian blackberries were not ingredients in the food items linked to the Swedish cases.



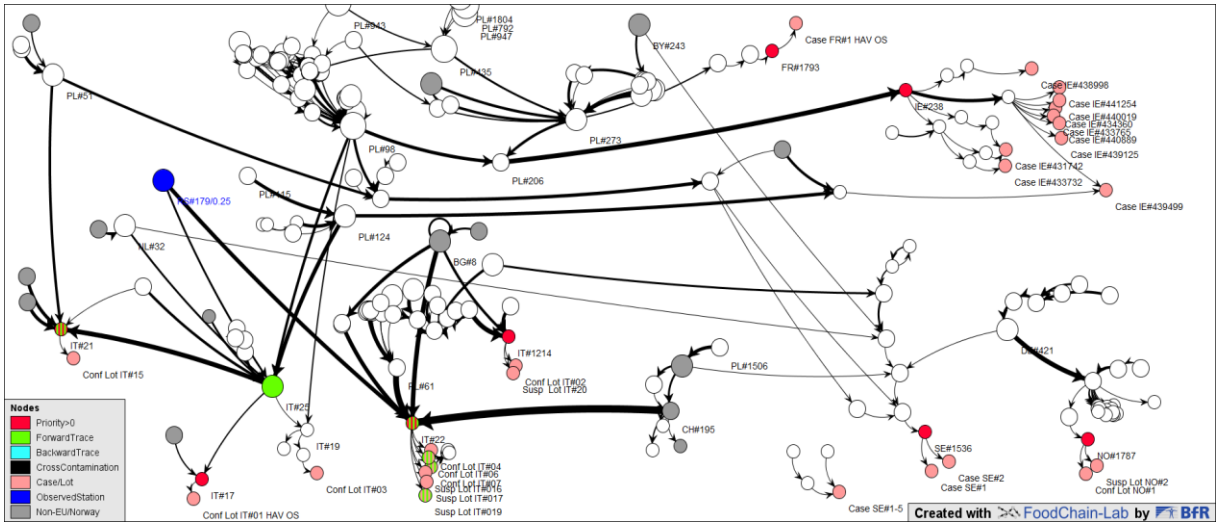
The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 30: Network visualisation of connections between all blackberry suppliers in Bulgaria (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

Table 41: Cases/lots explained by Bulgarian suppliers of blackberries

"Hotspot" Bulgaria	Class											
	1		2A		2B		2C		3A		Total	
	Very high-strength evidence				High-strength evidence				Medium-strength evidence			
	No	%	No	%	No	%	No	%	No	%	No	%
All BG blackberries	1	50	5	83	6	100	2	25	9	69	23	66
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**13**	**100**	**35**	**100**

"Hotspot" RS#179



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 31: Network visualisation of connections between identified "hotspot" RS#179 (blue node) and starting points (lots, cases) on the complete dataset (excluding the Netherlands)

"Hotspot" RS#179 is a freezing processor in Serbia with connections to the Italian outbreak. The origin (fresh supplier or primary producer) of the raspberries is unknown.

Italy: Contamination of raspberries at RS#179 could explain two starting points (IT#21 and IT#22) with five connected lots: two confirmed lots (lots IT#06 and IT#07) of class 2A, two suspected lots (lots IT#18 and IT#19) of class 2B and one confirmed lot (lot IT#14) of class 2C.

Assuming cross-contamination at packager (IT#22) level, three more confirmed lots (lots IT#08, IT#09 and IT#17) of class 2C could be contaminated because the production date is after the direct contaminations.

"Hotspot" RS#179 has no connections to other countries, and connects to only of seven Italian starting points. As explained before, it is not likely that raspberries are the origin of the multinational outbreak. None of the later outbreaks in France, Norway and Sweden could be connected to this former "hotspot".

5.2.1.2. Additional "hotspots" identified with the Irish outbreak data

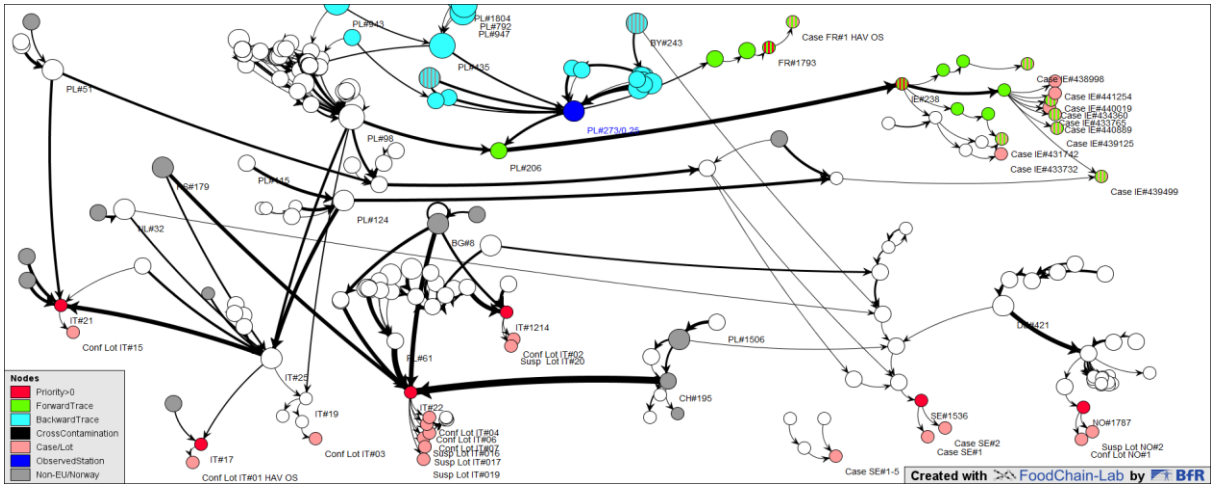
"Hotspot" PL#98 is described in section 5.2.1.1.

"Hotspot" PL#273

"Hotspot" PL#273 is a freezing processor in Poland, that also mixes frozen berries. It has connections with the Irish and French outbreaks. The company is based in the eastern region of Poland named Lubelskie. Freezing processor PL#98 is also located in this region.

Ireland: Company PL#273 delivered two different berry mixes to Ireland: both mixes contained bilberries, blackberries, raspberries, redcurrants, strawberries and blackcurrants. These mixes were consumed by six Irish cases (all class 3A).

France: Company PL#273 also delivered a mix of redcurrants, blackberries and bilberries to French producer FR#1793, which produced the confirmed lot (lot FR#1) of class 2A.



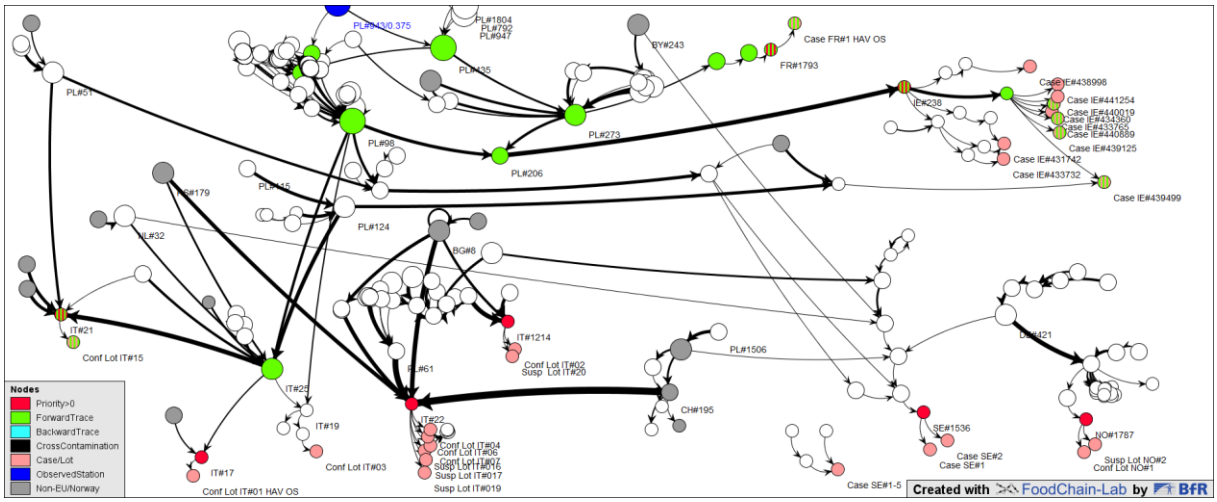
The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 32: Network visualisation of connections between identified "hotspot" PL#273 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

The redcurrants used in the mixes supplied to France and Ireland were frozen by PL#273 and were harvested in 2012. Sixteen common primary producers can be identified for the redcurrants used in the mixed berry lots supplied to Ireland and France. In addition, fresh berry trader PL#435 and primary producers PL#943, PL#947, PL#1804 and PL#792 supplied redcurrants to freezing processor PL#98 and also supplied redcurrants used in the French and Irish berry mixes.

Both the French and Irish berry mixes contained Bulgarian blackberries from supplier BG#1884 ("hotspot" BG#8; section 5.2.1.1)

The bilberries came from different sources; the bilberries in the French mix originated from Belarus (BY#242 and BY#243) and the bilberries in the Irish mixes were picked in the forests of Poland.



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 33: Network visualization of connections between identified primary producer PL#943 (blue node) and starting points (lots, cases) auf the complete dataset (excluding the Netherlands)

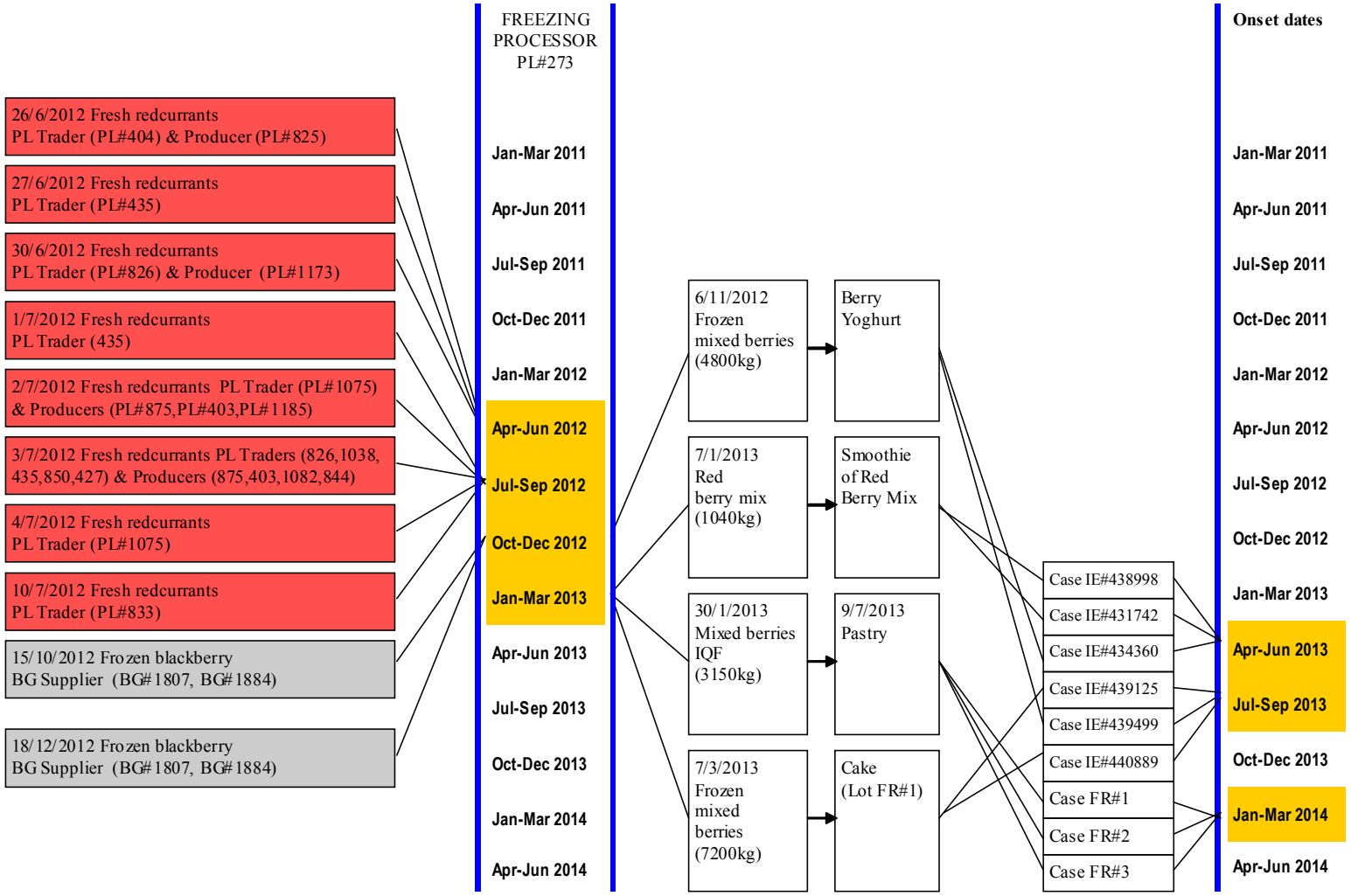


Figure 34: Time line of deliveries of summer fruit mixes from Polish processor PL#273 to lots in Ireland and France

5.2.1.3. Tracing results for the Norwegian outbreak

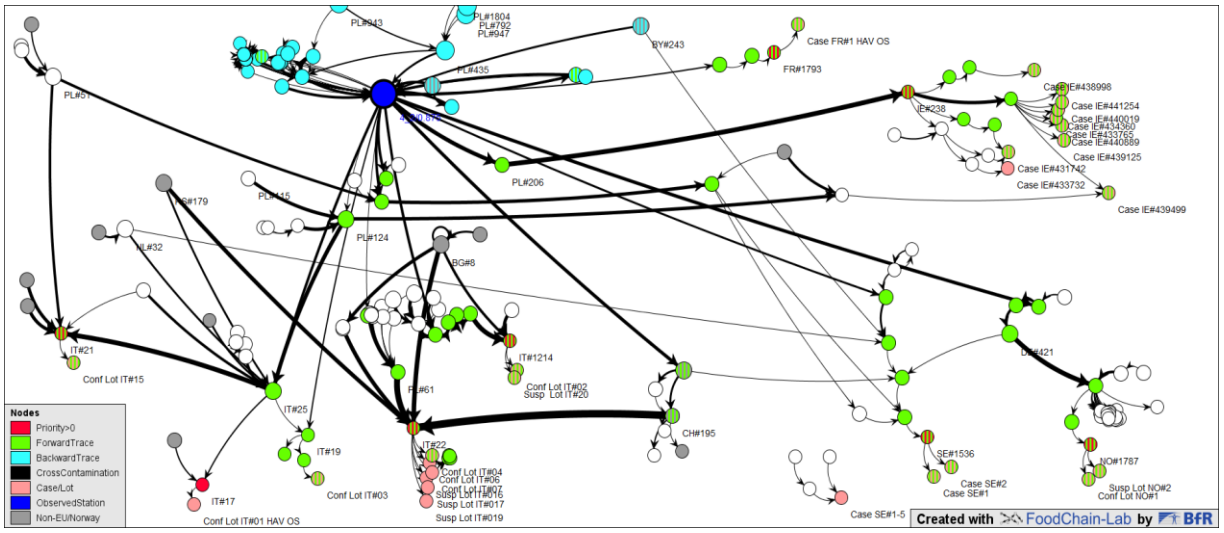
None of the identified "hotspots" (PL#98, PL#115, PL#273, BG#8 or RS#179) are able to explain the Norwegian lots (lots NO#1 and NO#2). The two Norwegian lots contained four types of berries: redcurrants from Poland (freezing processor PL#1810), blackberries from Bulgaria (BG#1808), raspberries from Chile (CL#1978 and CL#1812) and strawberries from Morocco (MA#1961 and MA#1813). The supply chain appears to be distinct, with no links to the previously identified "hotspots".

Again the common factors are Bulgarian blackberries and Polish redcurrants. In contrast to the Bulgarian situation, there is detailed information on the network of berry primary producers in Poland.

5.2.1.4. Results of the regional "hotspot" analysis

The failure to identify a common "hotspot" linking starting points in all countries might be explained by incomplete tracing data; alternatively, there could be interactions on other levels, such as shared fruit pickers or workers in freezing processors, sharing of agricultural equipment or contamination of watersheds. Because detailed and correctly geocoded data were available from Poland it was possible to examine regional clustering of stations. The algorithm of the FoodChain-Lab software clusters all station which are located less than 10 km from at least one other station within the cluster.

Applying the cluster algorithm to the Polish stations shows that two of the three Polish "hotspots" (PL#98 and PL#273) are located in one cluster. This cluster consists of 726 stations and includes some of the suppliers to the freezing processor (PL#1810) that produced redcurrants in the Norwegian lots (NO#1 and NO#2) and the freezing processor (PL#260) linked to the two Swedish cases.



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 35: Network visualisation of connections between identified Polish cluster PL#Cluster4 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

The cluster shown in Figure 35 could connect the Italian, Irish, French, Norwegian and Swedish outbreaks. Assuming cross-contamination at both PL#98 and one Italian starting point (IT#25), in total three of the seven Italian starting points could be reached.

As shown in Figure 36, redcurrants produced in Poland could explain the following starting points for tracing:

- French lot FR#1 (class 2A) and seven Irish cases (class 3A), plus potentially other Irish cases, assuming cross-contamination at the berry product manufacturer, are linked to "hotspot" PL#273. In addition, PL#273 is linked to "hotspot" PL#98 through a common primary producer that supplied the redcurrants used in Italian lot IT#15 (class 2A). Cross-contamination at an Italian packager IT#25 supplied by "hotspot" PL#98 could link lots IT#13 and IT#14 (classes 2A and 2B). Italian lots IT#01 (class 1) and IT#03 (class 2C) are linked to "hotspot" PL#115. It is noted that these lots passed through the same berry trader (PL#124) as lot IT#15.

- Norwegian lots NO#1 (class 1) and NO#2 (class 2b) are linked to freezing processor PL#1810.

- Italian packager IT#22, which produced two class 2A lots, four class 2B lots and three class 2C lots, is linked to freezing processor PL#61.

- Italian packager IT#1214, which produced two class 2A lots and one class 2B lot, is linked to freezing processor PL#1237.

- Swedish cases SE#1 and SE#2 (class 3A) are linked to freezing processor PL#260.

Frozen redcurrants from Poland cannot explain the cases in the Netherlands and two Italian lots which did not contain redcurrants (lots IT#11 and IT#12, both class 2C).

Table 42: Cases/lots explained by Poland and the Polish cluster

Redcurrants at	**Class**											
	1		**2A**		**2B**		**2C**		**3A**		**Total**	
	Very high-strength evidence				**High-strength evidence**				**Medium-strength evidence**			
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
PL#98			1	17					7	54	8	23
PL#98 with cross-contamination	1	50	1	17			3	38	9	69	14	40
PL#273			1	17					9	69	10	29
PL#1810	1	50			1	17					2	6
PL#Cluster4	1	50	2	33	1	17			9	69	13	37
PL#Cluster4 with cross-contamination	2	100	2	33	1	17	3	38	9	69	17	49
All Polish redcurrants with cross-contamination	2	100	6	100	6	100	6	75	11	85	31	89
No of lots or cases	**2**	**100**	**6**	**100**	**6**	**100**	**8**	**100**	**13**	**100**	**35**	**100**

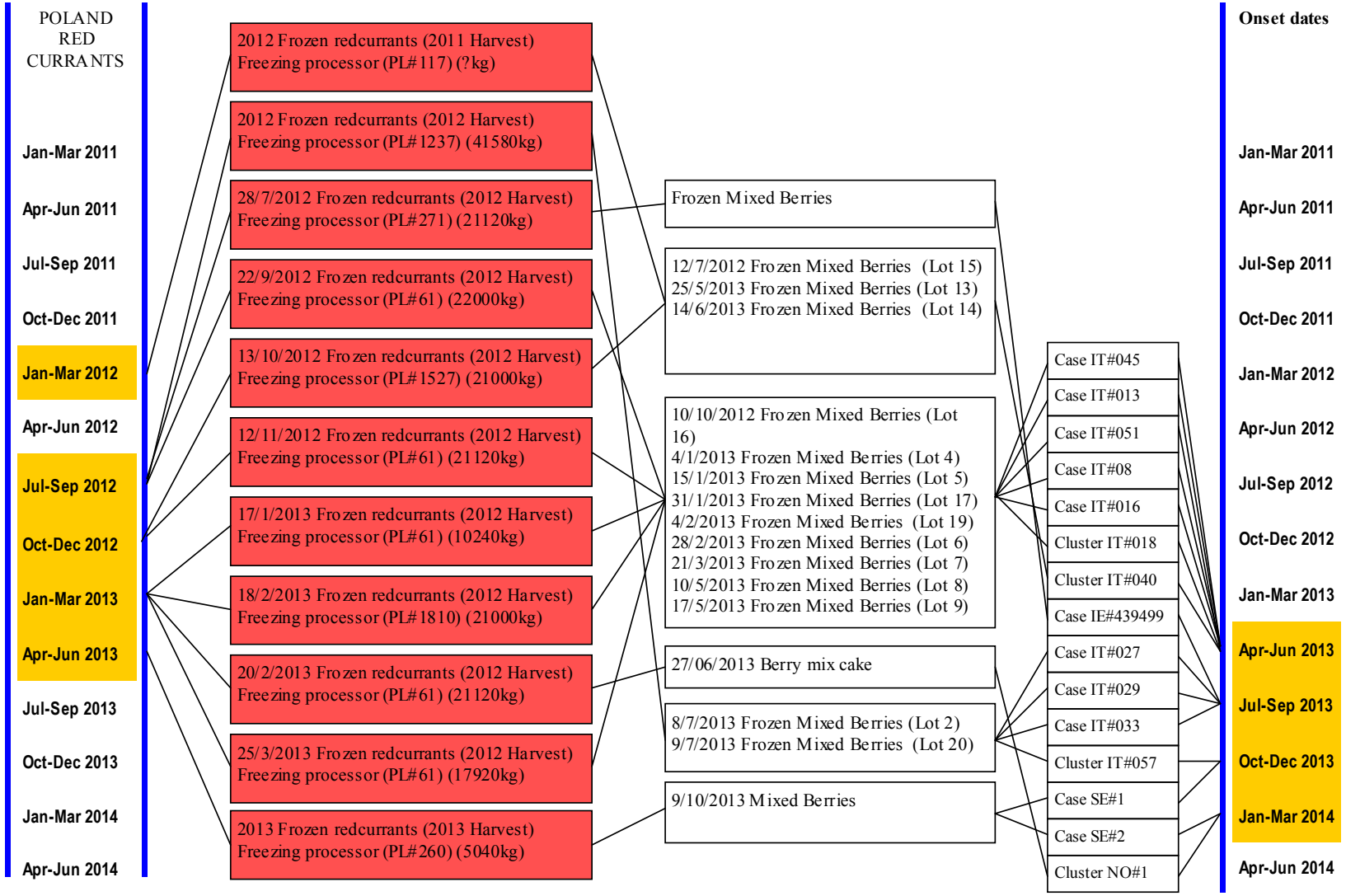


Figure 36: Time line of deliveries of redcurrants from Poland to cases in Italy, Sweden and Norway (excluding those already presented in "hotspots" PL#273, PL#98 and PL#115; only confirmed cases are represented)

5.3. Final hypothesis

Summary

Two final hypotheses were identified with comparable weight of evidence.

Hypothesis 1: Redcurrants produced in Poland

The tracing analysis showed that 31 of 35 contaminated lots/HAV cases could be connected to redcurrants produced in Poland (eight fresh berry lots are excluded). One of more of the three "hotspots" PL#273, PL#98 and PL#115 are linked to Italian and French lots plus the Irish cases. Four common primary producers for redcurrants linking these hotspots were identified. A further two Polish freezing processors are linked to Italian lots (PL#61 and PL#1237). The Norwegian lots are linked to Polish freezing processor PL#1810 and the Swedish cases to Polish freezing processor PL#260. Possible cross-contamination at stations further down the food chain (e.g. at IT#25) could link additional cases and lots to these freezing processors.

Particular emphasis was given to the search for connections between the "hotspots", but only a few common suppliers (e.g. PL#435) were identified. This suggests that a single point source of contamination (e.g. a primary producer) was unlikely to have caused the contamination of all the redcurrants used to produce the lots consumed by confirmed cases.

It is possible that information which could link these processors is missing. There might have been sharing of resources between the freezing processors, e.g. exchange of temporary workers, shared use of equipment during harvest, storage or processing, a common contaminated reservoir of water for irrigation, pesticide application or cleaning or flooding of a wider production area.

Since the redcurrants came from three consecutive harvest years (2011–2013), an alternative explanation might be that a high-risk practice in the production or freezing of redcurrants or endemic occurrence of HAV of the outbreak strain in the region of production or the subpopulation of seasonal workers resulted in HAV contamination in multiple locations and at multiple time points.

Investigation of the Polish HAV cases in 2011–2012 in the national register gave no indication of a connection to the production of redcurrants.

Finally, it should be noted that Poland is the main producer of redcurrants in Europe and, therefore, when tracing redcurrants, there is a high probability that the primary producer will be located in Poland.

Hypothesis 2: Blackberries from Bulgaria

The tracing analysis showed that 23 of 35 contaminated lots/HAV cases could be connected to blackberries originating in Bulgaria. In most cases tracing could not be completed to the level of primary producer or fresh berry supplier.

The network analysis did not identify a common source of contamination or possible cross-contaminations in the food supply chain before export from Bulgaria.

The precise origin of the blackberries is often unknown. Blackberry production is not generally connected with agricultural holdings; instead harvesting is performed by local pickers in public areas and forests. In the case of this type of production, biosecurity would be minimal and contamination from an environmental source is probable. A common source could also have been imported to Bulgaria, as Bulgaria showed in 2012 an excess of import of fresh blackberries.

It should be noted that Bulgaria had the highest reported incidence of HAV in Europe in 2011 (76 cases per 100 000 population) and 2012 (67 cases per 100 000 population), which decreased to 25

cases per 100 000 in 2013. Information on the occurrence of the outbreak strain in Bulgaria was not available as only serological testing is performed there.

Reasoning

Table 43 summarises the tracing end points for each lot or food item connected to the starting points for tracing. The connections between cases and food items are given in Tables 28 and 29. Connections with hypotheses 1 and 2 are given in separate columns, lots and food items are ordered by classes and related evidence.

Poland and Bulgaria provided further information describing the local situation and the status of their food safety investigations. This is included in section 5.3.1 and 5.3.2 plus appendix B.7.

Table 43: Relation between traced lots/cases and frozen berry trader/processor/freezing processors/fresh traders for "redcurrants in Poland"/"blackberries in Bulgaria" (

No	Lot: product	Country	Class (up to 3A)	Connection to redcurrants from Poland[(a)]	Connection to blackberries from Bulgaria[(a)]	Connection to other berries [(a)]
Very high-strength evidence						
1	**Confirmed lot IT#01:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	1	**Redcurrants from PL#115** (harvest 2011, three suppliers)/**possible cross-contamination** at IT#25		**Blackberries from Serbia Raspberries from BG#1508** (harvest 2011, local producer) Blueberries from Canada
21	**Confirmed lot NO#1:** cake (redcurrants, blackberries, raspberries, strawberries)	Norway	1	**Redcurrants from PL#1810** PL#Cluster4 (harvest 2012)	**Blackberries from BG#1808** (no further tracing)	**Raspberries from Chile** Strawberries from Morocco
2	**Confirmed lot IT#02:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2A	**Redcurrants from PL#1237** (harvest 2012, four processors)	**Blackberries from BG#1503 via BG#1222** (harvest 2012, no further tracing)	**Raspberries from BG#8** (eight primary producers in Bulgaria) Blueberries from Italy
3	**Confirmed lot IT#04:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2A	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from RS#75** (harvest 2011, primary producer in Serbia) Blueberries from Canada
5	**Confirmed lot IT#06:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2A	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from RS#179** (harvest 2012) Blueberries from Canada

(a): Bold incates ingredients of redcurrants from Poland or blackberries from Bulgaria or neighbouring countries

6	**Confirmed lot IT#07:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2A	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Blackberries from UA#199** (no further tracing) **Raspberries from RS#179** Blueberries from Canada
14	**Confirmed lot IT#15:** frozen berries (redcurrants, blackberries, raspberries, blueberries, cranberries)	Italy	2A	**Redcurrants from PL#117**, PL#Cluster4 (harvest 2011, 11 suppliers/ producers) **Redcurrants from PL#98**, PL#Cluster4 (harvest 2011, 40 suppliers/producers)		Blackberries from Chile **Raspberries from RS#188** Blueberries from Chile and Belarus Cranberries from Sweden
20	**Confirmed lot FR#1:** pastry (redcurrants, blackberries, bilberries)	France	2A	**Redcurrants from PL#273**, PL#Cluster4 (harvest 2012)	**Blackberries from BG#1807** (harvest 2012)	Bilberries from Belarus
High-strength evidence						
4	**Suspected lot IT#20:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2B	**Redcurrants from PL#1237** (harvest 2012, four processors)	**Blackberries** from **BG#1222** (harvest 2012, no further tracing)	**Blackberries from RS#1534** (no further back-tracing) **Raspberries from BG#8** (harvest 2012, no further tracing) **Blueberries from RO#1535** (no further back-tracing)
7	**Suspected lot IT#16:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2B	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from BG#8** (harvest 2012) Blueberries from unknown
8	**Suspected lot IT#17:** frozen berries (redcurrants, blackberries, blueberries)	Italy	2B	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	Blueberries from Canada
9	**Suspected lot IT#18:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2B	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from RS#179** Blueberries from Canada

10	**Suspected lot IT#019:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2B	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from RS#179** Blueberries from Canada
22	**Suspected lot NO#2:** cake (redcurrants, blackberries, raspberries, strawberries)	Norway	2B	**Redcurrants from PL#1810** PL#Cluster4 (harvest 2012)	**Blackberries from BG#1808**	Raspberries from Chile Strawberries from Morocco
11	**Confirmed lot IT#05:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2C	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)	**Blackberries from BG#1502, BG#1509 via BG#8** (no further tracing)	**Raspberries from Serbia** (harvest 2011, primary producer in Serbia) Blueberries from Canada
12	**Confirmed lot IT#08:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2C	**Redcurrants from PL#61** (Harvest 2011/12, 87 suppliers/producers)		**Blackberries from UA#199** (no further tracing) **Raspberries from PL#1596** (harvest 2012, two lots, 21 primary producers) Blueberries from Canada
13	**Confirmed lot IT#09:** Frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2C	**Redcurrants from PL#61** (harvest 2011/12, 87 suppliers/producers)		**Blackberries from UA#199** (no further tracing) **Raspberries from PL#1596** (harvest 2012, two lots, 21 primary producers) Blueberries from Canada
15	**Confirmed lot IT#13:** Frozen berries (redcurrants, blackberries, raspberries, blueberries, lingonberries)	Italy	2C	**Redcurrants from PL#1522, PL#1526** (harvest 2012, three primary producer) / **possible cross-contamination** at IT#21		**Blackberries** from **BA#7** (no further tracing) **Blackberries from Chile Raspberries from RS#1270 Blueberries from RO#173** and Chile Lingonberries not traced

16	**Confirmed lot IT#14:** frozen berries (redcurrants, blackberries, raspberries, blueberries, lingonberries)	Italy	2C	**Redcurrants from PL#1522, PL#1526** (harvest 2012, three primary producers) / **possible cross-contamination** at IT#21		**Blackberries f**rom **BA#7** (no further tracing) **Blackberries from Chile Raspberries from RS#179 Blueberries from RO#173** and Chile Lingonberries not traced
17	**Confirmed lot IT#03:** frozen berries (redcurrants, blackberries, raspberries, blueberries)	Italy	2C	**Redcurrants from PL#115** (harvest 2011, 3 supplier)/**Possible cross-contamination** at IT#25	**Blackberries from BG#1504 via BG#1260** (harvest 2011, local pickers in Bulgaria)	**Raspberries from PL#98** (harvest 2012, 64 suppliers/producers in Poland) **Blueberries from RO#172**
18	**Confirmed lot IT#11:** frozen blackberries	Italy	2C			**Blackberries from RO#282** (no further tracing
19	**Confirmed lot IT#12:** frozen berries (blackcurrants, blackberries, raspberries, blueberries)	Italy	2C			**Blackberries from PL#1001, PL#1220** (no further tracing) **Raspberries from BG#1790, BG#1791** (harvest 2012) **Blueberries from PL#1001, PL#1220** (no further tracing) **Blackcurrants from PL#1225** (nine primary producers)
Medium-strength evidence						
23–33	**5 of 11 cases in Ireland:** yoghurt RB (raspberries)	Ireland	3A	**Poss. cross-cont.** at PL#98, PL#Cluster4	**May be confounded** with yoghurt MB	**Raspberries from PL#98**
	4 of 11 cases in Ireland: yogurt MB (raspberries and a berry mix (containing redcurrants, blackberries, raspberries, bilberries, strawberries, blackcurrants))	Ireland	3A	**Redcurrants from PL#273, PL#98,** PL#Cluster4 (harvest 2012)	**Blackberries f**rom **BG#1884, BG#1807** (Harvest:2012)	**Raspberries from PL#98 Raspberries from RS** Bilberries from Poland Strawberries from Poland Blackcurrants from Poland

	7 of 11 cases in Ireland: cake (raspberries and a berry mix (containing redcurrants, blackberries, raspberries, bilberries, strawberries, blackcurrants))	Ireland	3A	**Redcurrants from PL#273, PL#98,** PL#Cluster4 (harvest 2012)	**Blackberries** from **BG#1884, BG#1807** (harvest 2012)	**Raspberries from PL#98** **Raspberries from Serbia** Bilberries from Poland Strawberries from Poland Blackcurrants from PL
	2 of 11 cases in Ireland: smoothie of mixed berries (redcurrants, blackberries, raspberries, bilberries, strawberries, blackcurrants)	Ireland	3A	**Redcurrants from PL#273,** PL#Cluster4 (harvest 2012)	**Blackberries** from **BG#1884, BG#1807** (harvest 2012)	**Raspberries from PL#98** **Raspberries from RS** Bilberries from Poland Strawberries from Poland Blackcurrants from Poland
	1 of 11 cases in Ireland: frozen mixed berries (redcurrants, blackberries, raspberries, blackcurrants)	Ireland	3A	**Redcurrants from PL#271** (harvest 2012)		Blackberries from Chile **Raspberries from Serbia** **Blackcurrants from PL#271** (harvest 2012)
	1 of 11 cases in Ireland: frozen BB (blackberries)	Ireland	3A	**Uncertain interview**	**Uncertain interview**	**Blackberries from Serbia**
	1 of 11 cases in Ireland: smoothie made with three berries (raspberries, blueberries, strawberries)	Ireland	3A	**May be confounded** with other smoothie	**May be confounded** with other smoothie	**Raspberries from Serbia** Blueberries from Poland and Canada Strawberries from unknown
	1 of 11 cases in Ireland: smoothie made with three berries (blackberries, raspberries, blueberries)	Ireland	3A	**May be confounded** with other smoothie	**May be confounded** with other smoothie	**Blackberries from Serbia,** China **Raspberries from Serbia** Blueberries from Canada
34 and 35	**2 of 2 cases in Sweden:** berry mix (redcurrants, blackberries, raspberries, bilberries, blackcurrants, cherries)	Sweden	3A	**Redcurrants from PL#260**		Blackberries from Chile **Raspberries from Bulgaria** Bilberries from Belarus **Blackcurrants from PL#1989** (trader) **Cherries from Serbia**
	2 of 2 cases in Sweden: purée (blackberries, raspberries, blueberries, strawberries, blackcurrants, and others (passion fruit, buckthorn, pomegranate))	Sweden	3A		–	Blackberries from Chile **Raspberries from Serbia** and Chile **Strawberries from PL#1782** (harvest 2013, three primary producers) **Blackcurrants from PL#1782** (harvest 2012, three suppliers/producers)

In Figure 37, the tracing end points for redcurrants are shown in Poland, which accounts for all locations in Europe. Since the tracing is mostly completed to the level of primary production (dark-green triangles) or fresh berry traders (light green) the triangles indicate the regions of production of redcurrants with operators linked to the starting points.

In contrast Figure 38 shows the location of end points for blackberries. The triangles indicate unspecified suppliers (black), exporters (red/pink) or freezing processors (blue/turquoise). Therefore, the precise area of production is unknown.

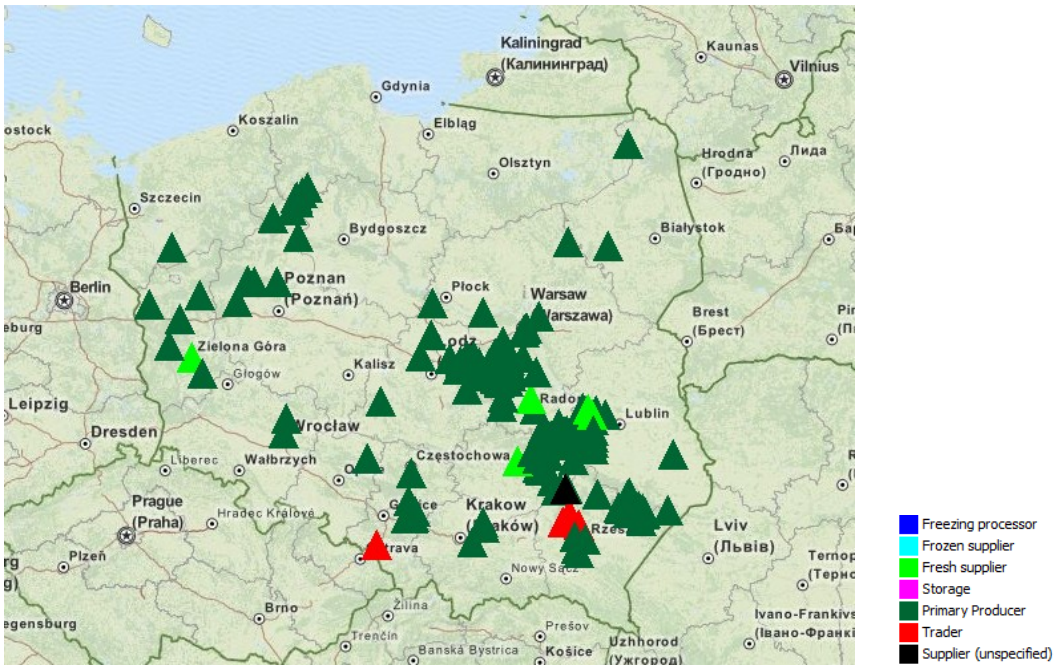


Figure 37: Map of tracing end points for redcurrants in Poland (EU/EFTA)

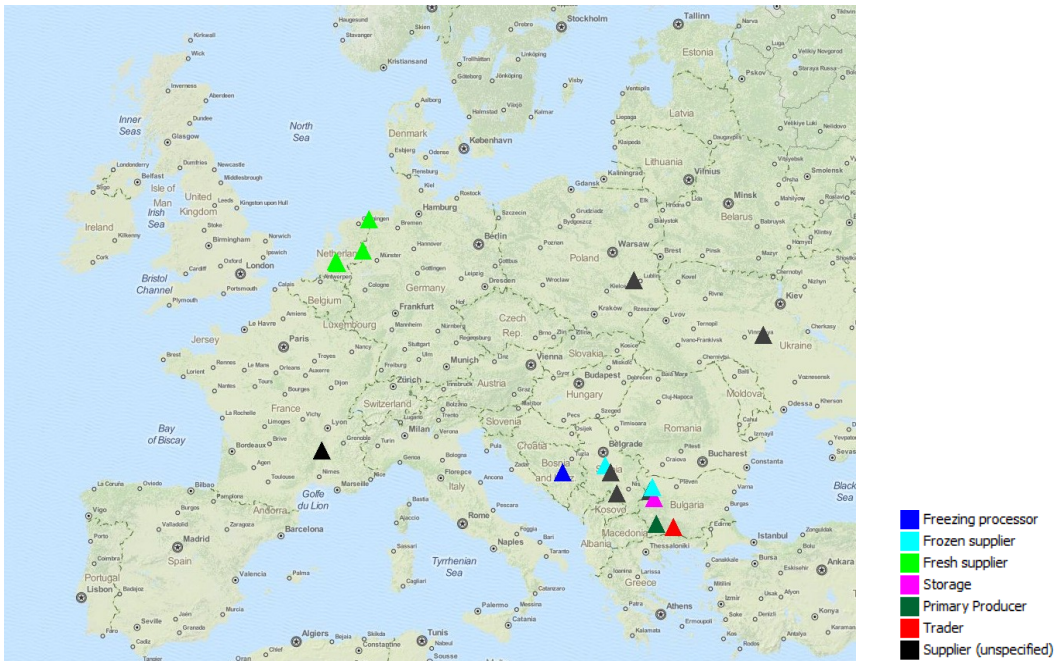


Figure 38: Map of tracing end points for blackberries in EU/EFTA

5.3.1. Investigations in Poland

5.3.1.1. Tracing activities and results of microbiological investigations

Intensive food safety investigations, including tracing back activities, started in Poland in May 2013 when Italian authorities reported via RASFF a series of notifications for HAV in frozen mixed berries processed in Italy. The raw material came from different countries, including Poland. Polish authorities responded to all requests for assistance in tracing back suspected berries. Altogether, 44 follow-up notifications were reported in reaction to 8 notifications where suppliers of berries from Poland were identified. Detailed reports on tracing activities and the operation of identified companies were shared with members of the RASFF network.

When investigations in relation to the outbreak in Ireland started, Polish authorities contributed to the investigations by responding to many detailed requests for tracing back and forward information. Tracing data and data requests linked to investigations in Ireland were collected in RASFF NEWS No 13-706. Polish authorities provided 15 follow-ups to the NEWS in response to Irish requests for data.

Poland is the country which provided the largest number of transaction data used in the analysis. It should be noted that, owing to the excellent cooperation of regional authorities in Poland, it was possible to trace all supply chains connecting Poland, in the majority of cases up to primary production level.

5.3.1.2. Measures taken in Poland

The Polish sanitary authorities took actions to verify the hypotheses generated from the results of the trace-back analysis.

- All identified "hotspots" in Poland are under the regular control of competent authorities and underwent several additional inspections during the investigation period. Inspections by the authorities at the "hotspots" confirmed that high hygienic standards are maintained there. All the "hotspots" operate in accordance with implemented food safety systems and follow HACCP principles.
- During the initial analysis, a farm "hotspot" which could be associated with cases in Ireland was identified. The farm was located in Lubelskie, 14 km from PL#98 and 6 km from PL#273. Epidemiologists from the district sanitary-epidemiological station conducted an epidemiological investigation at this farm. The investigation showed that the same 10 people worked at the farm during the harvests in 2011 and 2012. A blood sample was taken from all 10 workers and tested for IgM and total anti-HAV antibodies. All tested samples were negative for IgM; two people had a positive result for total anti-HAV antibodies. These were two men, one aged 43 and one aged 62 years, one of whom was the farmer. To confirm that they did not have hepatitis A in years 2009–2013, their primary health care and hospital medical records were checked. Neither of the men had been treated or hospitalised as a result of hepatitis A in previous years. The presence of the antibodies in these two persons could be explained by their age. Both were born in a period of high endemicity for hepatitis A in Poland.
- The national databases of hepatitis A and other or unspecified hepatitis cases in 2011–2012 were reviewed to identify possibly infected workers at farms or at fruit processing plants. The following criteria were used: date of onset May–October 2011 or 2012; no travel history to other countries during the incubation period; occupation: farmer or working in food processing or unemployed (seasonal work); living in a rural area. In 2011, from May to October, a total of 32 cases were registered. Among them were 18 domestic cases. Only one person met the following criteria: unemployed and lives in rural area. The district

epidemiologists interviewed the case and her husband. The investigation showed in 2011 that they did not work in the harvesting or processing of berries. In 2012, from May to October, 21 domestic cases were registered. Of these, two cases were unemployed and living in rural areas. Neither of the cases was involved in cultivating or picking berries or worked for berry processors.

- National Institute of Public Health—National Institute of Hygiene and Chief Sanitary Inspectorate prepared:
  - "Food safety strategies for the sector of soft fruits in Poland"
    - preparation of the principles of surveillance under production and processing of soft fruit for prevent contamination of foodborne virus, with particular regard to hepatitis A
    - preparation of information campaign for farmers and soft fruit processors
  - "Strategies for monitoring of genetic variability of HAV circulated in Poland"
- It is planned to conduct a spatial analysis on the potential impact of the floods in 2009 and 2010 for epidemiological situation of hepatitis A in Poland.

5.3.2. Investigations in Bulgaria

Food safety investigations, including tracing back activities, started in Bulgaria in May 2013 when Italian authorities reported via RASFF a series of notifications for HAV in frozen mixed berries processed in Italy.

Bulgaria reported on their activity per company involved in the outbreak investigations. The following sections give a summary of their activities. A detailed description can be found in appendix B.7.

5.3.2.1. Tracing activities

Answering the requests of the RASFF network the regional authorities of Bulgaria inspected (at least) 12 companies handling fresh or frozen berries. Special attention was given to:

- Back-trace of the supply chain to the end point primary production or pickers;
- health status of the workers, pickers under civil law contracts and individuals;
- compliance with the principles of good production and good hygienic practice, (e.g. the compliance with the temperature regime during storage and transport).

One of the companies (BG#1509) had ceased their activities before the inspection and the facilities were already demolished. Another was only active during 3 months in 2012 (BG#1505). In these cases the local authorities were unable to retrieve the health status of the workers or individual pickers, they used the official register of cases of contagious diseases, including HAV cases, to get further information.

No source for the outbreak and no cases of hepatitis A among the workers or pickers could be identified by the inspections.

5.3.2.2. Measures taken in Bulgaria

Bulgaria reports compliance with EC in the production requirements for berries

- Monitoring of the registered companies by the Bulgarian Food Safety Agency (BFSA) according to the Bulgarian Food Law Act. Companies being evaluated as medium risk (e.g. BG#8) are subject to official control and on-spot checks at least four times per year.

- obligatory health check of workers and pickers under civil law contracts in food business;
- self-control and control of suppliers by the companies to guarantee good production and good hygienic practice;
- European requirements for keeping land in good environmental conditions.

5.3.3. Discussion of the evidence

- Two lots (IT#01 and NO#1) were confirmed to be contaminated with HAV OS (very high strength of evidence). Both lots included redcurrants and blackberries. Both lots contained redcurrants produced in Poland. The redcurrants were produced at two different production sites (freezing processors PL#115 and PL#1810) over two harvest years (2011 and 2012). The Norwegian lot contained blackberries delivered from Bulgaria (BG#1808), whilst the blackberries in the Italian lot were supplied by Serbia (however, the raspberries were from Bulgaria, BG#1508). Information on primary production and further processing is incomplete; thus, common sources or cross-contamination cannot be excluded.
- There is strong evidence of a contamination event either at Polish freezing processor PL#273 or at one or more of the fresh berry suppliers/primary producers used by this freezing processor. Operator PL#273 freezes and packages custom mixes of frozen berries. Berry mixes from this freezing processor were used in the contaminated pastry from France and supplied to the berry product manufacturer in Ireland whose products were consumed by seven confirmed Irish cases. Suppliers of Polish redcurrants and Bulgarian blackberries were common to both the Irish and French berry mixes. Four primary producers that supplied redcurrant s to PL#273 (harvest 2012) also supplied redcurrants to PL#98 (harvest 2011).
- All lots classified with very high or high strength of evidence contained blackberries, and the majority contained redcurrants. Two class 2C lots did not contain Polish redcurrants. Bulgarian blackberries were not found in all lots for any of the evidence classes; blackberries in four lots came from the neighbouring country of Serbia.
- HAV cases/lots in five countries could be linked to three “hotspots” (PL#98, PL#115 and PL#273) and four Polish freezing processors (PL#61, PL#260, PL#1237 and PL#1810) and/or to five frozen berry suppliers in Bulgaria, including “hotspot” BG#8. This indicates that HAV contamination could be occurring at the freezing processor or in primary production.
- During the production of frozen berries critical risk factors for contamination by HAV include environmental factors (e.g. flooding with contaminated water), use of sewage-contaminated agricultural water and contamination by infected workers. In addition, the long survival of HAV after freezing increases the risk of multinational outbreaks.
- Cross-contamination could occur post-harvest along the supplying chain through contact with contaminated surface of machines, equipment and facilities during freezing, mixing and packaging processes
- Production of redcurrants in Poland and blackberries in Bulgaria is mostly done in smaller units (e.g. family-run farms (EC, 2006), individual pickers in public forests), where effective biosecurity is more difficult to guarantee.
- Bulgaria and Romania had the highest incidences of HAV in 2011 and 2012 in the EU (Table 1).

5.3.4. Discussion of the uncertainties

- The majority of tested lots and berry products consisted of mixed berries with similar ingredients (e.g. redcurrants, blackberries, raspberries), making the identification of the contaminated ingredient difficult. No information on the frequency of berry combinations was available, for example it is not known if all berry mixes contain redcurrants or if redcurrants appear in the majority of lots because this was the source of contamination.

- Lack of availability of single ingredients remaining for laboratory testing was an issue as combining of berries frequently occurred at a point in the supply chain distant from the starting point in tracing. Forward tracing of single ingredients and their related food items and active identification of possible further cases is not foreseen in tracing actions and would require the voluntary cooperation of the companies involved.

- Sampling strategies were focused on confirmed and suspect lots (suspect sampling). No data from a representative sampling programme were available in order to understand the background contamination of different types of berries (fresh or frozen) with biological pathogens.

- Sampling strategies varied between the countries. It is important to note that tracing information used in the analysis is based on epidemiological and microbiological evidence of differing strengths, from possible lots that may have been consumed by cases based on onset dates to lots in which HAV contamination was confirmed by genotyping. As a consequence, the reliability of back-tracing data in identifying the possible source of berries contamination decreases proportionally as the strength of evidence decreases, suggesting the need for a step-by-step approach in the interpretation of the back-traced data based on classes. Back-tracing data for class 1 lots are considered the most reliable since the association between frozen berries and HAV OS is confirmed.

- Poland is the main producer of berries in Europe. Thus, it is likely that back tracing will identify primary producers in Poland. No controls (e.g. tracing of negative lots, starting points of non-infected berry consumers) were used in the analysis. The study design and the availability of back-tracing data for only contaminated or suspected lots and not for frozen berries lots not connected with the outbreak does not allow for comparative analyses that would support the identification of specific supplying chain or stations associated with HAV contamination. Instead the collected data support only descriptive and hot-spot analysis.

- Genotyping following diagnostic analyses of human samples is a practice that currently is not routine in most countries, and the available HAV database is based largely on information from available of HAVnetwork reference laboratories in some countries (www.HAVnet.nl) and samples from patients with a travel history. It is therefore challenging to interpret the genotyping results from the outbreak investigation. It is possible that the HAV outbreak strain is endemic within certain areas of Europe but that currently no genotyping results are available from these regions. If this were the case, contamination events could occur over a number of years and the assumption of a single point source of contamination would be incorrect.

- Even in countries where genotyping is available, routine genotyping of all hepatitis A cases does not always occur. Owing to the large number of cases, Italy genotyped only a proportion of HAV cases to confirm the existence and the geographical extent of the HAV outbreak. As a consequence, in countries where genotyping is not routinely applied, cases may be missed as being part of this international outbreak and the strength of evidence of lots may be underestimated when genotyping data are not available to support epidemiological evidence.

- Misclassification of contaminated food samples could have occurred; if HAV contamination is not homogeneously spread throughout a food item, detection of the virus can be difficult and

multiple samples need to taken; a negative result cannot exclude the possibility of HAV contamination. Moreover, genotyping of HAV from food items is more difficult than from human samples as the viral count is often too low to allow sequencing and, as a consequence, sequence homology with outbreak strain could not be confirmed

- Evidence of exposure to berries may be subject to recall bias, owing to the long interval between exposure and onset of symptoms/diagnosis (15–50 days) and the fact that berries may be a minor ingredient or used as a decoration in the food. This could result in the failure to identify the contaminated food item or tracing of food items which are not contaminated. The restriction of tracing to fresh berries in the Netherlands could have been caused by a recall bias.

- Consumption of berries could be a confounding factor for example; high consumers of berries could also be high consumers of other food items (e.g. salads, sprouts and raw vegetables) that are subject to minimal cooking or processing.

- An additional source of uncertainty is related to record keeping and adherence to safety procedures within investigated premises. It is important to identify the specific lots of single ingredients used to create berry mixes and berry products. The accuracy of record keeping and compliance with procedures at a food operator could be dependent on access to information management tools and availability of well-trained staff.

- Based on the available data, hypotheses of HAV contamination of berries by means of a cross-contamination mechanism in manufacturing environment may be only partially explored as more data would be needed to discover missing links. Cross-contamination of berries might result from contact with other foodstuffs contaminated with HAV that have been processed in the same plants and facilities, or even in multiple plants, but which were not used as ingredients for the back-traced berry lots. This implies that other supply chains, including other foodstuffs manufactured by the food operators involved in the back-tracing of berries (e.g. mushrooms and other fruits), should have been back-traced. Evidence of overlapping use of lots of ingredients for products and possible cross-contamination during processing might be obtained only by local inspections.

6. Conclusions

Differences in the epidemiological features and health impact of the HAV epidemic outbreak in the involved countries led to the adoption of different approaches in the assessment of the implicated lots of berries.

No single point source of contamination ("hotspot") could be identified which links to all cases and contaminated lots identified during the multinational outbreak. Instead the analysis points to a more sustained problem in berry production rather than a single source of contamination with HAV as the cause of the outbreak.

The outcome of this outbreak investigation could be limited to two possible sources with a similar level of evidence:

- redcurrant production in certain regions and years in Poland

or

- blackberry production in unknown regions and years in Bulgaria.

Further local investigations are necessary to substantiate or reject the two hypotheses proposed in section 5.3.

In Poland, detailed information on primary production and fresh berry supply was obtained. Further investigation should focus on a risk assessment of the local conditions for redcurrant production, including risk factors such as exchange of temporary workers, shared use of equipment for production/harvest, common water reservoirs for irrigation, use of sewage-contaminated agricultural water for application of chemicals (e.g. pesticides/fungicides) or environmental events (e.g. flooding).

In Bulgaria, limited information on the traceability of fresh and frozen berries was obtained through the RASSF requests. Communication channels, transparency and rapidity of response need to be improved, as does understanding of the food safety issues raised. More information on the location of harvests is necessary to understand whether contamination of blackberries is due to single point source or to a continuous source.

Detection and sampling of leftover material at food operators or other batches using only some ingredients of the suspected fruit mixtures might provide additional information that can help determine which of the two hypotheses is correct. Special emphasis should be given to single ingredients or products that uses only redcurrants or blackberries from the suspect lots.

7. Recommendations

The following recommendations are applicable for countries producing frozen berries and take into consideration the critical risk factors for contamination by HAV, which include environmental factors, use of sewage-contaminated agricultural water and contamination by infected workers.

Good Hygiene Practice (GHP). Workers (including migrant pickers) in the frozen berry production chain should receive hygiene training with a focus on hand hygiene and personal cleanliness. Furthermore, periodic assessments are needed to ensure compliance with GHP. Food handlers, managers and other company personnel should take particular note of the 'Sanitation' and 'Personal Hygiene' sections of the Codex Alimentarius and guidelines on the application of general principles of food hygiene to the control of viruses in food (WHO and FAO, 2012), preferably translated into the national language and incorporated into national hygiene codes.

From: WHO/FAO, 2012. Codex Committee on Food Hygiene (CCFH). Codex Alimentarius Guidelines on the application of general principles of food hygiene to the control of viruses in food. CAC GL 79-2012, Rome. [13 p.] Annex II: Control of hepatitis A virus (HAV) and norovirus (NoV) in fresh produce. (Sections 4.4.4.1, §§21-25; 7.5, §58; 10.2, §19)

Changing facilities and toilets:

Hygienic and sanitary facilities should be available to ensure that an appropriate and acceptable degree of personal hygiene can be maintained.

Harvest and production may be subject to seasonal influx of workers to meet the needs of producers and may vary for different products. An inherent danger at the farm and production level is an under-supply of suitable toilet and hand washing facilities to meet this influx. Food business operators should ensure that suitable facilities are provided, are readily accessible and meet appropriate hygiene standards.

Hygienic and sanitary facilities should:

- be located in proximity to the production area;
- be located in areas adjacent to the processing area, but without direct access to it;
- be in sufficient numbers to accommodate personnel;
- be of appropriate design to ensure hygienic removal of wastes;
- be designed so that there is no seepage into underground water or enter the agricultural field;
- have adequate means for washing and drying hands;
- be maintained under sanitary conditions and good repair;
- be appropriately cleaned and disinfected (…); and
- be separate for guests and personnel of the establishment, when feasible.

Hand washing facilities:

Hand washing facilities should be supplied with hand cleanser (soap). Where possible, hand washing facilities should have non-hand operable taps and single-use towels to help prevent the re-contamination of clean hands. Hand washing and drying instructions should be visibly present for all users of these facilities.

Hand washing and drying facilities should be suitably located in food preparation or production areas to ensure food handlers have ready access to them. There should be hand washing facilities within close proximity to the toilets and positioned so that the personnel must pass by them before returning to the food handling area.

Visitors:

Non-authorized persons and, to the extent possible, children should not be present in food handling areas where food is grown, harvested, stored or prepared

Training programmes

Personnel involved in growing, harvesting, processing and storage of fresh produce should have appropriate training in:

- The general characteristics of NoV and HAV and their resistance to various environmental conditions, e.g., conditions of sewage treatment, temperature.
- Personal hygiene (…).
- Control measures to prevent faecally contaminated water being used in primary production and processing.
- The risks associated with the use of human waste excreta as a fertilizer.
- Control measures to prevent fresh produce becoming contaminated by contagious food

Good Manufacturing Practice (GMP) and Good Agricultural Practice (GAP). Operators freezing, mixing and packing frozen berries should follow GMP and ensure that HACCP principles are complied with throughout the production process to reduce the risk of contamination and to prevent cross-contamination (EFSA BIOHAZ panel, 2014). Since many small-scale primary producers are involved in berry production, operators freezing berries represent a point which centralisation occurs. These operators could act as advocates for GAP, informing fresh berry suppliers of the necessary actions to comply with GAP requirements. This could include, where agricultural or transportation equipment is shared between primary producers, procedures to reduce the risks of HAV contamination and cross-contamination.

Environmental factors. Berry production areas could be subjected to an evaluation for hazards in order to identify potential sources of faecal contamination. This would apply not only to farms, but also to areas where wild berries are being picked. Only water sources known to be free from faecal contamination, as established by monitoring programmes, could be used both for irrigation and for the application of agricultural chemicals, but regular or occasional flooding also has to be considered.

Record keeping. To guarantee full traceability, operators freezing, mixing and packing frozen berries should ensure that all information on incoming materials is carefully recorded. This would include information on the supplier's name and location, berry type, amount supplied and date of harvest for both primary producers and local pickers. Preferably, this information could be collated in a standardised way to facilitate tracing back activities.

Investigations. Futher information on local conditions is needed to identifiy the source of contamination and detect weaknesses in the supply chain where mitigation measures could be implemented. This could include production sector inspections that evaluate operational procedures, such as sanitary surveys, training, observational audits and verification of GHP and GAP compliance.

The following public health recommendations are made as contaminated product related to this outbreak could still be circulating in the food chain and without improvements in the production of frozen berries a HAV contamination event could occur in the future.

Surveillance. MSs could consider enhancing epidemiological and microbiological surveillance for HAV to make sure that possible new cases are promptly detected. Improvements in the timeliness and effectiveness of HAV outbreak detection, investigation and comparison of human/food molecular typing findings are possible by developing a framework for HAV molecular surveillance that combines the public health and food sectors. Such a framework shall include surveillance objectives, standard methods and recommendations for implementation.

Genotyping of diagnostic samples (460 nt fragment spanning the VP1–2a junction region that ranges from nt 2873 to nt 3376 in GenBank Accession No NC 001489—Stene-Johansen et al., 2007; www.havnet.nl) could be considered to support outbreak investigations. In addition, testing of monitoring or outbreak-related food samples using ISO/TS 15216:2013 (Horizontal method for determination of hepatitis A virus and norovirus in food using real-time RT-PCR) could be considered. Where possible, genotyping the positive food isolates, targeting the same VP1–2a fragment, could be considered.

Support laboratory preparedness. Laboratory preparedness in the food sector and harmonisation of methods for HAV detection and genotyping could be encouraged at the EU level. Similarly, guidelines for frozen berry sampling and testing for HAV according to the existing international standard could be encouraged.

Vaccination. MSs could also consider HAV vaccination of close contacts of cases and throughout the larger community, taking into account the epidemiological situation and/or immune status of the

local population. Ideally, HAV vaccination status could be requested from all berry pickers and handlers. HAV vaccination is recommended for all non-immune berry pickers and handlers.

Risk assessment. The multistate outbreak of HAV and other HAV outbreak reports available in the literature showed that frozen berries represent an important vehicle for HAV transmission to humans. In order to support any mitigation strategies, risk management and risk communication options, a formal assessment of the risk posed by HAV in frozen berries could be carried out to review the assurance of safety for berries.

Risk communication. In the present outbreak, HAV infection is mainly acquired through the consumption of raw or undercooked frozen berries. Therefore, in relation to the multistate HAV outbreak, the importance to adopt and or maintain policies for outbreak risk communication to consumers and other stakeholders at the EU level could be carefully considered. Clear information could be provided to consumers and manufacturers on appropriate handling of frozen berries. This could include labelling of all packages of frozen berries, hygiene and HAV vaccine recommendations to food handlers, and, during outbreaks, recommendations on heat treatment of frozen berries before consumption to avoid both norovirus and HAV infections outbreak associated.

Research. Submission of genotyping sequences to a central database, e.g. the HAVNET (Database coordinated by the Dutch National Institute of Health and Environment) project, will improve understanding of the ecology of HAV and improve interpretation of genotyping data when applied to outbreak investigations. Whole-genome sequencing (WGS) to examine viral isolates from different times during the outbreak could be considered to explore the evolution of the virus in a multinational outbreak. However, it should be considered that WGS has been rarely used in previous outbreak investigations, and the interpretation of WGS results can be challenging.

The following recommendations are made based on the lessons learned from the project group formed to investigate the multinational HAV outbreak in order to support future tracing activities.

Coordination. Flexible systems should be put in place to allow the rapid formation of project teams involving the relevant experts from both public health and food safety sectors (public health experts, epidemiologists, microbiologists, food inspectors, food safety experts, tracing experts, communication experts, analysts and statisticians) and ensure effective coordination of outbreak investigations using supply chain tracing.

Data management. Procedures to improve and standardise data collection, exchange, storage, management and analysis along complex food production chains should be developed. The agreement of quality standards to ensure fidelity during data collection and transfer would ensure this. To support the exchange of transaction data (product descriptions, delivery dates, production dates, expiry dates, quantities, lot identifiers, supplier names and addresses) at each step in the supply chain, improved data management tools are required. These data management tools would require importation of company registers for food business operators, the use of controlled terminology to describe food items (e.g. FoodEx 2 (EFSA, 2011)) and the development of system to system protocols to allow direct importation of transaction details from food business operator record-keeping applications.

Analytics. The volume of data collected in supply chain tracing requires the use of computational algorithms and advanced visualisation tools (including both spatial and temporal analysis) in order to derive intelligence from the underlying dataset. Tools, such as FoodChain-Lab, with the functionality to import from or connect to the data management system described above and to perform real-time analysis on the transaction dataset, should be available to outbreak investigation teams to enable them to quickly identify possible "hotspots" for further investigations.

7.1. Lessons learnt for future trace-back activities in outbreak investigations

This is the second formal request to EFSA to coordinate tracing activities related to a multinational foodborne outbreak. The same data format and tool for information exchange and analytical method were applied in both outbreaks, but incorporating enhancements developed since the EHEC outbreak. The following recommendations are given to prepare for future activities, strengthening positive aspects and identifying areas for improvement.

- Tracing of the food supply chain in foodborne outbreak investigations requires close collaboration between the epidemiologists and the tracing analysts of all countries involved.
  - The working group established for this task demonstrated the advantages and synergies of this kind of collaboration. In order to have a rapid response, a network of responsible scientists and/or institutions should be established in advance. Initial members could be identified from the two networks on food- and waterborne diseases of ECDC and on microbiological risk assessment of EFSA. The option of including experts in the food chain sector under investigation should be considered on a case-by-case basis.
  - In preparation for future outbreak investigations the two networks could improve cooperation and promote exchange of best practices at the European level.
- The most critical part of the investigations is a timely and complete data collection at the local level. This requires a common understanding of the needs at local level and proactive storage of information in an accessible format.
  - The investigations showed that the data model used allows sufficient insight into the food supply chain and can be used for outbreak investigations. Nevertheless, field definitions should be clarified and existing controlled terminologies (in particular, classification of food products) should be integrated to reduce errors and the requirements for recoding. A revision of the data model with a focus on the feasibility of system-to-system data exchange and a proposal for the future implementation should be done with high priority.
  - Data collection in outbreak investigations is the task of the local competent authorities and can be very resource intensive. The development and dissemination of user manuals, training and data input/import tools using modern data technology (e.g. mobile apps) would improve preparedness and will support national or regional authorities in performing their tasks.
- Investigations in emergency situation need a smooth and failure-free exchange of information between the Member States and the investigation group.
  - The RASFF system is a well-defined structure with clear responsibilities, data protection and information features. Nevertheless, the uploading of Excel files for data exchange impedes the use of predefined databases (e.g. terminologies, registers) and manual data entry is an error-prone procedure for data collation. The RASFF system could be extended to support easy exchange of transaction data with minimal requirements for manual data entry, advanced querying of stored transaction data and web services to allow connections to supply chain visualisation tools.
- Access to interactive visualisation tools in order to perform real-time analysis on the transaction dataset in order to quickly identify possible “hotspots” for further investigations
  - The FoodChain-Software showed the feasibility and value of interactive software to analyse tracing data. Several features were developed to support the outbreak investigation (e.g. clustering and virtual regional “hotspots”). Nevertheless, the existing methodology to analyse tracing data should be systematically reviewed and evaluated. Alternative methods already exist in different areas (e.g. product fraud, ecology, criminology) and could suitable for adaptation to outbreak investigations. A review is needed to identify and

prioritise analysis methodologies for software development and highlight critical functionalities and features.

- Reporting during ongoing outbreaks needs flexible timelines.
  - Continuous feedback to the Member States involved in the outbreak, to the EC as requestor and to the Standing Committee on the Food Chain and Animal Health (SCFCAH) is important to enable adequate risk management actions, to justify the effort expended during the tracing activities and to motivate future activities in the Member States. However, project planning is associated with several important uncertainties, such as additional outbreak clusters and involvement of other Member States, delays in data collection at the local level, or unexpected findings which generate new hypotheses that need to be evaluated. Regular feedback to different groups seems to be more feasible than predefined milestones/deadlines for reporting. A steering group including the EC and EFSA may decide on the finalisation of the tracing activities if the source of the outbreak cannot be clearly identified by tracing.

DOCUMENTATION PROVIDED TO EFSA

- Request letter of the European Commission: Ares(2013)2576387 of 4 July 2013.
- Request letter of the European Commission: Ares(2013)3322396 of 23 October 2013.

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APPENDICES

Appendix A. Detailed description of the starting points for tracing

A.1. Starting points for tracing in Italy

According to the class classification adopted (Table 10), the starting points linked to the outbreak in Italy were as follows: 1 lot of class 1, 5 lots of class 2A, 5 lots of class 2B, 9 lots of class 2C and 32 lots class 3B. The starting points of class 1 or classes 2A, 2B and 2C were linked with a total of 113 human cases (29 confirmed and 84 probable), of which 67 were sporadic cases and 48 belonged to 11 different clusters of 9 to 42 persons.

Owing to the high number of identified lots, information was collected only on the lots with the highest level of evidence of connection with the outbreak cases (classes 1, 2A, 2B and 2C). The lots that have been traced back are listed in Table 29. For one starting point of class 2C, no tracing information was obtainable.

In Italy, a total of 19 frozen berry lots manufactured by 7 packager companies were back-traced. These included: all the identified lots of class 1 (n = 1) and 2A (n = 5), eight lots of class 2C (n = 9) and five lots of class 2B (n = 13). One lot of class 2C (lot #10) was excluded because the positive sample had been taken from an open package in the house of a suspected epidemic case that was subsequently not confirmed. Lots constituting class 2B were all manufactured by the same companies that had also produced lots at a higher classification level. Based on this consideration, and for feasibility reasons, not all lots were back-traced. Moreover, some of these lots were identified as class 2B lots after data collection had been undertaken.

Table 44: Starting points for tracing in Italy

Sample date	Laboratory and Method	Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID	Product[a]	Lot No[b]	Expiry date	Production date	Business
Class 1 (very high evidence): Confirmed lots contaminated with HAV genotype 1A, outbreak strain												
19/04/13	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos, OS**	29/03/2013 - 12/04/2013	Cluster of 4 HAV pos (Cluster IT#037)	Class 1	Mixed frozen berries	**Conf Lot IT#01**	Mixed frozen berries		02/2015	05/02/2013	Frozen berry processor (packager) IT#17
Class 2A (very high evidence): Confirmed lots consumed by at least one confirmed case affected with HAV genotype 1A outbreak strain												
27/09/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**	12/09/2013 - 20/09/2013	3 cases **HAV pos, OS** (Case IT#027, Case IT#029, Case IT#033) 3 cases HAV pos (Case IT#026, Case IT#025, Case IT#042)	Class 2A	Mixed frozen berries	**Conf Lot IT#02**	Mixed frozen berries		06/2015	09/07/2013	Frozen berry processor (packager) IT#1214
2013		**HAV pos**	24/04/2013 - 12/05/2013	2 cases **HAV pos, OS** (Case IT#013, Case IT#045)	Class 2A	Mixed frozen berries	**Conf Lot IT#04**	Mixed frozen berries		12/2014	04/01/2013	Frozen berry processor (packager) IT#1214
21/09/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**	12/05/2013 - 04/09/2013	1 case **HAV pos, OS** (Case IT#013) 2 cases HAV pos (Case IT#011, Case IT#024)	Class 2A	Mixed frozen berries	**Conf Lot IT#06**	Mixed frozen berries		01/2015	28/02/2013	Frozen berry processor (packager) IT#22
10/06/2013	IZPLVL LaSpezia, IT PCR (MI10PB068 REV.1 2011)	**HAV pos**	16/05/2013	1 case **HAV pos, OS** (Case IT#08)	Class 2A	Mixed frozen berries	**Conf Lot IT#07**	Mixed frozen berries		02/2015	21/03/2013	Frozen berry processor (packager) IT#22

Sample date	Laboratory and Method	Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID	Product	Lot No.	Expiry date	Production date	Business
08/07/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**	10/06/2013	1 case **HAV pos, OS** (Case IT#040)	Class 2A	Mixed frozen berries	**Conf Lot IT#015**	Mixed frozen berries		07/2014	12/07/2012	Frozen berry processor (packager) IT#21
Class 2B (high evidence): All suspected lots consumed by at least one confirmed case affected with HAV genotype 1A, outbreak strain												
			04/03/2013 - 12/05/2013	1 case **HAV pos, OS** (Case IT#051) 1 case HAV pos (Case IT#031)	Class 2B	Mixed frozen berries	**SuspLot IT#016**	Mixed frozen berries		30/09/2014	10/10/2012	Frozen berry processor (packager) IT#22
			20/06/2013	1 case **HAV pos, OS** (Case IT#016)	Class 2B	Mixed frozen berries	**SuspLot IT#017**	Mixed frozen berries		12/2014	31/01/2013	Frozen berry processor (packager) IT#22
			15/10/2013	1 case **HAV pos, OS** (Case IT#004)	Class 2B	Mixed frozen berries	**SuspLot IT#018**	Mixed frozen berries		12/2014	31/01/2013	Frozen berry processor (packager) IT#22
			16/04/2013 - 28/09/2013	Cluster of 4 HAV pos, OS (Cluster IT#018) 2 cases HAV pos (Case IT#041, Case IT#054)	Class 2B	Mixed frozen berries	**SuspLot IT#019**	Mixed frozen berries		01/2015	04/02/2013	Frozen berry processor (packager) IT#22
			09/10/2013 - 21/10/2013	cluster of 9 **HAV pos, OS** (Cluster IT#057)	Class 2B	Mixed frozen berries	**SuspLot IT#020**	Mixed frozen berries			10/07/2013	Frozen berry processor (packager) IT#1214

Sample date	Laboratory and Method	Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID	Product	Lot No.	Expiry date	Production date	Business
Class 2C (high evidence): Confirmed lots contaminated with HAV, no cases affected with HAV genotype 1A, outbreak strain												
13/05/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#03**	Mixed frozen berries			19/02/2013	Frozen berry processor (packager) IT#19
13/05/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**	09/04/2013 - 11/06/2013	3 cases HAV pos (Case IT#010, Case IT#039, Case IT#044)	Class 2C	Mixed frozen berries	**Conf Lot IT#05**	Mixed frozen berries		12/2014	15/01/2013	Frozen berry processor (packager) IT#22
2013		**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#08**	Mixed frozen berries			10/05/2013	Frozen berry processor (packager) IT#22
2013		**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#09**	Mixed frozen berries			17/05/2013	Frozen berry processor (packager) IT#22
04/09/2013	IZSLER, IT PCR (MP 05/004 rev. 1)	**HAV pos**			Class 2C	Frozen Blackberries	**Conf Lot IT#011**	Frozen blackberries				IT#234
2013		**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#012**	Mixed frozen berries			18/04/2013	IT#236
22/08/2013	IZS Torino, IT PCR (MI10PB068 REV.1 2011)	**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#013**	Mixed frozen berries		05/2015	25/05/2013	Frozen berry processor (packager) IT#21
2013		**HAV pos**			Class 2C	Mixed frozen berries	**Conf Lot IT#014**	Mixed frozen berries			14/06/2013	Frozen berry processor (packager) IT#21

(a) Product name deleted for confidentiality
(b) Lot number deleted for confidentiality
Note: confirmed lot 10 (IT#10) was not traced back to source.

A.2. Starting points for tracing in Ireland

In Ireland, confirmed cases were the starting points because no confirmed lots were identified. Tracing was conducted on lots which confirmed cases most likely consumed during their estimated exposure periods. The most likely exposure period for each case was estimated based on date of onset of illness combined with the minimum and maximum incubation period for HAV. Lots, or multiple lots, for 11 confirmed cases were identified. These lots were all class level 3A (according to the classification in Table 10).

Table 45: Starting points for tracing in Ireland; class 3A (medium evidence): all possible products consumed by at least one confirmed case infected with HAV genotype 1A, outbreak strain

Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID[a]	Product[b]	Lot No.	Expiry date	Production date	Business
	26/04/2013 - 09/08/2013	5 cases **HAV pos, OS** (Case IE#441254, Case IE#440019, Case IE#439499, Case IE#434360, Case IE#433765)	Class 3A	Frozen Raspberries	RaspYog: **Case IE#441254 Case IE#440019 Case IE#439499 (C) Case IE#434360 (B) Case IE#433765**	Raspberry Yogurt & Cake	Exposure from 7/3/2013 to 25/7/2013			Berry product producer (Manufacturer) IE#1215
	26/04/2013 - 07/07/2013	4 cases **HAV pos, OS** (Case IE#434360, Case IE#439499, Case IE#440889, Case IE#439125)	Class 3A	Mixed frozen berries	BerryYog: **Case IE#434360 (A) Case IE#439499 (B) Case IE#440889 Case IE#439125**	Mixed berry Yoghurt & Cake	Exposure from 7/3/2013 to 22/6/2013			Berry product producer (Manufacturer) IE#1215
	03/07/2013	1 case **HAV pos, OS** (Case IE#439499)	Class 3A	Mixed frozen berries	**Case IE#439499 (A)**	Frozen Mixed berries	Exposure from 14/5/2013 to 18/6/2013			Frozen berry trader (Supplier) IE#229
	19/05/2013	1 case **HAV pos, OS** (Case IE#439110)	Class 3A	Frozen Blackberries	**Case IE#439110**	Frozen Blackberries	Exposure from 30/3/2013 to 4/5/2013			Berry product retailer (Local retailer) IE#235
	27/06/2013	1 case **HAV pos, OS** (Case IE#438998)	Class 3A	Mixed frozen berries	**Case IE#438998**	Berry Smoothie made using a frozen red berry mix	Exposure from 8/5/2013 to 12/6/2013			Berry product retailer (Local retailer) IE#1211

Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID	Product	Lot No.	Expiry date	Production date	Business
	05/04/2013	1 case **HAV pos, OS** (Case IE#431742)	Class 3A	Mixed frozen berries	**Case IE#431742 (B)**	Smoothie made using a red berry mix	Exposure from 14/2/2013 to 21/3/2013			Berry product retailer (Local retailer) IE#1207
	05/04/2013	1 case **HAV pos, OS** (Case IE#431742)	Class 3A	Mixed frozen berries	**Case IE#431742 (A)**	Smoothie of made using mixed frozen berries	Exposure from 14/2/2013 to 21/3/2013			Berry product retailer (Local retailer) IE#1208
	08/04/2013	1 case **HAV pos, OS** (Case IE#433732)	Class 3A	Mixed frozen berries	**Case IE#433732**	Smoothie of made using mixed frozen berries	Exposure from 17/2/2013 to 24/3/2013			Berry product retailer (Local retailer) IE#1209

(a): Starting points were defined by combinations of products eaten by the cases.
(b): Product name deleted for confidentiality.

A.3. Starting points for tracing in France

Table 46: Starting points for tracing in France Class 2A (very high evidence): Confirmed lots consumed by at least one confirmed case affected with HAV genotype 1A outbreak strain

Sample date	Laboratory and Method	Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID[a]	Product[b]	Lot No.[c]	Expiry date	Production date	Business
25/03/2014	SCL 34 PCR (CEERAM Kit) ISO/TS 15216-2	HAV pos	08, 10, 17th Feb. 2014	3 cases HAV pos, OS	Class 2A	Mixed berries (redcurrants, blackberries, billberries)	**Conf Lot FR#1** Case FR#1 Case FR#2 Case FR#3	Mixed berries (redcurrants, blackberries, billberries)		01/2015	01/2013	Berry product producer (Manufacturer) FR#1793
27/03/2014	SCL 34 PCR (CEERAM Kit) ISO/TS 15216-2	HAV pos	08, 10, 17th Feb. 2014	3 cases HAV pos, OS	Class 2A	Fruit tarts with mixed berries (redcurrants, blackberries, billberries)	(Conf Lot FR#1) Case FR#1 Case FR#2 Case FR#3	Pastries with mixed berries (redcurrants, blackberries, billberries)		01/09/2015	09/07/2013	Berry product retailer (Caterer)

(a): Three cases were counted as one starting point, i.e. mixed berry tarts.
(b): Product name deleted for confidentiality.
(c): Lot number deleted for confidentiality.

A.4. Starting points for tracing in Norway

Table 47: Starting points for tracing in Norway

Sample date	Laboratory and Method	Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID[a]	Product[b]	Lot No.[3]	Expiry date	Production date	Business
Class 1 (very high evidence): Confirmed lots contaminated with HAV genotype 1A, outbreak strain												
22/04/2014	Norwegian University of Life Sciences	**HAV pos OS**		Cases[1] **HAV pos, OS**	Class 1	Frozen cake with berries	**Conf Lot NO#1** CaseNO#X	Berry mix cake		27/12/2014	27/06/2013	Berry product retailer NO#1787
Class 2B (high evidence): All suspected lots consumed by at least one confirmed case affected with HAV genotype 1A, outbreak strain												
				Cases[1] **HAV pos, OS**	Class 2B	Frozen cake with berries	**Susp Lot NO#2** CaseNO#X	Berry mix cake		28/11/2014		Berry product retailer NO#1787

(a): As both lot 3148079434 and lot 3178079418 were distributed in the same area within overlapping periods, it is not possible to add more information about which patients were exposed to which lots. In total, 21 out of the 29 primary cases stated that they may have eaten the cake in question.
(b): Product name deleted for confidentiality.
(c): Lot number deleted for confidentiality.

A.5. Starting points for tracing in Sweden

Table 48: Starting points for tracing in Sweden Class 3A (medium-strength evidence): All possible products consumed by at least one confirmed case infected with HAV genotype 1A, OS

Link microbiology	Onset of disease	Link epidemiology (OS: outbreak strain)	Status	Type of product	ID[a]	Product[b]	Lot No	Expiry date	Production date	Business
	25/1/2014 and 1/2/2014	2 cases **HAV pos, OS**	Class 3A	Frozen berries for breakfast	**Case SE#1 Case SE#2**	Mixed berries (bilberries, blackberries, raspberries, black and red currant), purée (raspberries, blackberries, passion fruit), raspberries, black currant, strawberries, buckthorn, pomegranate)	Exposure 20/12/2013 and 4/1/2014, respectively			Berry product retailer (Restaurant) SE#1536

(a): Starting points were defined by combinations of products eaten by the cases.
(b): Product name deleted for confidentiality.

A.6. Starting points for tracing in the Netherlands

Table 49: Starting points for tracing in the Netherlands; class 3A (medium evidence): all possible products consumed by at least one confirmed case infected with HAV genotype 1A, outbreak strain

Link microbiology	Onset of disease	Link epidemiology	Status	Type of product	ID	Product	Lot No.	Expiry date	Production date	Business
	22/08/2013 24/08/2013 07/09/2013 15/09/2013 04/12/2013	5 cases HAV pos, OS* (**pt3**=Lot NL# CASE_0018, **pt6**=Lot NL# CASE_0014, **pt7**=Lot NL# CASE_0005 &Lot NL# CASE_0015 &Lot NL# CASE_0021, **pt8**= Lot NL# CASE_0002 & Lot NL# CASE_0006 & Lot NL# CASE_0011 &Lot NL# CASE_0016, **pt12**=Lot NL# CASE_0003 & Lot NL# CASE_0007 &Lot NL# CASE_0017)	Class 3A	Fresh Strawberries	FSB1: **pt3** **pt6** **pt7** **pt8** **pt12**	Fresh Strawberries	Exposure from July to December 2013			Berry product retailer (Super market) NL#1301
	07/09/2013 15/09/2013 04/12/2013	3 cases HAV pos, OS (**pt7**= Lot NL# CASE_0005& Lot NL# CASE_0015& Lot NL# CASE_0021, **pt8**= Lot NL# CASE_0002& Lot NL# CASE_0006 & Lot NL# CASE_0011 & Lot NL# CASE_0016 & Lot NL# CASE_0002, **pt12**= Lot NL# CASE_0003 & Lot NL# CASE_0007 & Lot NL# CASE_0017)	Class 3A	Fresh Raspberries	FRB1: **pt7** **pt8** **pt12**	Fresh Raspberries	Exposure from July to December 2013			Berry product retailer (Super market) NL#1301

	15/09/2013 04/12/2013	2 case HAV pos, OS (**pt8**= Lot NL# CASE_0002 & Lot NL# CASE_0006 & Lot NL# CASE_0011 & Lot NL# CASE_ 0016 **pt12**= Lot NL# CASE_0003 & Lot NL# CASE_0007 & Lot NL# CASE_0017))	Class 3A	Fresh Blueberries	FBL1: **pt8** **pt12**	Fresh Blueberries	Exposure from July to December 2013			Berry product retailer (Super market) NL#1301
	15/09/2013	1 case HAV pos, OS (**pt8**= Lot NL# CASE_0002 & Lot NL# CASE_0006 & Lot NL# CASE_0011 & Lot NL# CASE_0016)	Class 3A	Fresh Blackberries	FBB: **pt8**	Fresh Blackberries	Exposure from July to August 2013			Berry product retailer (Super market) NL#1301
	16/08/2013 02/09/2013 10/09/2013	3 cases HAV pos, OS (**pt2**= Lot NL# CASE_0018, **pt4**= Lot NL# CASE_0004 & Lot NL# CASE_0008 & Lot NL# CASE_0019, **pt9**= Lot NL# CASE_0009 & Lot NL# CASE_0020)	Class 3A	Fresh Strawberries	FSB2: **pt2** **pt4** **pt9**	Fresh Strawberries	Exposure from July to August 2013			Berry product retailer (Super market) NL#1314 &NL#1315
	02/09/2013 10/09/2013	2 cases HAV pos, OS (**pt4**= Lot NL# CASE_0004 & Lot NL# CASE_0008 & Lot NL# CASE_0019, **pt9**= Lot NL# CASE_0009 & Lot NL# CASE_0020)	Class 3A	Fresh Raspberries	FRB2: **pt4** **pt9**	Fresh Raspberries	Exposure from July to August 2013			Berry product retailer (Super market) NL#1314 &NL#1315
	02/09/2013	1 case HAV pos, OS (**pt4**= Lot NL# CASE_0004 & Lot NL# CASE_0008 & Lot NL# CASE_0019)	Class 3A	Fresh Blueberries	FBL2: **pt4**	Fresh Blueberries	Exposure from July to August 2013			Berry product retailer (Super market) NL#1314 &NL#1315

Appendix B. Detailed description of "hotspots"

Using tracing data for Italy, Ireland and the Netherlands in April/May 2014, "hotspots" in the food chain were identified for each country. This analysis was later updated and is presented here in sections B.1 to B.3.

Additional tracing information from the French, Norwegian and Swedish outbreaks was analysed in June 2014 to substantiate the evidence that single "hotspots" were the potential source of the outbreak. sections B.4 to B.6 describe the tracing results of France, Norway and Sweden in detail.

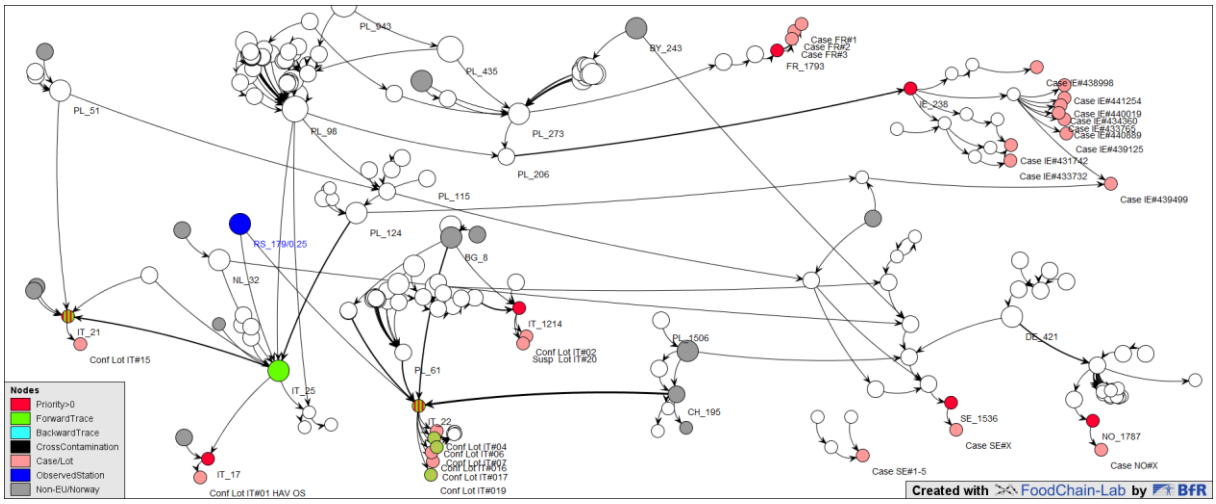
B.1. Results for Italy

The description of the Italian "hotspots" was aimed at estimating the maximum possible number of back-traced lots and manufacturing companies that could be explained by frozen berries supplied by a certain station (the "*hotspot*") which had delivered berries to at least two different packaging companies. To estimate the maximum number of lots that could be explained by the "hotspot", two hypotheses of possible contamination were considered direct contamination and cross contamination

The back-tracing activity is based on lots of classes 1 (n = 1), 2A (n = 5), 2B (n = 5) and 2C (n = 9). One lot of class 2C has been excluded because no information on back-tracing was available as the sample had been taken from an open package in the house of a suspected outbreak case that was not confirmed.

Four "hotspots" were identified:

B.1.1. "Hotspot" RS#179



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 39: Network visualisation with identified "hotspot" RS#179 (blue node) and starting points (lots, cases) in the complete dataset (without the Netherlands)

Part A: Freezing processor RS#179, in Serbia, sent 18 480 kg of raspberries on 21 May 2013 to frozen berry trader IT#25. Frozen berry trader IT#25 stored the raspberries without re-packing.

- Raspberries delivered to IT#25 were tested for HAV presence on 29 May 2013 (company control, test performed at IZSLER). The test was negative.
- No **cross-contamination** at the IT#25 level could have occurred.

From IT#25, raspberry lot 14751 (5 048 kg) was delivered on 29 May 2013 to packager IT#21.

- **Direct contamination**: The raspberries were mixed with four other types of berries, producing confirmed lot #14 (class 2C, production date 14 June 2013). No epidemic cases were reported to have consumed these berries.
- If we assume **cross-contamination** at the packager level, no other lots could be explained. Lot #13 (production date 25 May 2013) and lot #15 (production date 12 July 2012), from the same packager, had been produced before the arrival of the RS#179 raspberries (via IT#25).

Part B: Freezing processor RS#179, in Serbia, sent two lots of raspberries to packager IT#22 on 25 January 2013 (19 498 kg) and 7 March 2013 (11 690 kg).

- **Direct contamination** of lots:
  - Packager IT#22 mixed raspberries, delivered on 25 January 2013, with other berries to produce:
    - Lot #6 (class 2A, production date 28 February 2013), consumed by three cases.
    - Lot #18 (class 2B, production date 31 January 2013), consumed by one case.
    - Lot #19 (class 2B, production date 4 February 2013), consumed by four cases.
  - Packager IT#22 mixed raspberries, delivered on 25 January and on 7 March 2013, with other berries to produce:
    - Lot #7 (class 2A, production date 21 March 2013), consumed by one case.
- If we assume **cross-contamination** at packager level:
  - Packager IT#22 also mixed another six lots. However, three of the lots were produced prior to the arrival of raspberries from freezing processor RS#179:
    - Lot #17 (class 2B, production date 31 January 2013).
    - Lot #8 (class 2C, production date 10 May 2013) consumed by zero cases.
    - Lot #9 (class 2C, production date 17 May 2013) consumed by zero cases.

Conclusion on this "hotspot"

"Hotspot" RS#179 explains **direct** contamination arriving at two packaging companies (IT#21 and IT#22) and five lots (two lots of class 2A, one lot of class 1 and two lots of class 2B) consumed by nine cases. Assuming **cross-contamination**, zero additional packagers and a further three lots (two lots 2C and one lot 2B) consumed by zero cases were involved.

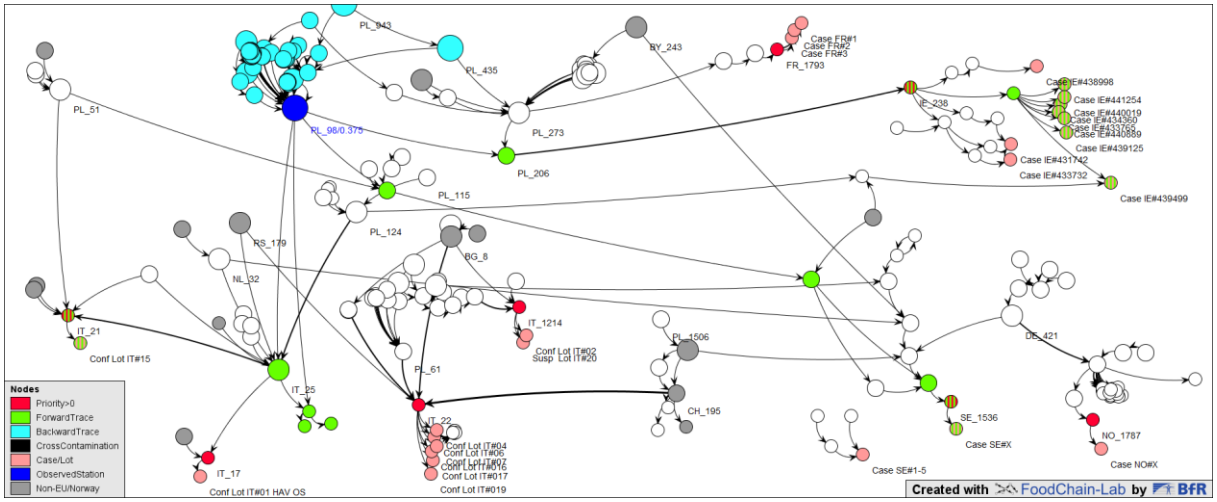
Globally, this story might explain:

- 2 packagers out of 7;
- 8 lots out of 19 lots traced:
  - 0 lots of class 1 out of 1
  - 2 lots of class 2A out of 5
  - 0 lots of class 2B out of 5
  - 3 lots of class 2C out of 8
  - 9 cases.

This story does not explain the other five packagers (IT#17, IT#19, IT#1214, IT#236 and IT#234) and does not explain 12 lots, including the lot of class 1.

It should be noted that packager IT#19 was also independently supplied by RS#179 (lots not entering in the back-tracing).

B.1.2. "Hotspot" PL#98



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 40: Network visualisation of connections between identified "hotspot" PL#98 (blue node) and starting points (lots, cases) in the complete dataset (without the Netherlands)

Part A: Freezing processor PL#98 sent raspberries (4 410 kg), on 24 August 2012, to packager IT#19 (a supplier to the catering trade). IT#19 mixed these raspberries with three other types of berries to make confirmed lot #3 (class 2C, production date 18 February 2013). IT#19 supplied this lot of mixed berries to wholesalers IT#28 and IT#16, and other catering wholesalers. An outbreak in a hotel indicated that berries from IT#28 had been used in the dinner.

- **Direct contamination:** One lot of class 2C and one packager are explained by "hotspot" PL#98.

Part B: Freezing processor PL#98 sent redcurrants (20 600 kg) to packager IT#25 on 2 April 2012.

IT#25 re-packed the lots and sent (2 091 kg), on 10 July 2012, to packager IT#21. These redcurrants were mixed with four other types of berries to produce lot #15 (class 2A, production date 12 July 2012). One case consumed lot #15.

- **Direct contamination:** This "hotspot", PL#98, explains contamination arriving at one packager and one lot of class 2A.
- Assuming **cross-contamination** at the packager IT#21 level, two more lots might be explained (lot #13 and lot #14, both of class 2C). However, it should be noted that the interval between the delivery of redcurrants from PL#98 to IT#21 (via IT#25) and the production of lot #13 and lot #14 was 13 and 14 months, respectively.
- Assuming **cross-contamination** at the IT#25 level, IT#25 also provided redcurrants to IT#17 (lot #1, class 1) and IT#19 (lot #3, class 2C) (see "hotspot" PL#115). In addition, IT#25 provided blackberries and blueberries to these same packagers. All the deliveries occurred after 2 April 2012 (the date that redcurrants were delivered from PL#98 to IT#25). In this case, one further packager and a further four cases might be explained.

Conclusion on this "hotspot"

At "hotspot" PL#98 two different types of berries were involved. Assuming a cross-contamination mechanism at the PL#98 level, this would explain the contamination of two packagers (IT#19 and IT#21), one lot of class 2A (lot #15) and one lot of class 2C (lot #3).

Assuming that cross-contamination also occurred at the IT#25 level and at the packager IT#21 level, one other packager could be explained (IT#17) and three other lots (lot #13, lot #14 of class 2C and lot #1 class 1) could be explained.

For these hypotheses, however, several steps and a long period of cross-contamination are assumed.

Globally, this "hotspot", PL#98, might explain:

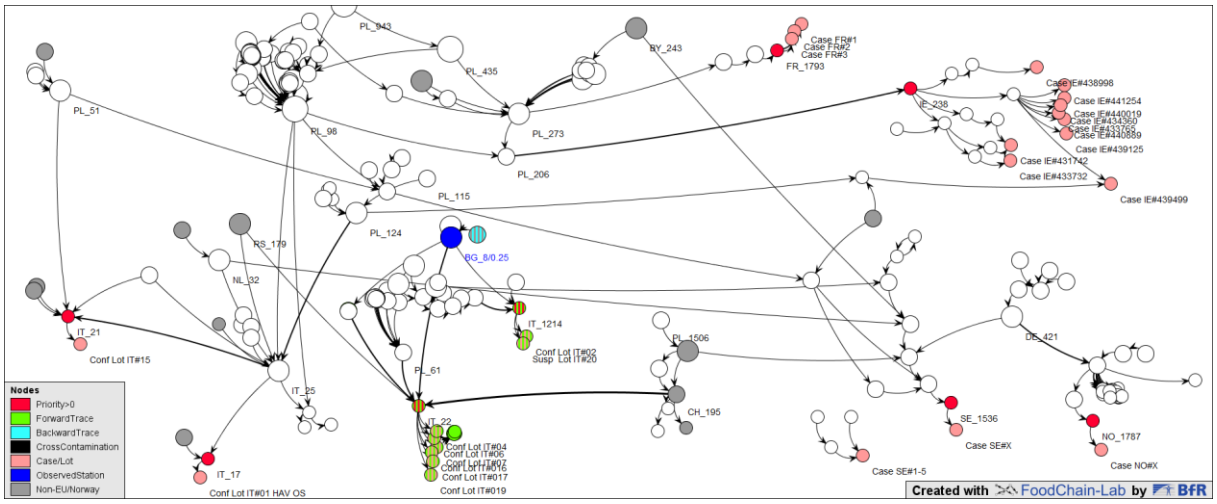
- 3 packagers out of 7;
- 5 lots out of 19 lots traced:
  - 1 lot of class 1 out of 1
  - 1 lot of class 2A out of 5
  - 3 lots of class 2C out of 8
  - 0 lots of class 2B out of 5
  - 5 cases of illness.

This "hotspot", PL#98, does not explain the other four packagers (IT#22, IT#1214, IT#236 and IT#234) and does not explain 14 lots.

This freezing processor, PL#98, is also linked to the Irish cases.

It should be noted that packager IT#19 also received redcurrants from PL#98, but they were not used to produce lot #3.

B.1.3. "Hotspot" BG#8



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.Starting points are marked as red notes, if in the delivery chain green/red.

Figure 41: Network visualisation of connections between identified "hotspot" BG#8 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands).

Part A: Freezing processor BG#8 sent blackberries (12 570 kg), on 25 November 2012, to packager IT#22. This lot was mixed with other berries to produce the following lots:

- Lot #17 (class 2B, production date 31 January 2013), consumed by one case.
- Lot #18 (class 2B, production date 31 January 2013), consumed by one case.
- Lot #19 (class 2B, production date 4 February 2013), consumed by four cases.
- Lot #6 (class 2A, production date 28 February 2013), consumed by three cases.
- Lot #7 (class 2A, production date 21 March 2013), consumed by one case

Freezing processor BG#8 sent blackberries (14 960 kg), on 27 August 2012, to packager IT#22. This lot was mixed with other berries to produce the following lot:

- Lot #16 (class 2B, production date 10 October 2012), consumed by two cases.

Freezing processor BG#8 sent blackberries (20 000 kg), on 14tSeptember 2012, to trader IT#16, who then sent (20 000 kg), on 17 October 2012, to mixed berry producer IT#22.

IT#22 mixed blackberries with other berries to make:

- Lot #5 (class 2C, production date 15 January 2013), consumed by three cases.
- Lot #4 (class 2A, production date 4 January 2013), consumed by two cases.

Freezing processor BG#8 also supplied raspberries (14 500 kg) to IT#22, on 14 August 2012, for:

- Lot #16 (class 2B, production date 10 October 2012), consumed by two cases.

- **Direct contamination** of lots: the blackberries and the raspberries were mixed with other berries to make seven lots. These were consumed by 15 cases.
- If we assume **cross-contamination** at the packager level, another two lots (lot #8, class 2C, and lot #9, class 2C) have been produced by IT#22 (production date 10 May 2013 and 17 May 2013, respectively).

Part B: Freezing processor BG#8 supplied the packager IT#1214 with raspberries (12 430 kg) on 18 October 2012. These were mixed with other berries to make the following lots:

- Lot #2 (class 2A, production date 8 July 2013), consumed by 10 cases.
- Lot #20 (class 2B, production date 9 July 2013), consumed by nine cases.
  - **Direct contamination** of lots: the raspberries were mixed with other berries to make two lots. These were consumed by 19 cases.

Conclusion on this "hotspot"

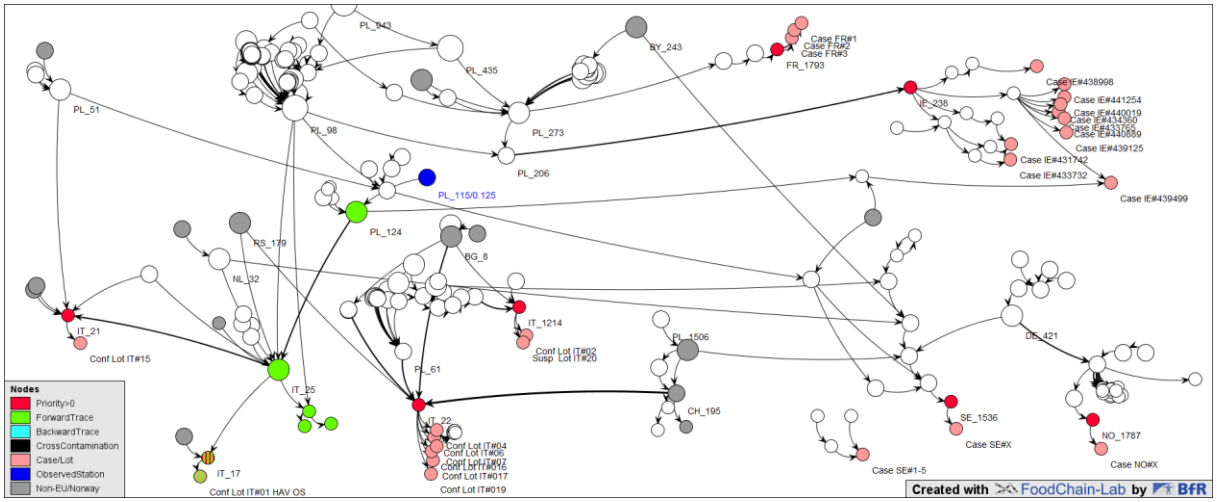
This "hotspot", BG#8, explains contamination arriving at two packagers and direct contamination of nine lots (five of class 2A and four of class 2B) consumed by 34 cases. Assuming cross-contamination at IT#22, three additional lots (two lots of class 2A and one lot of class 2B) and one more case could be explained. However, as two different types of berries were involved, a cross-contamination mechanism should be assumed at the BG#8 level.

Globally this story might explain

- 2 packagers out of 7;
- 12 lots out of 19 lots traced:
  - 0 lots of class 1 out of 1
  - 4 lots of class 2A out of 5
  - 3 lots of class 2C out of 8
  - 5 lots of class 2B out of 5
  - 34 cases.

This story does not explain the other five packagers (IT#17, IT#19, IT#21, IT#236 and IT#234) and does not explain seven lots, including the class 1 lot.

B.1.4. "Hotspot" PL#115



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 42: Network visualisation of connections between identified "hotspot" PL#115 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

Freezing processor PL#115 sent lot 69/2012 as a single delivery of redcurrants (22 000 kg), on 7 May 2012, to IT#25, via PL#124.

IT#25 re-packed the redcurrants and sent part of the consignment (3 600 kg), on 30 May 2012, to the packager IT#17, and part of the same consignment (1 440 kg) to the packager IT#19 on 14 June 2012.

Part A: Packager IT#17 mixed PL#115 redcurrants with other berries to produce the class 1 lot #1 (production date 5 February 2013), which was consumed by four cases.

Part B: Packager IT#19 mixed PL#115 redcurrants with other berries to produce the class 2C lot #3 (production date 18 February 2013). No cases consumed this lot. IT#19 supplied this lot of mixed berries to wholesalers IT#28 and IT#16, and other catering wholesalers. An outbreak in a hotel indicated that berries from IT#28 had been used in the dinner.

- **Direct contamination:** the redcurrants were mixed with other berries to make two lots at two different packagers. These were consumed by four cases.
- If we assume **cross-contamination** at the IT#25 level:
  - IT#25 also provided three consignments of redcurrants (from other suppliers) to IT#21.
    - 21 000 kg on the 13 October 2012. Lot not processed at the IT#25 level.
    - 5 040 kg on the 19 April 2012 (before the delivery from PL#115 to IT#25).
    - 10 800 kg on 10 July 2012. This lot was processed at the IT#25 level and re-packed. This lot was mixed with other berries by IT#21 to produce:
      - Lot 15 (class 2A, production date 12 July 2012), consumed by one case.
  - In 2011, IT#25 also provided IT#21 with cranberries and lingonberries. In addition the redcurrants produced by PL#115were delivered to IT#25 on the 16 January 2012 .

– IT#25 also provided raspberries to IT#21 (two consignments):
  - 5 320 kg on 10 May 2013. This lot was not re-packed by IT#25.
  - 5 048 kg on 29 May 2013. This lot was not re-packed by IT#25 before it was sent to IT#21.

– IT#25 also provided IT#21 with blackberries (6 032 kg) on 11 July 2012. IT#25 processed and re-packed this lot before sending it to IT#21. IT#21 used these blackberries to produce lot #15 (class 2A).

Therefore, assuming cross-contamination at the IT#25 level, the contamination of another packager and one lot, consumed by zero cases, may be explained.

Trace-forward of the consignment of redcurrants delivered from PL#115 (16 960 kg) to IT#25: other Italian packagers were supplied between 21 June 2012 and 26 September 2012:

- IT#21 (one delivery, 22 June 2012; 3 780 kg).
- IT#234 (two deliveries, 23 July 2012 and 3 August 2012; 40 kg and 80 kg, respectively).
- Other companies (one delivery, 1 000 kg; four deliveries, 396 kg, 540 kg, 2 340 kg and 1 100 kg; one delivery, 1 440 kg).

– IT#21: if cross-contamination at the packager level is assumed, IT#21 lots #13, #14 and #15 were all produced after the PL#115 redcurrants, via IT#25, had been delivered. Therefore, a further three lots, consumed by one case, might be explained as result of a possible cross-contamination at the IT#21 level. Of these, lot #15 was produced a few weeks after the delivery of PL#115 arrived in IT#21, while lots #13 and #14 were produced after 11 and 12 months, respectively.

– Company IT#234 was the packager that received, from Romania, the contaminated blackberries of lot #11 (date of sampling 4 September 2013). However, as the blackberries had been neither processed nor further distributed, a cross-contamination hypothesis is not considered to be plausible.

Conclusion on this "hotspot"

This "hotspot", PL#115, explains direct contamination arriving at two packagers and direct contamination of two lots (one of class 1 and one of class 2C). These were consumed by four cases.

Assuming cross-contamination:

- At the IT#25 level, this scenario might explain contamination of one other packager and one other lot of class 2A.
- At the IT#21 level (via IT#25), this scenario might explain contamination of one other packager and three other class 2A lots.

Globally, this scenario might explain:

- 3 packagers out of 7;
- 5 lots out of 19 lots traced:
  - 1 lot class 1 out of 1
  - 1 lot class 2A out of 5
  - 3 lots class 2C out of 8
  - 0 lots class 2B out of 5
  - 5 cases of illness.

This "hotspot", PL#115, does not explain the other four packagers (IT#236, IT#22, IT#1214 and IT#234) or 14 lots.

Table 50: Summary of Italian "hotspots" (classes 2A and 2C are combined)

	Story 1 (RS#179)		Story2 (PL#98)		Story3 (BG#8)		Story4 (PL#115)		
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	
no. of packagers, lots and cases explained by the specific hot spot via **direct contamination**									
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**total**
Packagers	2	28,6	2	28,6	2	28,6	2	28,6	**7**
Back Traced Lots	5	26,3	2	10,5	9	47,4	2	10,5	**19**
priority 1	0	0,0	0	0,0	0	0,0	1	100,0	**1**
priority 2a	3	23,1	2	15,4	5	38,5	1	7,7	**13**
priority 2b	2	40,0	0	0,0	4	80,0	0	0,0	**5**
cases (confirmed and possible)	9	22,0	1	2,4	34	82,9	4	9,8	**41**
additional no. of packagers, lots and cases explained by the specific hot spot **via cross contamination at the packager level**									
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**total**
Packagers	NA		NA		NA		1	14,3	**7**
Back Traced Lots	3	15,8	2	10,5	3	15,8	3	15,8	**19**
priority 1	0	0,0	0	0,0	0	0,0	0	0,0	**1**
priority 2a	2	15,4	2	15,4	2	15,4	3	23,1	**13**
priority 2b	1	20,0	0	0,0	1	20,0	0	0,0	**5**
cases (confirmed and possible)	0	0,0	0	0,0	1	2,4	1	2,4	**41**
additional no. of packagers, lots and cases explained by the specific hot spot **via cross contamination at higher level**									
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**total**
Packagers	0	0,0	1	14,3	0	0,0	1	14,3	**7**
Back Traced Lots	0	0,0	1	5,3	0	0,0	1	5,3	**19**
priority 1	0	0,0	1	100,0	0	0,0	0	0,0	**1**
priority 2a	0	0,0	0	0,0	0	0,0	1	7,7	**13**
priority 2b	0	0,0	0	0,0	0	0,0	0	0,0	**5**
cases (confirmed and possible)	0	0,0	4	9,8	0	0,0	1	2,4	**41**
total no. of packagers, lots and cases explained by the specific hot spot via all the possible contaminations									
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**total**
Packagers	2	28,6	3	42,9	2	28,6	3	42,9	**7**
Back Traced Lots	8	42,1	5	26,3	12	63,2	5	26,3	**19**
priority 1	0	0,0	1	100,0	0	0,0	1	100,0	**1**
priority 2a	5	38,5	4	30,8	7	53,8	4	30,8	**13**
priority 2b	3	60,0	0	0,0	5	100,0	0	0,0	**5**
cases (confirmed and possible)	9	22,0	5	12,2	34	82,9	5	12,2	**41**
link with other countries									
frozen processor linked with ?	no		yes		no		no		
Ireland			yes						
The Netherland			no						

BG, Bulgaria; NA, not applicable; PL, Poland; RS, Serbia.
Note: deliveries are a lot of a specific frozen berry produced by a freezing processor company that was directly or indirectly (via other companies) supplied by one or more Italian packagers and was used to produce at least one of the traced frozen berries lots.

B.2. Results for Ireland

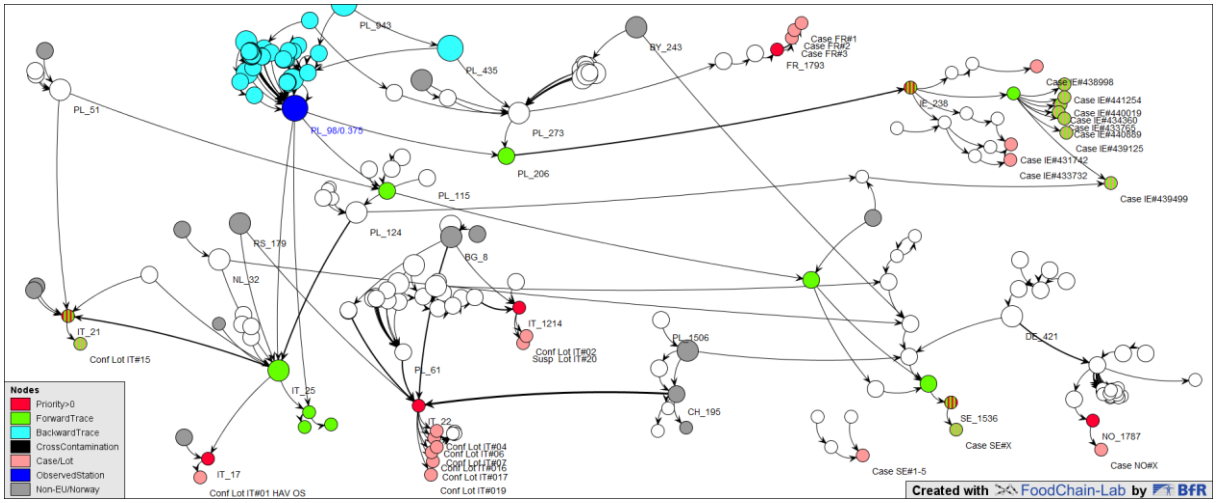
In Ireland, no confirmed lots were identified. Tracing was therefore carried out on lots which confirmed cases most likely consumed during the estimated exposure period.

Two "hotspots" were identified:

- Nine of 15 confirmed primary cases could be explained by exposure to four lots of raspberry crumb from a Polish freezing processor (PL#98) used in yoghurt and cake products.

- Six cases could be explained by exposure to (i) a batch of red fruit mix (which two cases consumed as smoothies) or (ii) two lots of mixed berries (which four cases consumed as yoghurt and cake products) from one Polish freezing processor (PL#273). These four cases are among the seven which could be explained by the raspberry crumb lots. However, it is feasible that two of the cases that reported consuming raspberry yoghurt may have actually consumed the mixed berry yoghurt from the same company and not realised or remembered. If that was the case, a total of eight Irish cases might be explained by exposure to mixed berries from PL#273, but as this is speculation it is not included in the data analysis in section 5.

B.2.1. "Hotspot" PL#98



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 43: Network visualisation of connections between identified "hotspot" PL#98 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

Raspberries harvested in 2012 were supplied to freezing processor PL#98 (most of the primary producers are small farms). This processor is in the eastern region of Poland named Lubelskie.

Freezing processor PL#98 produces whole frozen raspberries and raspberry crumb. The lots traced in relation to the Irish cases are raspberry crumb.

It should be noted that the frozen whole raspberries from PL#98 (4 410 kg), produced on 22 August 2012 and delivered to Italy on 24 August 2012, are linked to lot #03.

Four lots of raspberry crumb, linked to the Irish cases, were supplied by PL#98 to trader PL#206. They were:

- produced in January 2013; 10 400 kg delivered on 7 January 2013

- produced in February 2013; 10 400 kg delivered on 25 February 2013
- produced in May 2013; 10 400 kg delivered on 7 May 2013
- produced in May 2013; 10 400 kg delivered on 17 June 2013

These four lots of raspberry crumb were supplied by PL#206 to trader IE#238 (trader, storage).

- 10 400 kg delivered on 10 January 2013
- 10 400 kg delivered on 28 February 2013
- 10 400 kg delivered on 11 May 2013
- 10 400 kg delivered on 21 June 2013

It is assumed that the raspberry crumb lots were stored at PL#98 between production and delivery to IE#238, as PL#206 does not store raspberries.

The four lots of raspberry crumb were delivered by IE#238 to a manufacturer of dairy products, IE#1215:

- 9 600 kg delivered on 10 January 2013
- 6 600 kg delivered on 1 March 2013
- 8 300 kg delivered on 13 May 2013
- 4 800 kg delivered on 1 July 2013 and 4 800 kg delivered on 8 July 2013

The manufacturer IE#1215 used these four lots of raspberry crumb to produce three types of products identified in the food histories of the primary cases confirmed to be infected with the outbreak strain.

- raspberry yoghurt (containing raspberry crumb)
- mixed berry yoghurt (containing raspberry crumb and mixed berries)
- cheesecake containing (containing raspberry crumb and mixed berries).

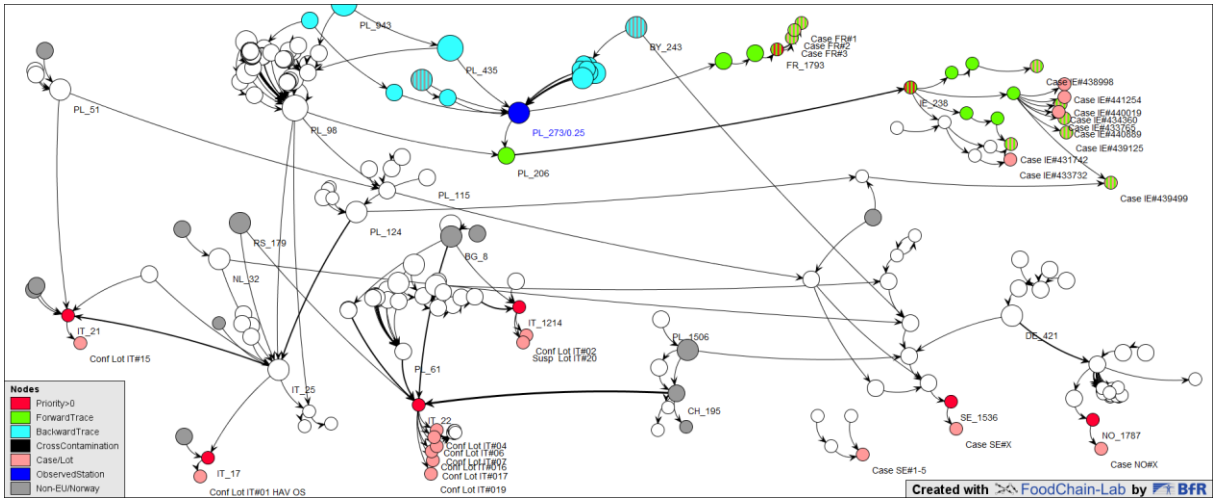
Five Irish cases (IE#434360, IE#433765, IE#439499, IE#440019 and IE#441254) consumed yoghurt containing raspberries. Two of these cases (IE#434360 and IE#439499) also consumed mixed berry yoghurt containing raspberry crumb. Two additional cases (IE#439125 and IE#440889) consumed cheesecake containing the raspberry crumb.

Conclusion on this "hotspot"

We can explain 7 of 15 confirmed primary cases by exposure to four lots of raspberry crumb from "hotspot" PL#98.

B.2.2. "Hotspot" PL#273

PL#273 is a freezing processor based in the eastern region of Poland named Lubelskie. This is the same region where "hotspot" PL#98 is found.



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 44: Network visualisation of connections between identified "hotspot" PL#273 (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

Four cases were exposed to a batch of **mixed berries** produced by PL#273, containing six types of berries harvested in 2012:

- redcurrants
- raspberries
- bilberries
- blackcurrants
- blackberries
- strawberries.

Two cases were exposed to one batch of **red berry mix** produced by PL#273, containing six types of berries harvested in 2012:

- blackcurrants
- redcurrants
- strawberries
- blackberries
- bilberries
- raspberries.

Part A: Freezing processor PL#273 supplied trader PL#206 with two lots of mixed berries which are of interest here.

- On 6 November 2012, PL#273 delivered 4 800 kg of a batch with a best before date of 10/2014.
- On 7 March 2013, PL#273 supplied 7 200 kg of batch Z-03-2013 59/03/2013, which had a best before date of 3/2015.

PL#206 delivered these lots to trader IE#238:

- 4 800 kg was delivered on 9 November 2012
- 7 200 kg was delivered on 14 March 2013.

Trader IE#238 delivered these lots to manufacturer IE#1215:

- 1 400 kg on 30 January 2013
- 3 000 kg on 1 May 2013.

The Manufacturer IE#1215 uses the mixed berries to produce two types of products identified in the food histories of the primary cases confirmed to be infected with the outbreak strain.

- mixed berry yoghurt (containing raspberry crumb and mixed berries)
- cheesecake containing (containing raspberry crumb and mixed berries).

Two cases (IE#434360 and IE#439499) consumed mixed berry yoghurt and two cases (IE#439125 and IE#440889) consumed cheesecake.

Part B.1: Freezing processor PL#273 supplied 10 400 kg of batch Z/59/2012/2, a red berry mix, to trader PL#206 on 7 January 2013, with a best before date of 3 December 2014. This batch was supplied to IE#238 on 10 January 2013.

IE#238 supplied 400 kg of this batch to frozen supplier IE#1217 on 1 May 2013. Frozen supplier IE#1217 made 11 deliveries of this batch to retailer IE#1211 between 10 May 2013 and 10 June 2013. Case IE#438998 consumed a smoothie containing this red fruit mix.

Part B.2: Freezing processor PL#273 supplied 10 400 kg of batch Z/59/2012/2, a red berry mix, to trader PL#206 on 7 January 2013, with a best before date of 3 December 2014. This batch was supplied to trader IE#238 on 10 January 2013.

Trader IE#238 supplied this batch to trader IE#1212 on four occasions of interest:

- 100 kg on 1 February 2013
- 200 kg on 8 February 2013
- 400 kg on 15 February 2013
- 100 kg on 22 February 2013.

Trader IE#1212 supplied retailer IE#1207 on five occasions of interest:

- 20 kg on 6 February 2013
- 20 kg on 20 February 2013

- 20 kg on 27 February 2013
- 20 kg on 6 March 2013
- 20 kg on 20 March 2013.

Case IE#431742 consumed a smoothie containing red berry mix from this batch.

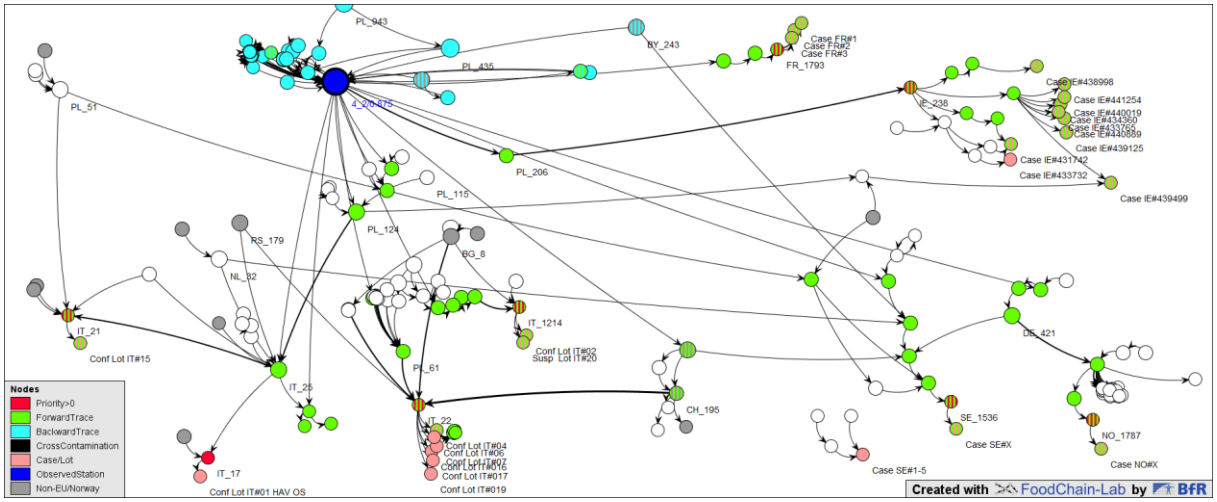
Conclusion on this "hotspot"

Mixed berries from PL#273 could explain six Irish cases:

- Four cases were exposed to mixed berries in products from IE#1215 (IE#434360, IE#439125, IE#439499 and IE#440889) and could also be explained by the raspberry crumb "Hotspot" PL#98.
- Two new cases were exposed to a batch of red fruit mix in berry smoothies (IE#438998 and IE#431742).
- It is also feasible that two cases that reported consuming raspberry yoghurt may have actually consumed the mixed berry yoghurt and not realised or remembered. If that was the case, a total of eight Irish cases might be explained by exposure to mixed berries from PL#273, but as this is speculation it is not included in the data analysis in section 5.

Combination of "hotspots" PL#98 and PL#273

Both Irish "hotspots" are located in the same Polish region, Lubelskie, which might cause dependencies between the contaminations (e.g. one common primary producer, common seasonal workers or environmental conditions for infection (e.g. flooding)). Further analysis is necessary to check possible connections between all identified "hotspots"; this explicitly includes "hotspots" outside the Lubelskie region. Therefore, the following visualisation is intended to be only an example for further investigations.



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 45: Network visualisation of connections between identified Polish cluster #4 (Lubelskie region) (blue node) and starting points (lots, cases) in the complete dataset (excluding the Netherlands)

This combined "hotspot" explains nine Irish cases in total. Further investigations are necessary to substantiate this hypothesis**.**

B.3. Results for the Netherlands

Dutch outbreak HAV cluster

The first eight confirmed primary cases with an unknown source in the Dutch HAV outbreak cluster had been infected by HAV OS between 1 July 2013 and 1 September 2013 (weeks 33–39). Information from administered food questionnaires, completed by these cases, suggested a possible connection to the consumption of fresh strawberries and not to frozen soft fruit items, as in the Italian and Irish outbreaks. In November and December 2013, two new confirmed primary HAV cases with an unknown source were identified in the Netherlands.

From compiled data, all primary confirmed cases in the Netherlands appeared to have consumed commercially available fresh strawberries (n = 10), but some also consumed raspberries (n = 5), blueberries (n = 3), blackberries (n = 2), mixed frozen red fruit (n = 1) or processed products containing soft fruits (i.e. various types of cheesecake, yoghurt and ice cream containing soft fruits (n = 4)). At least 8 out of the 10 cases reported having consumed fresh strawberries from two supermarket chains (NL#1301 and/or NL#1314/#1315). The remaining two patients consumed either strawberries bought at a local fresh market or fruit bought at various supermarkets, including NL#1301 and NL#1314/#1315.

This report describes the first analyses of trace-back data by the software FoodChain-Lab, carried out at the BfR, with the aim of identifying the outbreak vehicle and preventing further cases.

Hypothesis

The Dutch cases infected with HAV 1A with the genotype KF182323, i.e. the outbreak strain, which is related to the Italian–Irish berry outbreak, were caused by the consumption of contaminated fresh strawberries from two supermarket chains.

Results

The food chain network analyses on all four berry types, strawberries, blackberries, raspberries and blueberries, carried out by BfR (14 April 2014), revealed two "hotspots" linked to two national supermarket chains, NL#1301 and NL#1314/#1315 (Figure 46). The two "hotspots" are NL#213 and NL#1344.

B.3.1. "Hotspots" NL#213 and NL#1344

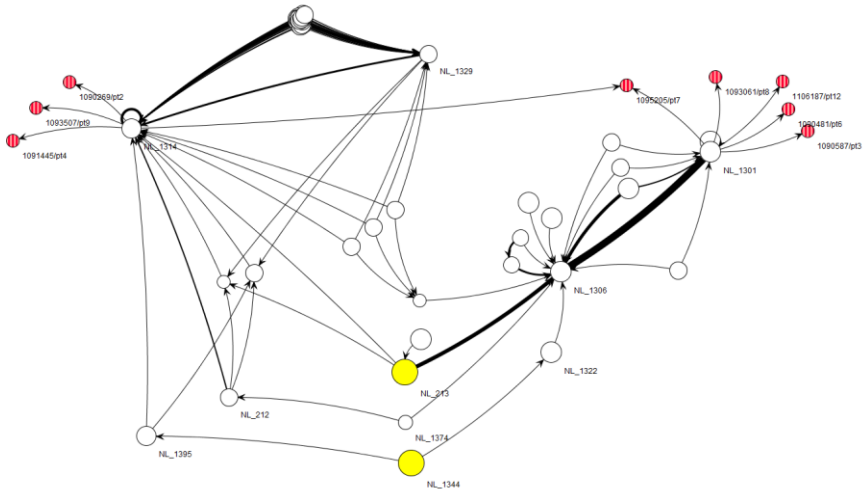


Figure 46: Network visualisation of fresh soft fruit (strawberries, blackberries, raspberries and blueberries) connected to "hotspots" NL#213 and NL#1344 (yellow nodes) and cases (red nodes)

NL#1344 is a primary producer of fresh strawberries. These strawberries end up via intermediate stations in both supermarket chains.

- At least eight patients bought fresh strawberries from one or the supermarket chains during the incubation period (NL#1301: NLpt3, 6, 7, 8 and 12; and NL#1314/#1315: NLpt2, 4 and 9). Pt1 had travelled to Italy and was, therefore, not taken into account, but had consumed strawberries in the Netherlands during the incubation period.

NL#213 is a trader of strawberries, raspberries and blueberries and supplies both supermarket chains. NL#1314/1315 received only strawberries, whereas NL#1301 received all three types of soft fruit from NL#213.

- At least eight patients bought strawberries from either supermarket chain during the incubation period (NL#1301: NLpt3, 6, 7, 8 and 12; and NL#1314/#1315: NLpt2, 4 and 9).
- Two patients consumed fresh blueberries purchased at NL#1301. One of them (NLpt12) purchased blueberries at various supermarkets, of which one was possibly NL#1301. The other patient (NLpt4) bought blueberries at NL#1314/#1315.
- Five patients purchased and consumed fresh raspberries, three of which most likely bought them from NL#1301 (NLpt7, 8 and 12) and the other two from NL#1314/#1315 (NLpt4 and 9).

NLpt1 had a travel history and was, therefore, not taken into account, but had consumed strawberries during the incubation period. The trace-back activities (within the period between 1 July 2013 and 1 September 2013) investigated exposures to fresh berries consumed by eight primary cases (NLpt2, 3, 4, 5, 6, 7, 8 and 9). Onset of illness for NLpt11 and 12 was in November and December, respectively.

When the analyses were rerun for strawberries alone, NL#213 and NL#1344 were again found to be "hotspots" for this cluster (Figure 46).

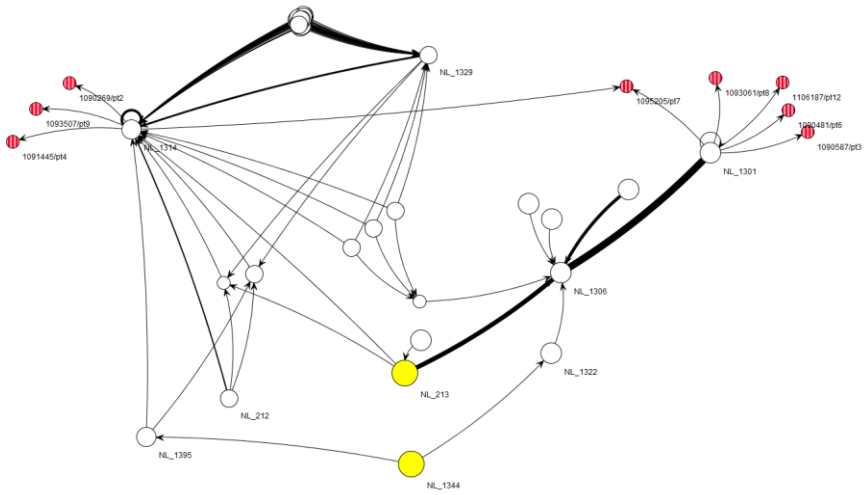


Figure 47: Network visualisation of strawberries without cross-contamination with identified "hotspots" NL#213 and NL#1344 (yellow nodes) and cases (red nodes)

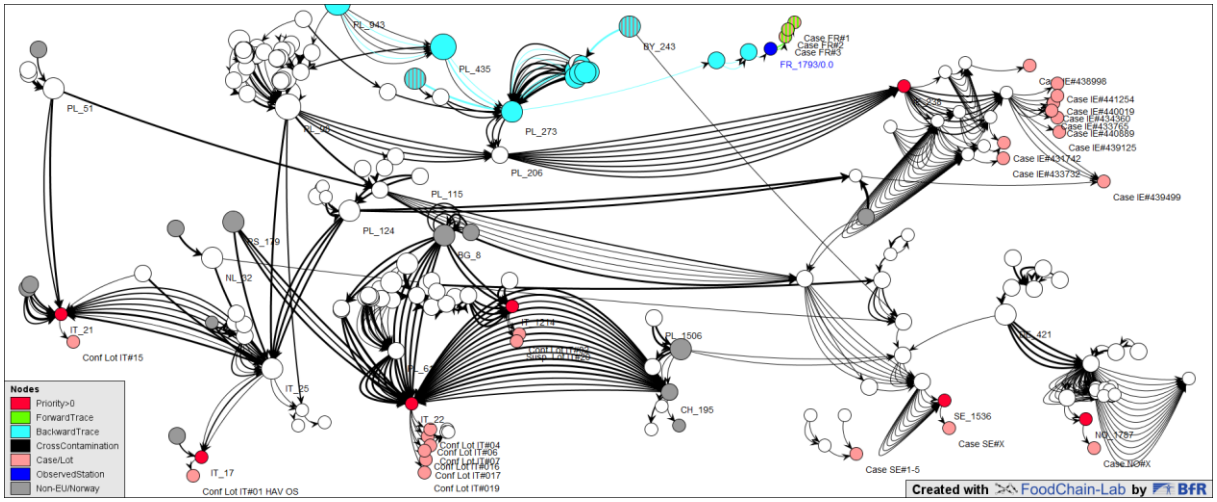
Conclusion on these "hotspots"

In summary, NL#213 and NL#1344, as "hotspots" in the analyses, explain at least 8 of the 10 primary cases through consumption of fresh strawberries. As other suppliers delivered strawberries to these two supermarket chains, it is uncertain whether the cases actually consumed the strawberries supplied by NL#213 and NL#1344.

For the other fresh berries investigated in this back-tracing, i.e. blackberries, blueberries and raspberries, no "hotspots" were identified in the Netherlands. On the other hand, we cannot exclude the possibility that the cases consumed a fresh, processed or frozen fruit product that was not recalled by them in the food questionnaires. Fresh soft fruit was widely available during the implicated trace-back period, and consumption of fresh soft fruit is assumed to have been very common during this period. Nor can processed or frozen soft fruit products be excluded as the source of infection in the Dutch cases, especially for the two cases with onset of disease in November and December 2013. However, no single processed or frozen fruit product was remembered by two or more patients, giving no lead for other items to be traced back.

Additional analyses focused on fresh fruit imported from Italy and trace-back data of frozen fruit food items with a relation to iRASFF 721 (Italy) and 722 (Ireland), which might also have been consumed in the Netherlands (trace-forward action). No connection has been established so far.

B.4. Results for France



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 48: Network visualization of back-tracing of "tarts" (all berries) from caterer FR#1793 (blue node)

As the lot of mixed berry tartlets (redcurrants, bilberries and blackberries) distributed by caterer FR#1793 and consumed by two cases was identified, backward tracing of this lot was performed. The wholesaler who supplied the caterer and the manufacturer of the tartlets were identified.

The tarts were made in France at pastry producer FR#1792 on 9 July 2013. A total of 231 200 kg of tartlets was produced (80 g/tart = 2 890 pieces). The tartlets (2 880 pieces) were received by the wholesaler, who then distributed 2 592 pieces to 10 different French départments from July 2013 to March 2014 (270 tartlets were distributed to the caterer located in Picardie in January 2014). Tartlets were supplied only to mass caterers.

The lot of mixed berries used the tarts was supplied by PL#273 (Poland) via a trader in Belgium.

There were two deliveries to FR#1792. One delivery of 630 kg arrived on 3 April 2013 and the other, of 1 260 kg, on 18 March 2014 (total = 1 890 kg).

Of the first delivery, 112 kg was used to produce lot no 0907138-3FR8 (tartlets). The remainder (153 kg) was used for the production of crumbles, which were heat treated. The second delivery was not used.

Samples of leftover frozen mixed berries were tested for HAV. Samples were HAV positive, but could not be genotyped.

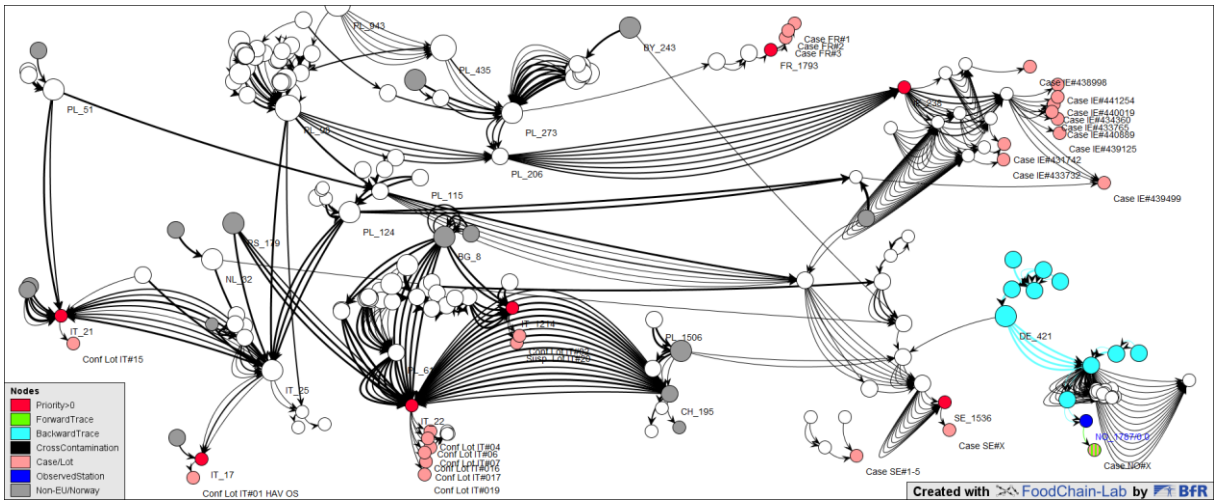
PL#273 produced lot no 170-064 (mixed berries—3 015 kg) in January 2013 (lots from October 2012 to March 2013 were sent to Ireland).

Part A: PL#273 froze 15 795 kg of redcurrants. Fresh redcurrants were supplied by 11 suppliers (5 primary producers and 6 traders) from Poland and harvested in 2012 (16 primary producers are also linked to the Irish berry matches).

Part B: 20 160 kg of frozen blackberries was supplied by Bulgarian trader BG#1807, delivered in December 2012. Blackberries were bought by freezing processor BG#1884 between 14 and 20 September 2012. These blackberries were picked in the vicinity of the towns of Berkovitsa, Varshets, Chiprovtsi, Belogradchik and Montana and the village of Georgi Damyanovo. The fruits were picked and supplied by individuals working within each area. Blackberry processing—freezing, sorting and packaging—was carried out by staff working at freezing processor BG#1884. For all manufacturing processes, from purchasing to shipping, the company keeps relevant records.

Part C: 21 600 kg of frozen bilberries/blueberries were supplied by a German trader via a Belgian trader and Polish trader. The chain ended at two companies in Belarus, BY#242 and BY#243. The berries were frozen at this point.

B.5. Results for Norway



The supply chain is shown in turquoise. The delivery chain is shown in green. Starting points are shown as red nodes, and, if in the delivery chain, in green and red stripes. Cases/lots are shown in pink and, if explained, in green and pink stripes.

Figure 49: Network visualisation of back-tracing of "berry-topped buttermilk cake" (all berries) from restaurant NO#1787 (blue node)

Two lots of "berry-topped buttermilk cake" were consumed by the Norwegian cases. Sampling was possible for only the second batch of cake. The HAV outbreak strain was detected in one of the six cakes sampled. The two lots were produced consecutively:

- lot NO#1, produced on 28 May 2013 with expiry date 28 November 2014
- lot NO#2, produced on 27 June 2013 with expiry date 27 December 2014.

The cake was produced by a German manufacturer, DE#1786. The cakes were produced with four different frozen berries:

- redcurrants
- blackberries
- raspberries
- strawberries

Only redcurrants and blackberries from the same lots were used in both cake lots.

Part A: Redcurrants (21 000 kg) arrived at German manufacturer DE#1786 on 20 February 2013 from Polish trader PL#1811 via Polish freezing processor PL#1810. Four fresh suppliers (PL#1892, PL#1908, PL#1909 and PL#1957) provided berries from 65 primary producers (2012 harvest).

Part B: Blackberries (10 080 kg) arrived at German manufacturer DE#1786 on 24 May 2013. The blackberries were supplied via German trader DE#1809 and cold store DE#1816 from Bulgarian company BG#1808, export date from Bulgaria was 31 August 2012 (BG#1808 has since ceased trading). Most of the berries were picked in the Berkovitsa area of Bulgaria.

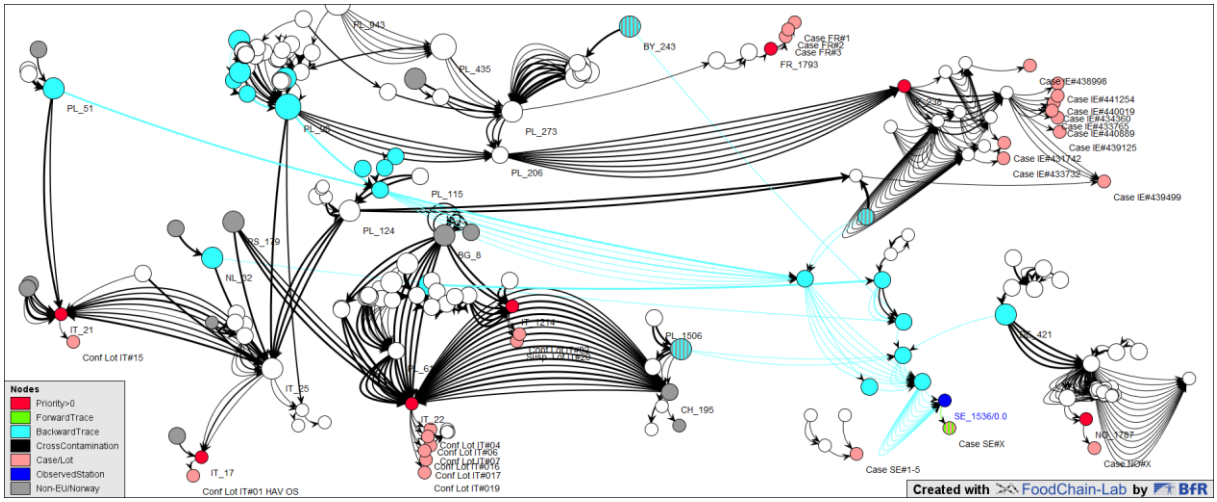
Part C: Two lots of raspberries were delivered to German manufacturer DE#1786:

- 22 000 kg, received on 11 May 2012, from German trader DE#421, originating from CL#1978 in Chile
- 22 000 kg, received on 6 June 2013, from German trader DE#1809 and cold store DE#1816 (sampled by the Netherlands), originating from company CL#1812 in Chile, sent on 4 June 2013.

Part D: Three lots of strawberries were delivered to German manufacturer DE#1786:

- 23 040 kg, received on 4 April 2013 ,from Moroccan company MA#1961
- 22 000 kg, received on 25 April 2013, from German trader DE#421, originating from Moroccan company MA#1813,
- 22 000 kg. received on 24 May 2013 from German trader DE#421, originating from Moroccan company MA#1813.

B.6. Results for Sweden



Starting points are shown as red nodes. Cases/lots are shown in pink and, if explained, in green and pink stripes. The supply chain is shown in turquoise. Trace-back end points are shown in turquoise and pink stripes.

Figure 50: Network visualisation of back-tracing of starting points from one restaurant, SE#1536, in Sweden (blue node)

Two domestic cases, case SE#1 and case SE#2, visited a resort, SE#1536, and consumed different berries for breakfast (the cases visited separately in December 2013 and January 2014). The berries consumed (mixed and purées) included:

- blackberries
- raspberries
- blackcurrants
- blueberries, and
- other berries/fruits (strawberries, passion fruit, buckthorn and pomegranate).

Part A: Mixed berries (60 kg, production date 9 October 2013) were delivered to the resort in December 2013 by French supplier FR#1537 via Swedish supplier SE#1962. The berries were mixed by French packager FR#1984. The composition of the mix and the origin of the berries are shown below (the tracing information is incomplete for the mixed berries).

- bilberries, delivered 16 September 2013, from a supplier in Belarus, BY#243
- blackberries, delivered April 2013, originating from Chile
- blackcurrants, delivered 1 July 2013, from Polish Trader PL#1989
- raspberries, delivered September 2013, from Dutch supplier NL#32, originating from Bulgaria
- redcurrants, delivered August 2013 (5 040 kg), from Polish trader PL#1989, originating from Poland and produced by Polish freezing processor PL#260 in 2013
- cherries, delivered 7 October 2013, from Austrian supplier AT#241, but originating in Serbia.

Part B: Unpasteurised raspberry purée (33 kg, production date 24 October 2014) was delivered to the resort in December 2013 by French supplier FR#1537 via Swedish supplier SE#1962. The purée was manufactured from raspberries from seven lots. The suppliers were CY#1982, DE#421 and CH#197. The raspberries originated from Serbia and Chile.

Part C: Pasteurised blackcurrant purée (6 kg, production date 15 July 2013) was delivered in December 2013 to the resort by the French supplier FR#1537. The blackcurrants supplied by FR#1979 were harvested from French primary producers in 2012.

Part D: Frozen raspberries (2 × 110 kg) were delivered in December 2013 to the resort by Swedish supplier SE#1962. The raspberries came from a Polish supplier, PL#1782, via a Swedish subsidiary, SE#1539. Polish supplier PL#1782 received frozen raspberries:

- on 31 July 2013 (20 000 kg) from Chilean frozen supplier CL#1964
- on 30 August 2013 (20 000kg) from Chilean frozen supplier CL#1964
- on 10 October 2013 (20 480 kg) from Polish freezing processor PL#98. Polish freezing processor PL#98 was identified as a "hotspot" with links to Irish cases and an Italian packager. One common Polish fresh supplier, PL#659, supplied raspberries harvested in 2012 to Ireland. However, the raspberries supplied to the Swedish resort were harvested in 2013
- on 7 November 2013 (20 480 kg) from Polish freezing processor PL#1970 (20 480 kg).

Part E: Frozen blackcurrants (15 kg) were delivered in December 2013 to the resort by Swedish supplier SE#1962. The frozen blackcurrants came from a Polish supplier, PL#1782, via a Swedish subsidiary, SE#1539. Supplier PL#1782 received fresh blackcurrants, harvested in July 2013, from two Polish primary producers and a Polish fresh supplier, PL#1973.

Part F: Frozen blackberries (2 × 20 kg) were delivered in December 2013 to the resort by Swedish supplier SE#1962 via Swedish subsidiary SE#1539 as two lots:

- on 31 May 2013 from Chilean supplier CL#1521
- on 7 June 2013 from Chilean supplier CL#1521.

Part G: Frozen strawberries (25 kg) were delivered in December 2013 to the resort by Swedish supplier SE#1962. The frozen strawberries came from a Polish supplier, PL#1782, via a Swedish subsidiary, SE#1539. The frozen strawberries (21 600 kg) were delivered by Polish freezing processor PL#51 on the 16th July 2013. The fresh strawberries, harvested in 2013, came from three Polish primary producers.

The back-tracing of food items of a third Swedish case (SE#3), with onset of disease at the end of April 2014, was not progressed until the closure of data collection in June. Therefore, this case was excluded from the analysis.

B.7. Results for Bulgaria

"Hot spot" BG#8

In 2012 BG#8 was supplied with blackberries by three outside fruit suppliers and hired 16 pickers by civil law contracts. The blackberries were processed by 12 workers at the premises of the company. All the pickers and the workers have undergone the obligatory health check. No cases of Hepatitis A were identified among them.

In 2013 there was only one outside supplier of blackberries. Most of the berries were gathered by 12 pickers hired by company BG#8 by civil law contracts. The berries were gathered in the certified region of State Forest Enterprise of Belovo. The blackberries were processed by 12 workers at the premises of the company. All the pickers and the workers have undergone the obligatory health check. No cases of Hepatitis A were identified among them.

BG#8 is the biggest supplier of frozen fruits from Bulgaria; it is registered in full compliance with the Bulgarian Food Law Act. Its activities are being monitored by the Bulgarian Food Safety Agency (BFSA). The company is listed in the official register of BFSA.

As a company evaluated as being of middle risk, it is subject to official state control and on-the-spot checks at least 4 times a year. The company has its integrated fully operational systems of self-control and control of suppliers of fresh and frozen fruits. All the workers undergo annual medical examinations, the results of which are recorded in personal health documentation. In addition, daily checks of the staff's personal hygiene status are carried out. All transportation vehicles used for fruit delivery, are equipped with special refrigerators to keep the necessary stable temperature regime in time of transportation.

Other Bulgarian companies in question:

BG#1528 associated with lot IT#12_00032, is a certified supplier of bio raspberries. Their Freezing is carried out by BG#1789 (located in Plovdiv) a subcontractor company for the supplying activities to BG#1528. BG#1528 purchased the bio raspberries in 2012 from the registered agricultural producer BG#1790, situated in the region of Samokov. Bio raspberries were also purchased from another certified producer BG#1791 situated in the region of Ihtiman. Both agricultural producers apply the European requirements for keeping the land in good environmental condition.

BG#1807 associated with LotFR#01_00009, purchased 20 160 kg of frozen blackberries from the certified in this type of production company BG#1884 located in Berkovitsa. The fruits were further sold to company PL#273 in Poland. The purchase, storage and processing of the fruits was carried out in **BG#1884**. Blackberries were purchased in the period between 14 to 20/09/2012 and were gathered in the regions of Berkovitsa, Varshets, the village of Georgi Damyanovo, Chiprovtsi, Belogradchik and Montana. Blackberries were gathered and supplied by local individuals. The processing of the blackberries –freezing, sorting and packaging was carried out by the staff of the company. Relevant records are kept for all the processing activities, from purchasing to expedition of the fruits. The company has established good production and hygiene practices. Records are kept for incoming control. According to the official information of the Region Health Inspection of Montana, during the period between January 2012 and May 2013 there have been no registered cases of contagious diseases, including hepatitis A. This conclusion refers to the local pickers and the workers hired by BG#1884.

BG#1505 has been presented a register of the pickers. Blackberries were gathered during the period between 10/08-03/09/2012 in the regions of Belogradchik, villages of Smolyanovtsi and Giurgich, Vidin region and Montana region. Nine local pickers were hired by BG#1505: All abovementioned persons are listed in the records of incoming control of the company. The company has established good production and hygiene practices.

BG#1509 - During on-the-spot check the inspectors found that the building in the village Goritsa, region Smolyan, in which the company BG#1509 was situated, was already demolished and the company had ceased its activities.

BG#1502 has bought the fruits from the company BG#1509 located in Devin. The Investigation of the Competent Authority found that the above mentioned company ceased its activities and the building in which the fruits were stored, was already demolished.

BG#1504 (Stara Zagora region) - The blackberries were gathered in the region of Pavel Banya /in the central part of Bulgaria/ during the period between 09/08 - 28/08/2011. The company is registered as an agricultural producer and has established good production and hygiene practices. As of 18/08/2011 BG#1504 has concluded agreements for processing and packaging of blackberries with BG#2248 Plovdiv region. The service includes reception, freezing, laser sorting and temporary storage of the production. All necessary hygiene requirements are applied.

BG#1260 located in Katunitza - The company has purchased the berries from BG#1504

BG#1508- Production based in the Pazardzik district. The company is registered in compliance with the Bulgaria Food Law Act and has established self-control systems. The raspberries were gathered by workers hired on civil law contract basis on the own raspberry fields of the company, which applies the European requirements for keeping the land in good agricultural and environmental condition. The result of the check carried out in the Regional Health Inspection of Pazardzik showed no registered cases of Hepatitis A among the workers of BG#1508 during the period of 2011 to 2012.

BG#1222 has declared that part of the raw material for the frozen berry mix of raspberries and blackberries was purchased from **BG#150**3 in Svoge. All temperature regimes for fruit processing were applied and controlled, according to the HACCP plan 1 – Production of frozen fruits. The final product was properly stored at temperatures between -18 -20° C until the moment of its expedition. This is obvious from the available records in the Register of Refrigerator Temperatures for the period 13/08-20/08/2013. The company has presented health check-lists for the period in question, proving that their staff were in perfect health, wearing clean clothing and with valid personal health status documents. The company uses all necessary washing, cleaning and disinfection materials and agents for preserving the hygiene of the production environment and staff. Inspectors were shown protocols from the certified laboratory for the results of the analysis carried out for cleanliness of contact surfaces and water used in the production process. No deviation of indicators, established according to the Technological documentation could be stated.

BG#1503 located in Svoge was active as a business operator only three months in 2012. The handover desk for the fruits had a temporary three-month registration in compliance with the requirements of the Food Law Act. The expiry date of its certificate is 12/09/2012. As a business operator it had the necessary buildings with storehouses, 4 refrigerators, and sanitary premises with running drinking water. The management of the company has declared that in 2012 blackberries were purchased from individual sellers.

Appendix C. Production and trade data

Table 51: Production of selected fresh berries in the EU in 2012 in metric tons (source: Eurostat: apro_cpp_crop/C2260, C2272, C2278, C2275, C2281, C2290)

Country	Strawberries	Blackcurrants	Raspberries	Redcurrants	Gooseberries	Other berries [(a)]
Production of fresh berries in 2012 (tonnes)						
Belgium	40 500	0	1 200	0	NR	NR
Bulgaria	4 800	0	4 900	0	NR	0
Czech Republic	1 800	2 500	0	1 800	NR	0
Denmark	6 700	10 200	100	NR	NR	NR
Germany	155 800	6 300	4 700	NR	NR	NR
Estonia	1 100	0	0	0	0	0
Ireland	7 600	NR	NR	NR	NR	NR
Greece	42 900	0	0	NR	NR	NR
Spain	290 800	0	12 900	NR	NR	NR
France	53 100	8 200	3 200	NR	NR	NR
Croatia	1 300	0	0	0	0	NR
Italy	40 900	NR	NR	NR	NR	NR
Cyprus	1 400	NR	NR	NR	NR	NR
Latvia	900	500	100	NR	NR	0
Lithuania	3 500	3 100	1 900	500	0	800
Luxembourg	0	NR	0	NR	NR	NR
Hungary	4 100	1 700	1 500	NR	NR	NR
Malta	900	NR	NR	NR	NR	NR
Netherlands	50 000	0	0	NR	NR	NR
Austria	9 900	1 200	800	0	0	900
Poland	170 800	149 100	127 100	45 900	16 800	64 600
Portugal	14 400	100	3 100	NR	NR	3 900
Romania	15 600	0	0	0	0	0
Slovenia	1 500	0	0	NR	NR	NR
Slovakia	700	0	0	0	0	0
Finland	14 200	1 300	700	NR	0	0
Sweden	16 300	0	0	0	0	0
UK	96 000	10 000	14 000	NR	NR	NR
Sum (reported values)	1 047 500	194 200	176 200	48 200	16 800	70 200
Norway	NR	NR	NR	NR	NR	NR
Switzerland	NR	NR	NR	NR	NR	NR
Serbia	NR	0	NR	0	0	NR
Turkey	352 000	NR	4 000	NR	NR	NR

(a): Including blackberries.
NR, not reported.

C.1. Redcurrant production and trade (fresh or processed)

Table 52: Fresh redcurrant production in metric tons (source: Eurostat: apro_cpp_crop/C2275)

EU Member State	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	45 400	88	45 900	95	47 100	97
Czech Republic	2 800	5	1 800	4		
Denmark	3 300	6				
Lithuania			500	1		
Austria	0	0	0	0	1 700	3
Belgium	0	0	0	0	0	0
Bulgaria	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Finland	0	0				
Croatia	0	0	0	0	0	0
Portugal	0	0				
Romania	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
Total	**51 500**	**100**	**48 200**	**100**	**48 800**	**100**

Table 53: Fresh or processed redcurrant trade balance in the EU in metric tons (source: Eurostat: CN 8103030/8112051)

Fresh or processed redcurrant trade balance (export–import) in the EU: positive numbers = excess of export; negative numbers = excess of import						
EU Member State	**Fresh**			**Processed, unsweetened**		
	2011[(a)]	**2012**	**2013**	**2011**	**2012**	**2013**
	Tonnes					
Poland		580.7	412.7	12 735	12 841.4	13 111.2
Denmark		54.9	719.1	1 124	702.9	1 341.2
Hungary		11.3	–388.8	1 646	699.5	748.2
Netherlands		1 133.9	1 058.8	369.7	469.7	501.4
Czech Republic		1 255.5	488.2	190.3	147.6	156.8
Greece		84.8	251.9	–9.0	–36.4	129.4
Lithuania		–22.3	–48.5	111.1	38.9	69.2
Portugal		1.9	–130.1	–8.2	–4.5	38.8
Spain		34.3	148.1	–71.0	–29.9	21.7
Slovakia		–7.4	–17.8		7.1	0.5
Cyprus						
Croatia						
Malta		–0.5				
Romania		1.6	–39.4			
Slovenia		–2.2	–1.7	–0.9		
Ireland		–5.3	25.3		–55.1	
Luxembourg		–18.7	–18.2	–2.9	–0.9	–1.0
Latvia		–1.4	–1.0	–17.8	–13.9	–17.1
Estonia			6.4	–37.7	1.2	–21.0
Bulgaria				6.3	–8.6	–55.3
Finland		–4.3				–105.2
Austria		–56.4	–169.6	–269.4	–446.3	–496.9
Sweden		–30.2	–20.9	–272.7	–409.9	–565.4
Belgium		–170.9	–165.8	–1595.3	–779.4	–833.5
UK		–90.2	–44.5	–627.9	–644.1	–1 143.8
Italy		59.1	544.1	–1052.4	–987.8	–1 267.0
France		–373.3	–391.1	–676.3	–1 158.5	–1 514.2
Germany		–2 007.2	–1 104.2	–9 312.8	–8 276.6	–7 590.3

(a): No data available

Table 54: Fresh or processed redcurrant import into the EU in metric tons (source: Eurostat: CN 8103030/8112051)

Exporting country	Fresh					Processed, unsweetened					
	2011[(a)]	2012		2013		2011		2012		2013	
		Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Chile		244	100	169	98						
Serbia		0	0			44	92	51	59	120	90
Ukraine						0	0	30	35		
Ecuador										9	7
Macedonia								5	6		
Turkey										5	4
Switzerland						3	6				
Norway				3	2						
Dominica		0	0			1	2	0	0	0	0
Bosnia and Herzegovina						0	0				
Russia				0	0					0	0
Switzerland						3	6				
Total		**244**	**100**	**172**	**100**	**48**	**100**	**86**	**100**	**134**	**100**

(a): No data available

C.2. Raspberry production and trade (fresh or processed)

Table 55: Fresh raspberry production in metric tons (source: Eurostat: apro_cpp_crop/C2278)

Country	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	118 000	71	127 100	72	121 500	71
UK	16 000	10	14 000	8	14 000	8
Spain	9 600	6	12 900	7	11 700	7
Bulgaria	7 600	5	4 900	3	5 400	3
Germany	4 800	3	4 700	3	5 100	3
France	3 700	2	3 200	2	4 000	2
Portugal	0	0	3 100	2	2 700	2
Lithuania	1 300	1	1 900	1	2 000	1
Hungary	2 100	1	1 500	1	1 800	1
Italy	700	0			1 100	1
Belgium	900	1	1 200	1	1 000	1
Austria	1 200	1	800	0	900	1
Finland	700	0	700	0	700	0
Croatia	0	0	0	0	200	0
Denmark	100	0	100	0	100	0
Latvia	400	0	100	0	100	0
Czech Republic	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Ireland	0	0				
Greece	0	0	0	0		
Luxembourg	0	0	0	0	0	0
Netherlands	0	0	0	0	0	0
Romania	0	0	0	0	0	0
Slovenia	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
Iceland	0	0	0	0	0	0
Total	**167 100**	**100**	**176 200**	**100**	**172 300**	**100**

Table 56: Fresh or processed raspberry trade balance in the EU in metric tons (source: Eurostat: CN 8102010/8112031)

EU Member State	Fresh or processed raspberry trade balance (export – import) in the EU: positive numbers = excess of export; negative numbers = excess of import					
	Fresh			Processed, unsweetened		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Poland	18 441.9	13 931.3	13 360.3	32 934.0	54 631.1	60 416.0
Bulgaria	90.8	108.0	61.3	1 943.9	2 924.4	2 707.4
Cyprus	19.7	–1.1	22.7	1 964.4	1 951.1	2 287.3
Netherlands	–1 743.9	1 634.3	6 288.4	76.3	1 655.6	567.9
Spain	16 354.1	16 803.4	18 106.9	–623.6	–292.7	490.8
Romania	–2.7	–6.0	77.7	109.6	256.2	23.9
Malta	–1.7	–17.2				
Luxembourg	–129.0	–141.7	–128.8	–42.2	–46.6	–12.0
Lithuania	21.0	–20.5	–50.7	–124.8	–20.3	–21.6
Slovakia	–75.5	–137.2	–140.3	–118.5	–166.9	–85.3
Greece	26.6	9.0	–2.8	–148.4	–78.1	–133.7
Portugal	341.8	477.6	841.4	–47.6	–198.3	–192.9
Ireland	–557.6	–465.3	–549.9	–176.0	–302.2	–250.0
Croatia	–2.0	–42.6	–3.8	–170.4	–130.0	–260.2
Estonia	–42.2	–12.8	–10.6	–363.5	–234.9	–353.7
Latvia	–18.4	–15.7	–35.5	–336.8	–431.0	–374.0
Slovenia	–32.7	–34.9	–29.3	–166.9	–222.9	–460.2
Hungary	367.3	140.7	62.3	–108.7	–288.7	–462.5
Czech Republic	–103.5	–41.9	–206.6	–969.3	–1 022.4	–1 397.8
Finland	–139.4	–185.1	–209.9	–2 921.4	–2 543.0	–2 395.9
Denmark	–351.0	–108.1	152.0	–3 724.5	–3 018.3	–2 481.9
Italy	–2 005.7	–977.8	–1 069.2	–4 320.4	–4 403.5	–4 722.7
Sweden	–339.8	–516.3	–821.7	–2 738.7	–4 776.4	–5 492.9
Austria	–5 408.7	–4 177.9	–4 442.9	–10 518.5	–8 638.4	–6 617.0
Belgium	–2 012.7	–585.0	–3 325.9	–6 413.0	–4 264.3	–8 255.6
UK	–8 577.1	–9 130.2	–9 754.9	–5 924.8	–8 504.6	–11 026.7
France	–6 594.7	–6 793.4	–6 408.9	–30 819.9	–31 704.9	–32 987.0
Germany	–14 401.0	–12 108.8	–14 216.0	–52 765.6	–54 046.9	–52 078.2

Table 57: Fresh or processed raspberry import into the EU in metric tons (source: Eurostat: CN 8102010/8112031)

Exporting country	Fresh						Processed, unsweetened					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Serbia	3 883	41	389	6	471	6	67 686	71	59 570	78	55 666	72
Chile	12	0	21	0	2	0	21 628	23	11 382	15	12 589	16
China							2 696	3	2 392	3	5 014	7
Morocco	1 989	21	2 361	36	3 375	46	298	0	251	0	331	0
Bosnia and Herzegovina	21	0	77	1	121	2	2 586	3	2 525	3	2 180	3
Mexico	968	10	1 520	23	1 602	22	20	0	6	0	30	0
USA	741	8	1 150	18	852	12	2	0	49	0	136	0
South Africa	655	7	805	12	684	9					0	0
Turkey							119	0	151	0	723	1
Macedonia	952	10			1	0	14	0	20	0		
Norway	31	0	46	1	61	1	161	0	154	0	169	0
Tanzania	87	1	105	2	96	1						
Ukraine					31	0	2	0	10	0	203	0
Kenya	5	0	6	0	40	1						
Canada									49	0		
Kosovo			0	0			21	0			10	0
Switzerland	1	0	3	0	5	0	4	0	11	0	0	0
Côte d'Ivoire											24	0
Tunisia	10	0										
Montenegro											8	0
Guatemala			2	0	3	0						
Egypt			1	0							3	0
Thailand											4	0
Zimbabwe			4	0								
Ethiopia			2	0								
Ghana	2	0										
Israel	1	0	1	0								
Japan							2	0				
Russia	0	0			0	0					1	0
Colombia											0	0
Indonesia	0	0										
Kazakhstan									0	0		
Total	**9 358**	**100**	**6 493**	**100**	**7 344**	**100**	**95 239**	**100**	**76 570**	**100**	**77 091**	**100**

Table 58: Frozen raspberry imports from extra-EU in metric tons

Exporting country	2005	2009	2010	2011	2012
Morocco	2	567	241	298	251
China	279	1 713	3 636	2 701	2 334
Egypt	NR	NR	0	NR	NR
Turkey	74	183	105	119	151
Peru	NR	NR	NR	NR	NR
Chile	13 523	12 913	19 485	21 628	11 382
Serbia	28 754	54 225	57 036	67 734	57 897
Mexico	NR	NR	NR	20	6
Norway	96	130	155	161	122
Tunisia	NR	NR	NR	NR	NR
Argentina	52	14	NR	NR	NR
Canada	23	NR	NR	NR	49
USA	45	106	153	2	49
Ukraine	141	4	17	2	10
FYROM [(a)]	82	1	4	14	20
Switzerland	19	38	9	4	11
Bosnia and Herzegovina	1 429	1 678	2 143	2 633	2 575
Other	1	101	68	2	0
Total	**44 518**	**71 673**	**83 052**	**95 317**	**74 856**

(a): Former Yugoslav Republic of Macedonia.
NR, not reported at the time of production of the table.

C.3. Blackberry production and trade (fresh or processed)

Table 59: Fresh other berries (excluding strawberries, currants, raspberries and gooseberries) production in metric tons (source: Eurostat: apro_cpp_crop/C2290)

Country	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Poland	57 500	93	64 600	92	67 900	93
Portugal	3 500	6	3 900	6	4 000	5
Austria	900	1	900	1	900	1
Lithuania			800	1		
Romania	0	0	0	0	200	0
Denmark	100	0				
Bulgaria	0	0	0	0	0	0
Czech Republic	0	0	0	0	0	0
Estonia	0	0	0	0	0	0
Ireland	0	0				
Latvia	0	0	0	0	0	0
Slovakia	0	0	0	0	0	0
Finland	0	0	0	0	0	0
Sweden	0	0	0	0	0	0
Total	**62 000**	**100**	**70 200**	**100**	**73 000**	**100**

Table 60: Fresh or processed blackberry trade balance in the EU in metric tons (source: Eurostat: CN 8102090/8112059)

EU Member State	Fresh or processed blackberry trade balance (export – import) in the EU: positive numbers = excess of export; negative numbers = excess of import					
	Fresh [a]			Processed, unsweetened [b]		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Bulgaria	–18.8	–683.2	–29.8	831.3	885.4	1 359.5
Cyprus	–24.1	–7.8	–2.2	233.7	583.5	211.9
Romania	–21.8	–7.1	–49.2	108.1	287.8	197.3
Luxembourg	–22.8	–20.4	–22.2	–1.6		39.0
Slovakia	–35.3	–32.8	–47.3	0.9	13.4	9.8
Estonia	16.0	13.3	0.4	–10.8	4.5	4.4
Malta		–5.3				
Finland	–30.4	–35.1	–15.8	–28.2	–40.8	
Latvia	–2.5	–7.4	–21.6	–33.8	–134.5	–25.8
Lithuania	2.0	–22.5	–454.3	94.6	30.6	–28.6
Sweden	–36.3	47.4	–21.1	16.5	–224.2	–31.4
Croatia		–8.1		–74.2	–50.0	–39.1
Ireland	–542.5	–650.7	–769.6		–76.6	–71.3
Spain	3 389.0	4 222.5	5 551.8	–417.9	–272.5	–202.6
Slovenia	–18.5	74.1	12.6	–43.9	–62.8	–294.4
Czech Republic	–18.7	25.4	–1.7	–229.4	–94.6	–305.5
Hungary	–6.6	–15.9	–18.2	–757.7	10.0	–317.7
Denmark	–126.4	–72.0	–135.8	–544.1	–400.6	–322.0
Greece	–30.7	171.5	–86.3	–145.5		–365.4
Netherlands	1 153.7	2 326.7	2 630.4	–2 127.5	–2 362.6	–397.9
Portugal	–48.2	–42.9	–39.2	–140.6	–312.6	–432.4
Belgium	242.2	328.1	136.7	–1 571.2	–615.8	–1 238.8
Poland	–119.4	320.8	72.2	–1 133.6	–314.9	–1 573.3
Austria	–1 195.3	–740.2	–2 217.7	–3 065.2	–1 924.1	–1 950.1
UK	–3 121.8	–4 228.1	–4 280.7	–2 562.6	–2 758.7	–2 243.7
Italy	–1 712.6	–3 548.8	–3 308.5	–2 185.5	–2 988.9	–2 779.4
France	–661.8	–510.3	–711.6	–3 368.5	–4 090.1	–4 301.4
Germany	–1 789.2	–1 385.6	–1 587.6	–11 235.2	–12 989.5	–8 981.3

(a): Fresh berries: blackberries, mulberries and loganberries (CN 8102090).
(b): Processed berries: blackberries, mulberries (CN 8112059).

Table 61: Fresh or processed blackberry import into the EU in metric tons (source: Eurostat: CN 8102090/8112059)

Exporting country	Fresh [a]						Processed, unsweetened [b]					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Serbia	1 485	28	1 503	29	2 505	37	22 542	74	19 269	64	15 760	62
Chile	16	0			6	0	5 031	17	6 387	21	6 760	27
Mexico	2 950	55	2 749	52	2 856	42	33	0	83	0	390	2
China	14	0	17	0	18	0	1 548	5	2 531	8	1 126	4
Guatemala	263	5	670	13	792	12	19	0	43	0	56	0
Bosnia and Herzegovina	0	0	0	0	1	0	513	2	478	2	650	3
Ukraine							179	1	764	3	499	2
Macedonia	489	9	70	1	100	1	116	0	137	0	38	0
Turkey	2	0			1	0	73	0	335	1	140	1
Kosovo			74	1	252	4						
USA	32	1	89	2	112	2						
Colombia	0	0					58	0	44	0	26	0
Montenegro			24	0	75	1						
Georgia							60	0				
Ecuador							31	0	12	0	10	0
Morocco	21	0			9	0	23	0				
Peru									24	0	25	0
South Africa	16	0	18	0	11	0						
Uruguay	28	1	3	0								
Russia	0	0			0	0	6	0	20	0	1	0
Brazil	10	0	4	0			4	0	5	0		
India							22	0				
Barbados			8	0								
Mauritius			8	0								
Armenia									5	0		
Jamaica			4	0								
Norway					4	0					0	0
Argentina	1	0	1	0	1	0						
Kenya	0	0	1	0	1	0						
Bangladesh							1	0				
Egypt	1	0	0	0								
New Zealand					1	0						
Pakistan			1	0								
Suriname	0	0	1	0								
Tajikistan							1	0				
Uzbekistan			1	0								
Afghanistan					0	0						
Switzerland	0	0										
Costa Rica									0	0		
Hong Kong									0	0		
Israel			0	0								
Iran			0	0	0	0						
Malaysia			0	0								
Thailand	0	0	0	0								
Tanzania	0	0										
Total	**5 328**	**100**	**5 246**	**100**	**6 745**	**100**	**30 260**	**100**	**30 137**	**100**	**25 481**	**100**

(a): Fresh berries: blackberries, mulberries and loganberries (CN 8102090).
(b): Processed berries: blackberries, mulberries (CN 8112059).

C.4. Blueberry/bilberry production and trade (fresh or processed)

Table 62: Fresh or processed blueberry/bilberry trade balance in the EU in metric tons (source: Eurostat: CN 8104030/8104050/8104090/8119050/8119070)

EU Member State	Fresh or processed blueberry/bilberry trade balance (export – import) in the EU: positive numbers = excess of export; negative numbers = excess of import					
	Fresh [a]			Processed, unsweetened [b]		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Sweden	353.8	1 043.4	1 160.1	2 375.9	4 366.4	6 346.8
Latvia	41.0	506.7	212.6	2 896.9	3 819.9	3 542.2
Romania	372.5	346.5	595.8	2 425.6	2 620.0	3 118.7
Estonia	–26.4	–22.4	321.2	–209.0	–855.4	873.3
Cyprus		36.1		354.0	946.0	517.6
Finland	–135.6	–530.4	–1 269.3	–1 038.3	–1 575.2	435.5
Netherlands	–9 839.3	–133.6	1 520.8	–1 265.0	–1 117.4	166.6
Spain	12 210.9	11 848.7	13 684.0	248.1	–102.1	23.3
Greece	–40.7	–142.7	–20.4	31.6	42.9	19.8
Malta	–1.9	–3.8				
Luxembourg	–45.0	–52.6	–57.7	–8.5	10.9	–12.3
Croatia	–21.1	–36.1	–32.2	–44.0	–77.7	–76.9
Slovakia	–41.1	48.8	–44.3	–25.4	–69.2	–122.5
Portugal	–166.6	–887.5	–416.1	–159.1	–169.6	–197.2
Bulgaria	–59.5	–6.4	–82.1	242.3	–386.0	–201.4
Lithuania	–415.1	–606.8	–626.5	–171.0	–670.2	–241.6
Slovenia	–82.6	–55.0	–62.0	–192.8	–271.3	–270.2
Ireland	–387.3	–172.4	–167.7		–284.9	–419.5
Hungary	10.1	–4.3	–30.6	–56.3	–295.5	–675.0
Czech Republic	–194.3	–209.4	–157.3	–953.8	–891.2	–834.0
Denmark	–1 381.6	–1 925.6	–1 819.4	–912.7	–1 408.9	–1 349.1
Austria	–2 468.4	–939.8	–3 721.6	–3 911.8	–2 618.5	–2 095.1
Poland	1 973.0	3 501.0	4 578.8	–3 347.1	–1 827.1	–2 451.3
UK	–19 219.1	–23 306.2	–23 900.4	–4 530.0	–3 549.7	–3 567.6
Belgium	311.8	359.9	–393.8	–4 526.1	–4 281.3	–4 856.3
Italy	–774.9	–1 084.0	–2 443.8	–9 466.5	–9 219.2	–8 697.8
France	–898.4	–1 480.0	–164.7	–5 091.0	–6 777.8	–8 750.5
Germany	2 349.7	–5 283.5	–6 679.1	–20 112.3	–20 368.9	–20 821.0

(a): Fresh berries: species *Vaccinium myrtillus*, *V. macrocarpum*, *V. corymbosum* and others (CN 8104030/8104050/8104090).
(b): Processed berries: *Vaccinium myrtillus*, *V. myrtilloides* and *V. angustifolium* (CN 8119050/8119070).

Table 63: Fresh or processed blueberry/bilberry import into the EU in metric tons (source: Eurostat: CN 8104030/8104050/8104090/8119050/8119070)

Exporting country	Fresh [a]						Processed, unsweetened [b]					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Canada	630	3	359	1	634	2	24 061	40	23 877	40	21 066	37
Russia	1 102	5	411	2	268	1	14 768	25	14 941	25	16 969	30
Chile	8 897	40	11 894	47	13 611	49	2 793	5	3 146	5	4 117	7
Ukraine	615	3	774	3	403	1	13 174	22	12 837	22	11 455	20
Argentina	4 851	22	4 476	18	3 943	14	753	1	874	1	631	1
USA	1 159	5	1 248	5	1 368	5	2 658	4	1 831	3	1 503	3
Morocco	1 866	8	2 928	12	3 415	12	123	0	376	1	112	0
Uruguay	1 433	6	1 265	5	1 043	4			220	0	63	0
South Africa	983	4	1 180	5	1 377	5						
Serbia	71	0	204	1	257	1	1026	2	688	1	1 052	2
Kosovo	184	1	85	0	170	1	57	0			161	0
Montenegro	235	1	150	1	172	1	55	0			43	0
Bosnia and Herzegovina	56	0	28	0	65	0	315	1	38	0	112	0
Peru	4	0	41	0	516	2						
Macedonia	94	0	48	0	210	1	91	0	25	0	76	0
China	0	0	0	0	13	0	108	0	100	0	71	0
Norway	3	0	51	0	27	0	66	0	33	0	13	0
Mexico	4	0	75	0	63	0						
Georgia							88	0	35	0		
Australia	107	0			2	0						
Turkey	0	0					92	0			1	0
Egypt	1	0			16	0			23	0	48	0
Antigua and Barbuda									24	0	24	0
South Korea									14	0		
New Zealand	10	0	4	0								
Uganda	9	0	0	0	3	0						
United Arab Emirates					10	0						
Brazil	5	0	1	0	2	0						
Ecuador			7	0								
Congo									4	0		
Colombia	0	0	4	0	0	0						
Zimbabwe			1	0	1	0						
Albania					1	0						
Guatemala					1	0						
Tunisia					1	0						
Switzerland	0	0			0	0						
Cameroon			0	0								
Indonesia			0	0								
Israel			0	0								
India			0	0	0	0						
Iran					0	0						
Total	**22 319**	**100**	**25 234**	**100**	**27 592**	**100**	**60 228**	**100**	**59 086**	**100**	**57 517**	**100**

(a): Fresh berries: species *Vaccinium myrtillus*, *V. macrocarpum*, *V. corymbosum* and others (CN 8104030/8104050/8104090).
(b): Processed berries: *Vaccinium myrtillus*, *V. myrtilloides* and *V. angustifolium* (CN 8119050/8119070).

C.5. Strawberry production and trade (fresh or processed)

Table 64: Fresh strawberry production in metric tons (source: Eurostat: apro_cpp_crop/C2260)

EU Member State	2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%
Spain	262 700	26	290 800	28	312 500	28
Poland	175 100	17	170 800	16	165 900	15
Germany	154 400	15	155 800	15	149 700	14
Italy	46 000	4	40 900	4	120 200	11
UK	102 000	10	96 000	9	94 000	9
France	49 300	5	53 100	5	55 700	5
Netherlands	47 000	5	50 000	5	51 000	5
Greece	43 700	4	42 900	4		
Belgium	37 500	4	40 500	4	35 900	3
Romania	18 800	2	15 600	1	22 000	2
Austria	14 200	1	9 900	1	14 900	1
Sweden	12 900	1	16 300	2	13 800	1
Finland	12 800	1	14 200	1	13 200	1
Portugal	12 700	1	14 400	1	12 800	1
Ireland	5 400	1	7 600	1	7 900	1
Denmark	7 100	1	6 700	1	6 200	1
Hungary	4 300	0	4 100	0	4 600	0
Bulgaria	7 000	1	4 800	0	3 400	0
Croatia	2 000	0	1 300	0	2 900	0
Lithuania	2 600	0	3 500	0	2 800	0
Slovakia	800	0	700	0	2 800	0
Czech Republic	2200	0	1 800	0	2 200	0
Cyprus	1 200	0	1 400	0	1 600	0
Estonia	800	0	1 100	0	1 200	0
Latvia	800	0	900	0	1 100	0
Malta	800	0	900	0	700	0
Luxembourg	0	0	0	0	0	0
Slovenia	2 000	0	1 500	0	0	0
Iceland	0	0	0	0	0	0
Total	**1 026 100**	**100**	**1 047 500**	**100**	**1 099 000**	**100**

Table 65: Fresh or processed strawberry trade balance in the EU in metric tons (source: Eurostat: CN 8101000/8110090)

EU Member State	Fresh or processed strawberry trade balance (export – import) in the EU: positive numbers = excess of export; negative numbers = excess of import					
	Fresh			Processed, unsweetened		
	2011	2012	2013	2011	2012	2013
	Tonnes					
Poland	8 443.2	45.8	–18.5	68 098.2	50 694.9	64 408.3
Spain	231 970.0	295 252.4	276 724.8	14 864.6	17 439.0	18 925.0
Bulgaria	–688.5	–1 951.8	–1 588.2	1 135.2	595.3	786.7
Cyprus	–132.6	198.0	–103.9	160.9	311.9	96.0
Malta	462.4	359.2	–2.8			
Luxembourg	–1 468.6	–1 641.1	–1 463.7	–20.7	–18.3	–21.2
Slovakia	–1 209.2	–1 991.4	–2 431.5	–203.8	–134.0	–60.5
Romania	–5 423.2	–5 859.5	–5 170.5	–295.2	–199.3	–160.5
Estonia	–1 022.3	–1 042.4	–572.5	–314.9	–323.5	–234.9
Lithuania	–121.1	–525.9	–339.2	–249.0	–239.9	–268.3
Croatia	–741.8	–1 113.0	–872.0	–739.4	–662.4	–287.4
Greece	22 212.1	25 570.9	29 775.6	–808.6	–617.9	–529.5
Portugal	–9 228.6	–9 925.1	–11 223.5	–804.4	522.4	–590.3
Slovenia	–1 395.5	–1 772.0	–1 785.9	–1 123.6	–879.2	–661.6
Latvia	–376.8	–50.8	–407.0	–638.6	–716.9	–736.6
Hungary	–2 186.7	–1 963.1	–2 458.2	–1 120.1	–1 372.9	–1 176.5
Ireland	–154.2	–934.2	–691.7	–2 163.9	–1 563.1	–1 881.4
Sweden	–6 235.3	–6 632.1	–5 965.4	–4 079.5	–2 700.0	–3 293.4
Czech Republic	–8 447.3	–9 959.6	–10 002.5	–2 948.1	–2 960.3	–3 392.0
Finland	–1 593.5	–1 663.7	–1 916.4	–3 777.9	–3 822.5	–3 393.6
Austria	–17 689.4	–27 462.0	–19 208.2	–9 286.6	–7 887.2	–7 530.0
Italy	–20 632.5	–25 324.1	–22 544.9	–12 007.2	–11 861.4	–8 867.6
Denmark	–7 412.8	–8 152.5	–6 835.3	–9 041.2	–9 698.9	–9 453.6
UK	–45 847.5	–48 062.3	–43 885.3	–11 702.3	–12 602.6	–10 787.6
Netherlands	20 414.4	22 366.3	28 287.0	–14 268.0	5 680.9	–12 370.0
Belgium	10 002.5	9 152.8	6 579.0	–12 541.8	–15 408.6	–14 583.1
France	–74 641.6	–85 264.6	–77 717.5	–37 557.7	–48 217.8	–39 295.7
Germany	–81 143.0	–88 100.5	–86 733.9	–81 479.3	–76 025.8	–75 156.6

Table 66: Fresh or processed strawberry import into the EU in metric tons (source: Eurostat: CN 8101000/8110090)

Exporting country	Fresh						Processed, unsweetened					
	2011		2012		2013		2011		2012		2013	
	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%	Tonnes	%
Morocco	24 228	59	22 632	59	17 749	58	42 720	32	59 660	45	56 006	45
China			49	0			67 553	50	46 300	35	40 317	32
Egypt	5 866	14	6 800	18	6 130	20	9 671	7	15 840	12	16 391	13
Turkey	5 531	13	5 197	13	3 554	12	6 982	5	5 537	4	5 743	5
Peru	336	1	313	1	255	1	2 891	2	3 050	2	3 233	3
USA	3 412	8	2 411	6	1 783	6	45	0	123	0	57	0
Chile	3	0			1	0	1 772	1	1 269	1	1 194	1
Serbia	249	1	78	0	304	1	1 860	1	804	1	743	1
Tunisia	33	0	0	0			562	0	281	0	446	0
Norway	23	0	69	0	63	0	285	0	406	0	364	0
Palestinian Territory	456	1	311	1	178	1						
Israel	602	1	160	0	98	0					0	0
Mexico	50	0	23	0	101	0	116	0	262	0	308	0
Jordan	90	0	154	0	189	1						
Ukraine							205	0	66	0	122	0
Argentina	42	0	25	0	6	0	114	0	127	0	61	0
Russia	11	0	202	1	73	0	20	0	7	0	20	0
Macedonia							141	0	66	0	62	0
Bosnia and Herzegovina	2	0	14	0	37	0	55	0	6	0	104	0
Ethiopia	53	0	71	0	42	0						
Canada									124	0	26	0
Hong Kong							113	0				
Switzerland	4	0	4	0	7	0	24	0	15	0		
Guatemala							23	0	4	0	20	0
Moldova			34	0								
India							22	0			5	0
Antigua and Barbuda									23	0		
Madagascar							23	0				
Brazil							6	0	5	0	7	0
Montenegro							7	0	5	0	2	0
Colombia	1	0	2	0			2	0	2	0		
Ecuador	6	0	1	0								
South Korea	3	0	1	0	0	0						
The Philippines											4	0
Nicaragua					3	0						
Costa Rica	1	0	1	0								
Iran			2	0								
Uruguay	1	0										
South Africa	1	0										
Australia									0	0		
Dominica	0	0			0	0						
Algeria	0	0										
Ghana									0	0		
Lebanon					0	0			0	0		
Total	**41 004**	**100**	**38 554**	**100**	**30 573**	**100**	**135 212**	**100**	**133 982**	**100**	**125 235**	**100**

Appendix D. Food questionnaire

Reprint of the questionnaire with kind permission of the Health Protection Surveillance Centre (HPSC) of Ireland

Case ID (for HPSC use only) ☐☐☐☐☐☐

Outbreak Code: HPSC-1-6-2013

Case-Control Study for Hepatitis A Outbreak in Ireland, 2013

CASE QUESTIONNAIRE

Version 2.0: 22nd August 2013

Note: Text in grey or red font is an instruction to the interviewer and should not be read to the respondent.

CIDR Event ID:

Please tick boxes or write in the space(s) provided.

Name of interviewer:_____ **Date of interview:** _ _/_ _/_ _ _ _

Use a calendar to establish the 7 week period prior to onset of first symptoms, as this is the period during which the case became infected. (Check the original questionnaire(s) or CIDR for date of onset of symptoms; use specimen date if onset unavailable)

Date onset of symptoms: _ _/_ _/_ _ _ _

Date 50 days before onset of symptoms: _ _/_ _/_ _ _ _

Introduction and Consent:

Hello, my name is _____

I am from _____

I am ringing you about the recent illness that you have had due to Hepatitis A.

We are carrying out a study to identify the exact cause of your illness.

Would you be happy for me to ask you a few questions? It will take no more than 25 minutes.

<If respondent is not free now to do the interview, offer an opportunity for an appointment>

Your help in this study is very important as your information will go towards finding out what caused this illness.

All the information you give will be treated as confidential.

Your name or any other identifying information will not appear in any report from this study.

Consent given Yes ☐ No ☐

Thank you for your assistance

CASE QUESTIONNAIRE

Obtain and complete demographic (Section 1) and clinical details (Section 2) from the existing questionnaires first, confirm these details with the respondent and complete any missing information

1. PERSONAL DETAILS

First name:	**Surname:**
Address:	
County:	**Postcode (for Dublin):**
DOB: _ _/_ _/_ _ _ _	**Age:**
Sex: **Male** ☐ **Female** ☐	**Occupation:**
Food handler: Yes ☐ **No** ☐	**Workplace/school address:**
Mobile phone:	**Telephone:**
If age <18 years of age; administer the questionnaire to a relative: **Name of Relative:** **Relationship to the case:**	

2. CLINICAL DETAILS

When did you start to feel unwell? _ _/_ _/_ _ _ _

Check this tallies with onset date previously reported, clarify onset date if discrepancy and recalculate 7 week exposure period

Are you still ill?: Yes ☐ **No** ☐

If no, how long did your illness last?(days):

Did you have one or more of the following symptoms?	**Yes**	**No**	**Not sure**
Jaundice/Yellow eyes			
Dark urine			
Light coloured stools			
Fever (>38°C)			
Tiredness/Fatigue			
Vomiting			
Nausea			
Diarrhoea (3 or more loose stools within 24 hrs)			
Abdominal pain/discomfort			
Loss of appetite			

Did you attend your GP while ill?: Yes ☐ **No** ☐

If yes, name and address of GP:

Have you been admitted to hospital due to Hepatitis A infection?: Yes ☐ **No** ☐

If yes, Date of hospital admission: _ _/_ _/_ _ _ _

Name of hospital:

Date of discharge: _ _/_ _/_ _ _ _ Still hospitalised: **?: Yes** ☐ **No** ☐

If exact dates of admission or discharge are not known, how many days were you in hospital for:

3. TRAVEL HISTORY

Did you spend any nights outside of Ireland during the **seven week period before you became ill?**

This would have been from _ _/_ _/_ _ _ _ **to** _ _/_ _/_ _ _ _ **(Check dates from page 1 of questionnaire)**

Yes ☐ No ☐ Not sure ☐

If yes, please give details

Country(ies) visited	Region(s), cities visited Hotel/resort name(s) if known	Date Departure	Date Return
Notes:			

Note: If respondent travelled abroad, please clarify when taking exposure information in which country the food item was purchased/consumed.

4. EXPOSURE

Now I would like to move on how you may have acquired your illness.

I will ask you some questions about foods you are likely to have eaten in the seven weeks period before your illness.

Your answers are important for the success of the study, so in giving your responses please do so as accurately as you can.

As a reminder we are talking about the foods you are likely to have eaten in the seven weeks before you came ill, this is

from _ _/_ _/_ _ _ _to _ _/_ _/_ _ _ _

Please tick relevant cell(s) or write in the spaces provided for each of the questions overleaf.
As well as determining whether the respondent eats a particular food item or not.
If the respondent answers yes to one of the listed food items, please ensure questions on frequency, place of purchase and brand are asked. Also for certain food items please ask the questions relating to preparation in the home and type of fruit used (as specified in the relevant sections).
Regarding place of purchase, please ascertain where possible name and location of premises (name village, town, and suburb if a city).

4.1 FRESH BERRIES:

Q. In the seven weeks prior to your illness, were you likely to have eaten fresh berries either on their own or as a garnish with desserts and salads, these include strawberries, raspberries, blackberries, blueberries, cranberries and also blackcurrants and redcurrants (re-emphasise it is either on their own or as a garnish)

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following fresh berries were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Fresh Berries/Currants	Yes	No	Not sure	If yes, how often (frequency)								Place of Purchase (name and location of shop, supermarket, café, restaurant, market etc. where fruit purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/week	2-3 times/month	Once/month	Once in the 7 week period	Never	Don't remember		
Strawberries													
Raspberries													
Blackberries													
Blueberries													
Cranberries													
Blackcurrants													
Redcurrants													
Other, specify													
Notes:													

4.2 Berry-flavoured Smoothies:

Q. In the seven weeks prior to your illness, were you likely to have drunk berry-flavoured smoothies made in juice bars, deli bars, cafés, restaurants, markets or at home?

Flavours include mixed berry, strawberry, raspberry, blackberry, blueberry etc. (Note: in case clarification sought by the respondent smoothies are of thicker consistency than juices and may contain yoghurt and/or banana as the thickening agent, sometimes they may also contain milk and/or ice cream)

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following berry-flavoured smoothies were you likely to drink?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Smoothies	Yes	No	Not sure	If yes, how often (frequency)								Prepared at home			If yes, prepared at home; type of fruit used				Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market where smoothie(s) or berries for home-prepared smoothie(s) were purchased)	Brand
				5 or more times/week	3-4 times/ week	1-2 times/ week	2-3 times/month	Once/ month	Once in the 7 week period	Never	Don't remember	Yes	No	Don't know	Fresh	Frozen	Both	Don't know		
Mixed berry																				
Strawberry																				
Raspberry																				
Blackberry																				
Blueberry																				
Other, specify																				
Notes:																				

4.3 Berry-flavoured Juices:

Q. In the seven weeks prior to your illness, were you likely to have drunk berry-flavoured juices made in juice bars, deli bars, cafés, restaurants, markets, at home or berry-flavoured juices produced on Irish fruit farms, these can be craft/artisan style or organic juices ? Flavours include mixed berry, strawberry, raspberry, blackberry, blueberry etc.

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following berry-flavoured juices were you likely to drink?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Juice	Yes	No	Not sure	If yes, how often (frequency)								Prepared at home			If yes, prepared at home; type of fruit used				Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market where juices(s) or berries for home-prepared juice(s) were purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/month	Once/ month	Once in the 7 week period	Never	Don't remember	Yes	No	Don't know	Fresh	Frozen	Both	Don't know		
Mixed berry																				
Strawberry																				
Raspberry																				
Blackberry																				
Blueberry																				
Cranberry																				
Other, specify																				
Notes:																				

4.4 Berry-flavoured cheesecake:

Q. In the seven weeks prior to your illness, were you likely to have eaten berry-flavoured cheesecake?
Flavours include mixed berry, strawberry, raspberry, blackberry, blueberry and also blackcurrant or redcurrant etc.
Yes ☐ No ☐ Not sure ☐

If YES, which of the following berry-flavoured cheesecakes were you likely to eat?
(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Cheesecake	Yes	No	Not sure	If yes, how often (frequency)								Prepared at home			If yes, prepared at home; type of fruit used				Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market where cheesecake or berries/currants for home-prepared cheesecake were purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember	Yes	No	Don't know	Fresh	Frozen	Both	Don't know		
Mixed berry																				
Strawberry																				
Raspberry																				
Blackberry																				
Blueberry																				
Black currant																				
Redcurrant																				
Other, specify																				
Notes:																				

4.5 Yoghurt containing a layer of berry purée/berry compote or whole berries:

Q. In the seven weeks prior to your illness, were you likely to have eaten yoghurt containing a layer of berry purée/berry compote or whole berries?
Flavours include mixed berry e.g. fruit of the forest, strawberry, raspberry, blackberry, blueberry etc.

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following berry-flavoured yoghurts were you likely to eat?
(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Yoghurt	Yes	No	Not sure	If yes, how often (frequency)								Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market where yoghurt was purchased)	Brand Please ascertain brand of berry yoghurt
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/month	Once/ month	Once in the 7 week period	Never	Don't remember		
Mixed berry/ fruit of the forest etc.													
Strawberry													
Raspberry													
Blackberry													
Blueberry													
Other, specify													
Notes:													

4.6 Berry-flavoured Ice cream:

Q. In the seven weeks prior to your illness, were you likely to have eaten berry-flavoured ice cream that was handmade or craft/artisan/farmhouse style ice cream or homemade ice cream? Flavours include mixed berry, strawberry, raspberry, blackberry, blueberry etc.

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following berry-flavoured ice creams were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Ice cream	Yes	No	Not sure	If yes, how often (frequency)								Prepared at home			If yes, prepared at home; type of fruit used				Place of Purchase (**name** and **location** of shop supermarket, café, restaurant, market where ice cream or berries for home-prepared ice cream were purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/month	Once/ month	Once in the 7 week period	Never	Don't remember	Yes	No	Don't know	Fresh	Frozen	Both	Don't know		
Mixed berry																				
Strawberry																				
Raspberry																				
Blackberry																				
Blueberry																				
Other, specify																				
Notes:																				

4.7 Berry-flavoured sauce/coulis/purée:

Q. In the seven weeks prior to your illness, were you likely to have eaten berry-flavoured sauce/coulis/purée with sweet or savoury dishes such as with pannacotta, cheesecake, ice cream, yoghurt, game meat or poultry e.g. cranberry with turkey, berries with deep-fried brie or pâté?

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following berry-flavoured sauces/coulis/purées were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Sauce Coulis Purée	Yes	No	Not sure	If yes, how often (frequency)								Prepared at home			If yes, prepared at home; type of fruit used				Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market where sauce etc. or berries/currants for home-prepared sauce etc. were purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember	Yes	No	Don't know	Fresh	Frozen	Both	Don't know		
Mixed berry																				
Strawberry																				
Raspberry																				
Blackberry																				
Blueberry																				
Cranberry																				
Other, specify																				
Notes:																				

4.8 Frozen Berries:

Q. In the seven weeks prior to your illness, were you likely to have eaten frozen berries on their own or as a topping on cereals, yoghurts or desserts (e.g. mixed berries, strawberries, raspberries, blackberries, blueberries and also redcurrant s and black currants)

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following frozen berries were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Frozen berries	**Yes**	**No**	**Not sure**	**If yes, how often (frequency)**								**Place of Purchase** (**name** and **location** of shop, supermarket, café, restaurant, market where frozen berries were purchased)	**Brand**
				5 or more times/ week	3-4 times/w eek	1-2 times/w eek	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember		
Mixed berries													
Strawberries													
Raspberries													
Blackberries													
Blueberries													
Cranberries													
Redcurrants													
Blackcurrants													
Other, specify													
Notes:													

4.9 Other Frozen berries:

Q. Can you think of any other food item that you ate in the seven week period prior to your illness that may have contained frozen berries?

Yes ☐ **No** ☐ **Not sure** ☐

If YES, please give details

Item	**Yes**	**No**	**Not sure**	**If yes, how often (frequency)**								**Place of Purchase** (**name** and **location** of shop, supermarket, café, restaurant, market where frozen berries were purchased)	**Brand**
				5 or more times/ week	3-4 times/w eek	1-2 times/w eek	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember		
Notes:													

4.10 Pomegranate

Q. In the seven weeks prior to your illness were you likely to have eaten pomegranate fruit? (Note: it is the seeds of the pomegranate that are eaten)

Yes ☐ No ☐ Not sure ☐

If YES, which of the following pomegranate items were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Pomegranate	Yes	No	Not sure	If yes, how often (frequency)								Place of purchase (**name** and **location** of shop, supermarket, café, restaurant, market etc. where purchased)	Brand
				5 or more times/week	3-4 times/ week	1-2 times/ week	2-3 times/month	Once/ month	Once in the 7 week period	Never	Don't remember		
Raw/Fresh (on its own or as a garnish on desserts, salads or other dishes)													
Juice													
Dried													
Frozen product													
Antioxidant blend													
Other, specify													
Notes:													

4.11 Uncooked Dried fruit (excluding currants and raisins):

Q. In the seven weeks prior to your illness, were you likely to have eaten uncooked dried fruits (excluding currants and raisins) but including semi-dried tomatoes, dried dates, dried figs, dried cranberries or dried mixed berries?

Yes ☐ **No** ☐ **Not sure** ☐

If YES, which of the following dried fruits were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Dried fruit	Yes	No	Not sure	If yes, how often (frequency)								Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market etc. where purchased)	Brand
				5 or more times/ week	3-4 times/w eek	1-2 times/w eek	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember		
Semi-dried tomatoes													
Dates													
Figs													
Cranberries													
Mixed fruit													
Other, specify													
Notes:													

4.12 Raw/uncooked vegetables:

Q. In the seven weeks prior to your illness, were you likely to have eaten uncooked or raw vegetables e.g. in salads

Yes ☐ No ☐ Not sure ☐

If YES, which of the following items were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Raw vegetables	Yes	No	Not sure	If yes, how often (frequency)								Place of Purchase (**name** and **location** of shop, supermarket, café, restaurant, market etc. where purchased)	Brand or Type
				5 or more times/ week	3-4 times/week	1-2 times/week	2-3 times/month	Once/month	Once in the 7 week period	Never	Don't remember		
Lettuce													
Cucumbers													
Scallions/ Spring Onions													
Tomatoes													
Peppers													
Bean sprouts													
Carrots													
Celery													
Other, specify													
Notes:													

4.13 Seafood and Shellfish

Q. In the seven weeks prior to your illness, were you likely to have eaten either shellfish/mollusc such as oysters, mussels, prawns, scallop, octopus or raw seafood such as sushi?

Yes ☐ No ☐ Not sure ☐

If YES, which of the following items were you likely to eat?

(Please go through each of the items listed; if respondent answered "No" or "Not sure" above, go through each of the items listed to verify this is definitely the situation)

Food item	Yes	No	Not sure	If yes, how often (frequency)								Place of purchase (**name** and **location** of shop, supermarket, café, restaurant, market etc. where purchased)	Brand
				5 or more times/ week	3-4 times/ week	1-2 times/ week	2-3 times/m onth	Once/ month	Once in the 7 week period	Never	Don't remember		
Shell fish/mollusc (e.g. oysters, mussels, prawns, scallops, octopus)													
Raw seafood (including sushi)													
Notes:													

4.14 Final check

Q. During the course of the interview have you remembered having other berries or berry products during the seven week period that you haven't already mentioned?

Insert details below and if relevant in the related section of the questionnaire and checking on frequency, place or purchase etc.

5. Conclusion and Wrap up

That concludes the questions regarding your food preferences.

I would like to thank you very much for your time and co-operation in answering my questions.

If you should think of any further details following this interview, please feel free to contact me at
< Provide name and telephone number>

Thanks again!

Please fax completed questionnaires to:

GLOSSARY

Berry fruits According the UNECE Standard FFV-57 (UNECE, 2010), the following categories are defined for production and trade of fresh fruits (non-industrial processing):

Category	Berry fruits	Botanical name
Raspberries	Raspberries	*Rubus idaeus* L.
Blackberries	Blackberries	*Rubus* sect. Rubus
Loganberries	Loganberries	*Rubus loganobaccus* L. H. Bailey
Currants	Redcurrants Blackcurrants	*Ribes rubrum* L. *Ribes nigrum* L.
Gooseberries	Gooseberries	*Ribes uva-crispa* L.
Bilberries	Bilberries	*Vaccinium myrtillus* L.
Blueberries	Blueberries	*Vaccinium corymbosum* L. *Vaccinium formosum* Andrews *Vaccinium angustifolium* Aiton *Vaccinium virgatum* Aiton
Lingonberries	Cowberries or lingonberries	*Vaccinium vitis-idaea* L.
Cranberries	Cranberries	*Vaccinium macrocarpon* Aiton
Wild cranberries	Wild cranberries	*Vaccinium oxycoccos* L.
Cloudberries	Cloudberries	*Rubus chamaemorus* L.
Hybrids of these species	Such as Boysenberries Tayberries Jostaberries	 *Rubus ursinus* Cham. et Schltdl. × *Rubus idaeus* L. *Rubus* sect. Rubus × *Rubus idaeus* L. *Ribes nigrum* L. × *Ribes uva-crispa* L.

United Nations Economic Commission for Europe (UNECE), 2010. Standard FFV-57 concerning the marketing and commercial quality control of berry fruits, 2010 edition. New York, USA; Geneva, CH: United Nations, ECE/TRADE/C/WP.7/2010/2. 7 pp.

In addition to the above list, strawberries (*Fragaria* spp.) are considered in this opinion. Berries were previously defined (EFSA BIOHAZ Panel, 2013) to include açai berry, barberry, bearberry, bilberry, blackberry, blackcurrant, blueberry, boysenberry, cape gooseberry, chokeberry, cloudberry, cranberry, cowberry, elderberry, goji berry, gooseberry, huckleberry, juneberry, juniper berry, lingonberry, loganberry, marionberry, mulberry, nannyberry, ollaliberry, Oregon grape, raspberry, redcurrant, salmonberry, sea-buckthorn berry, serviceberry, strawberry and tayberry.

Confirmed case (for tracing activities) an EU/EEA resident with laboratory-confirmed HAV genotype 1A, outbreak strain infection, date of symptom onset on or after 1 January 2013, reported exposure to berries, no travel to an outbreak-country within 15–50 days before the disease onset and no secondary transmission via person-to-person or unknown route.

Confirmed lot any batch of fresh or frozen berries or berry products with a positive analytical result for the presence of HAV.

Connected lot any batch of fresh or frozen mixed berries or mixed berry products that shares with a confirmed batch at least one component of the mix.

Delivery movement of a product from one operator/station to another operator/station at a specified point in time.

End point the furthest point in the supply chain from the starting point that could be identified from the available tracing data; when the tracing dataset is complete this is the primary producer

HAV OS a sequence identical (i.e. with 100.0 % identity) to the 2013 HAV genotype IA outbreak strain (GenBank accession number KF182323) based on a fragment of 460 nucleotides at the region of VP1/2A or with 99.8 % similarity to this sequence (i.e. one nucleotide difference in 460 nucleotides) or a sequence identical (i.e. with100.0 % identity) to a shorter fragment of at least 174 nucleotides at the region of VP1/2A.

"Hotspot" a station (node) in the tracing net that is connected to a large number of starting points and is therefore able to explain a large number of contaminated lots or HAV cases.

Ingredient a component part or element of something, specifically a food item or substance combined with others to make a more complex product.

Node a point in the network graph where edges connect; an edge always connects two nodes, which represent stations.

Possible product any brand of fresh or frozen berries consumed before the onset of symptoms by at least one case affected with Hepatitis A after 1 January 2013, considering products present in the premises under investigation during incubation period for HAV (15–50 days).

Probable case (for tracing activities) or suspected/possible case is an EU/EEA resident with laboratory confirmed HAV infection, date of symptom onset on or after 1 January 2013, and having been in an outbreak-country within 15–50 days before the disease onset and no secondary transmission via person-to-person or unknown route.

Starting point of tracing a station in the food supply chain (e.g. company, restaurant) where a confirmed or suspect lot was produced or delivered to a confirmed or possible case.

Station in the tracing net any operator or similar which produces, trades, stores or handles a suspect food item.

Supect lot any batch of fresh or frozen berries or berry products consumed by at least one patient affected with hepatitis A after 1 January 2013, where the exact lot and brand could be identified from the food history.

Supply chain the network created amongst different operators/stations producing, handling and/or distributing a specific product.

Tracing net a visualisation of the food chain (including material flow) from the primary producers of all ingredients to all starting points of the tracing activities.

VP1–-2a this domain covers the C-terminal region of VP1 and spans protein 2A in the genome polyprotein of hepatitis A virus.

ABBREVIATIONS

AP	Autonomous Province
BfR	German Federal Institute for Risk Assessment
BFSA	Bulgarian Food Safety Authority
BE	Belgium
BG	Bulgaria
BY	Belarus
CA	Canada
CDC	Centers for Disease Control and Prevention
CI	confidence interval
CL	Chile
CN	Combined Nomenclature
DGCCRF	General Directorate for Competition Policy, Consumers affairs and Fraud Control
EC	European Commission
EEA	European Economic Area
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHEC	enterohaemorrhagic *Escherichia coli*
EPIS-FWD	Epidemic Intelligence Information System for Food- and Waterborne Diseases
ES	Spain
EU	European Union
EUROSTAT	Statistical Office of the European Communities
EWRS	Early Warning and Response System
FAO	Food and Agriculture Organization of the United Nations
FR	France
FYROM	Former Yugoslav Republic of Macedonia
GAP	Good Agricultural Practice

GHP	Good Hygiene Practice
GIS	geographic information system
GMP	Good Manufacturing Practice
GPL	General Public License
HAV	hepatitis A virus
HAVNET	Database coordinated by the Dutch National Institute of Health and Environment
HACCP	Hazard Analysis and Critical Control Points
HPSC	Health Protection Surveillance Centre
ICD-10	International Classification of Diseases version 10
IgM	immunoglobulin M
IE	Ireland
ISO/TS	International Organisation for Standardisation Technical Specification
ISS	Italian Public Health Institute
IT	Italy
IZSLER	Istituto Zooprofilattico Sperimentale della Lombardia ed Emilia Romagna
IZSPLV	Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta
MA	Morocco
MB	mixed berries
MoH	Ministry of Health
MS	Member State
MSIS	Norwegian Surveillance System for Communicable Diseases
MSM	men having sex with men
NIPH	Norwegian Institute of Public Health
NL	Netherlands
NO	Norway
NRC	National Reference Centre
NVWA	Nederlandse Voedsel-en Warenautoriteit
OR	odds ratio

OS	outbreak strain
PCR	polymerase chain reaction
PSSE	Powiatowa Stacja Sanitarno-Epidemiologiczne
PL	Poland
RASFF	Rapid Alert System for Food and Feed
RHA	Regional Health Authority
RHI	Regional Healthcare Inspectorates (Bulgaria)
RIVM	National Institute for Public Health and the Environment (Netherlands)
RNA	ribonucleic acid
RO	Romania
RS	Serbia
RT-PCR	Reverse transcription polymerase chain reaction
SANCO	DG Health and Consumers
SCFCAH	Standing Committee on the Food Chain and Animal Health
SE	Sweden
SEIEVA	Sistema Epidemiologico Integrato Epatiti Virali Acute
TESSy	The European Surveillance System
UA	Ukraine
UK	United Kingdom
USA	United States of America
VAT	value-added tax
WGS	whole-genome sequencing
WHO	World Health Organization