



The source of the outbreak (Trace back/Trace forward investigations) and scientific advice

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- Background on food-borne outbreaks due to *E. coli* and background on the causative organism
- EFSA's role in the outbreak
- Outbreak investigation and identification of the source
- Scientific advice

Causative organism

- **Shiga-toxin producing *Escherichia coli* (STEC) serotype O104:H4 and carries substantial antibiotic resistance.**
- **Reservoir:** not clear
 - shares virulence characteristics of STEC (animal reservoir) and of enteroaggregative *E. coli* (EAEC) (human reservoir) strains.
- **Origin:** Previously very rare in Europe

Human cases reported to ECDC										
2010	Austria	O104:H21	UNK ⁴	UNK	1	F	58	yes	UNK	ECDC/TESSy ⁵
2010	Sweden	O104:NT	2	neg.	1	F	45	no	travel (Tunisia)	ECDC/TESSy
2009	Norway	O104:H-	1	neg.	1	M	<1	no	UNK	ECDC/TESSy
2009	Norway	O104:NT	1	neg.	1	F	11	no	travel (Turkey)	ECDC/TESSy
2009	Norway	O104:NT	1	neg.	1	F	22	no	UNK	ECDC/TESSy
2008	Belgium	O104:H2	2	neg.	1	M	33	no	UNK	ECDC/TESSy
2008	Denmark	O104:H2	2 ⁶	neg.	1	M	23	no	travel (Afghanistan)	ECDC/TESSy
2006	Norway	O104:NT ⁷	2	neg.	1	M	> 70	no/ UNK	UNK	ECDC/EPIS
Other										
2010	Finland	O104:H4 ⁸	2	neg.	1	M	76	no	travel (Egypt)	THL ⁹ /Finland
2004	France	O104:H4	2	neg.	1	UNK	UNK	UNK	UNK	EN ¹⁰ / Denmark

- Germany

 - First case **1st week of May**

 - Epidemic peak 200 cases per day: **22 May**

- European level

 - Germany reports to Commission and MS on **21 May**

 - First audio conference of Commission **24 May**

- France

 - 24 June** cluster in Bègles (near Bordeaux)

- 7 July end of the outbreak

 - 4,000 cases, incl. 50 deaths**

- **First phase** (May 24 – 9 June): Preparatory Review
 - EFSA/ECDC advice published 3 June
 - Literature Review: presence of enteric pathogens in plant material
 - Summarisation of STEC data previously reported in the EU in humans, food and animals
- **Second phase** (5 – 16 June): Support Outbreak Investigation in Germany
 - Worked 'shoulder to shoulder' with the colleagues from the Federal Ministry and Research Institutes and the Länder to develop, set up and implement the tracing back and tracing forward investigation
 - Led to the identification of sprouts as the cause and Establishment A as the source of the sprouts
- **Third phase** (24 June – 5 July): Investigate common cause between French and German outbreaks
 - Set up a European Task Force to trace common link: seeds used to produce sprouts
 - Identified a Lot of Fenugreek seeds imported from Egypt in Germany via Antwerp/Rotterdam
- **Fourth phase**: follow-up mandate to BIOHAZ Panel (30 Oct)

This is stepwise and complex process:

- Which is the vehicle – fresh vegetables
 - Which fresh vegetable is it really – sprouts
 - Where do those sprouts come from – from Establishment A
 - Which of the sprouts from Establishment A – can't tell for sure
 - How do these sprouts get contaminated:
 - personnel?
 - water?
 - seeds?
- It comes with 'a lot of tears':
- The pressure is, understandably, enormous
 - The need for coordination of various organisations is substantial
 - The rule-book has not been written or rehearsed and many existing rules may take weeks
 - Mistakes can be made, when time is of the essence

Traceability (in food safety)

= means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

EC regulation 178/2002 article 3, 15

Tracing in outbreak investigations

From Fork back to Farm (backward):

- Detection of the origin / links between clusters

From Farm to Fork (forward):

- Tracing and recall of contaminated / unsafe products

Problem:

Information on the total food supply chain is needed as data at each knot of the food supply chain

Puzzle piece of information

Data at each knot of the food supply chain

Establishment where the data are collected:
1 record per ingredient-product combination



Customer of the Establishment:
Identification, e.g.
Name, address, tax no.

Product of the Establishment:
Identification, e.g.
Date of delivery, amount, name, article/lot no., production date, expire date

Establishment:
Identification, e.g.
Name, address, tax no.
Production process:
Recipe, processing

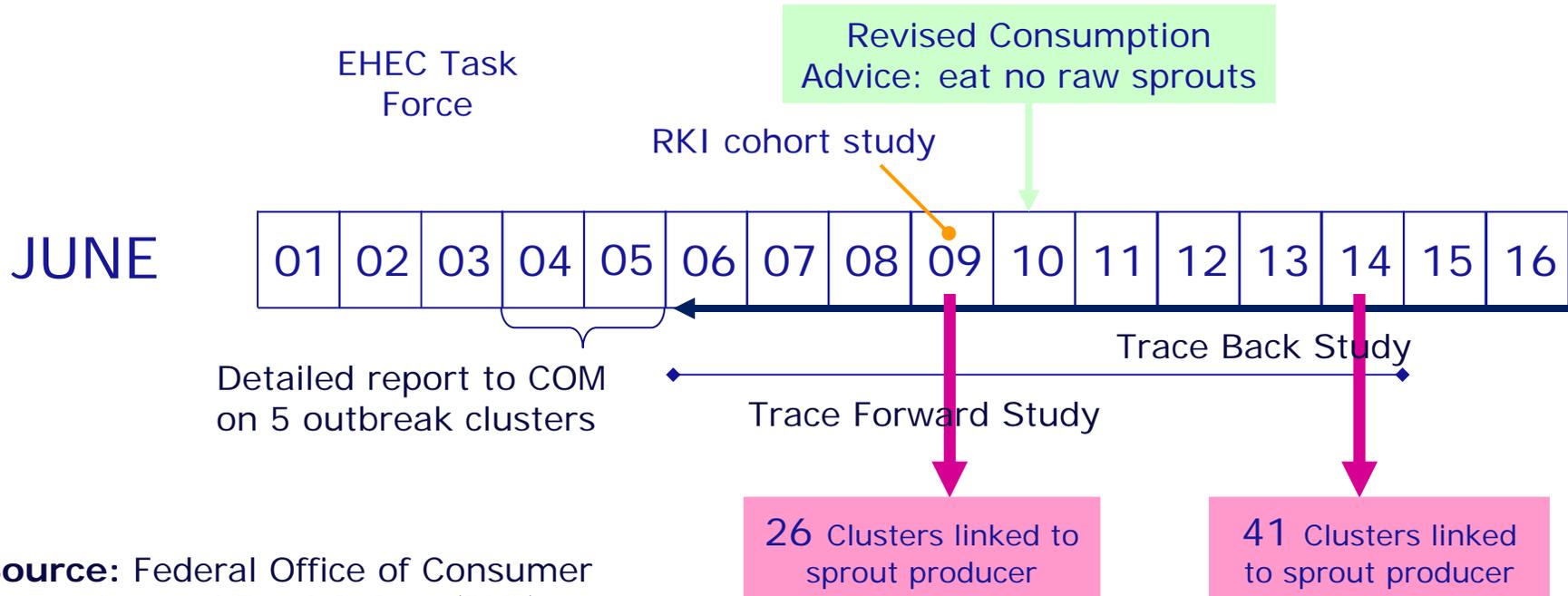
Ingredient of the product:
Identification, e.g.
Date of delivery, amount, name, article/lot no., expire date

Supplier of the Establishment:
Identification, e.g.
Name, address, tax no.

- On 21st May, **Germany** reported an ongoing outbreak of Shiga-toxin producing *Escherichia coli*, serotype O104:H4.
- Early after the onset of the outbreak in Germany, **case-control studies** conducted by the RKI demonstrated that the onset of clinical disease was linked to the consumption of fresh salad vegetables.
- Risk-based inspections of clusters was carried out and **samples were taken** from foods and the environment at clusters, suppliers, whole sale markets, and at retail.
 - None of the food samples taken during this monitoring activity has been found positive for the STEC serotype O104:H4

- To coordinate the activities for identifying the food source the **German Task Force EHEC** (Enterohaemorrhagic Escherichia coli) was established by the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).
- A detailed cohort study was carried out.
- Different strategies were used:
 - 5 clusters with the availability of precise information on the food intake of the affected cases were investigated → trace-back activities.
 - a trace forward analysis of the supply chains of a horticultural farm in Lower Saxony (Establishment A) was carried out. The production site was suspected early on by the local authorities as a possible source of infection for several clusters.
- Thus, the epidemiological investigations provided strong evidence that **sprouted seeds from Establishment A** were the vehicle of infection

Source of the Infection (I)- Chronology



- Before French outbreak, 13 EU/EEA countries reported cases associated to the outbreak in Germany. All cases linked to travel to northern Germany.
- On the 24 June , **France** reported to the RASFF a cluster of patients with bloody diarrhoea, after having participated in an event in the Commune of Begles near Bordeaux on the 8 June. None of the food handlers or guests had recently travelled to Germany or had contact with travellers from Germany.
- The strain of *E. coli* O104:H4 exhibits the characteristics common with the German outbreak strain:
 - *stx2* positive, *aggR* positive, *eae* negative, *hlyA* negative,
 - multi-resistance pattern to antimicrobials
 - indistinguishable with two molecular techniques (Repetitive sequence based Polymerase Chain Reaction (Rep-PCR) and PFGE).

- On 25th June EFSA asked by the European Commission to initiate tracing back investigation to identify possible link between French cluster and German outbreak.
- EFSA set up a **Task Force** composed of experts from European Commission, concerned MS (Germany, France, United Kingdom the Netherlands, Italy, Sweden, Austria and Spain), ECDC, WHO, and FAO.
- EFSA data collection, data management and data analysis using spreadsheets developed for German outbreak. RASFF for data exchange. Collaboration with German EHEC Task Force members: Exchange of staff from the BfR.

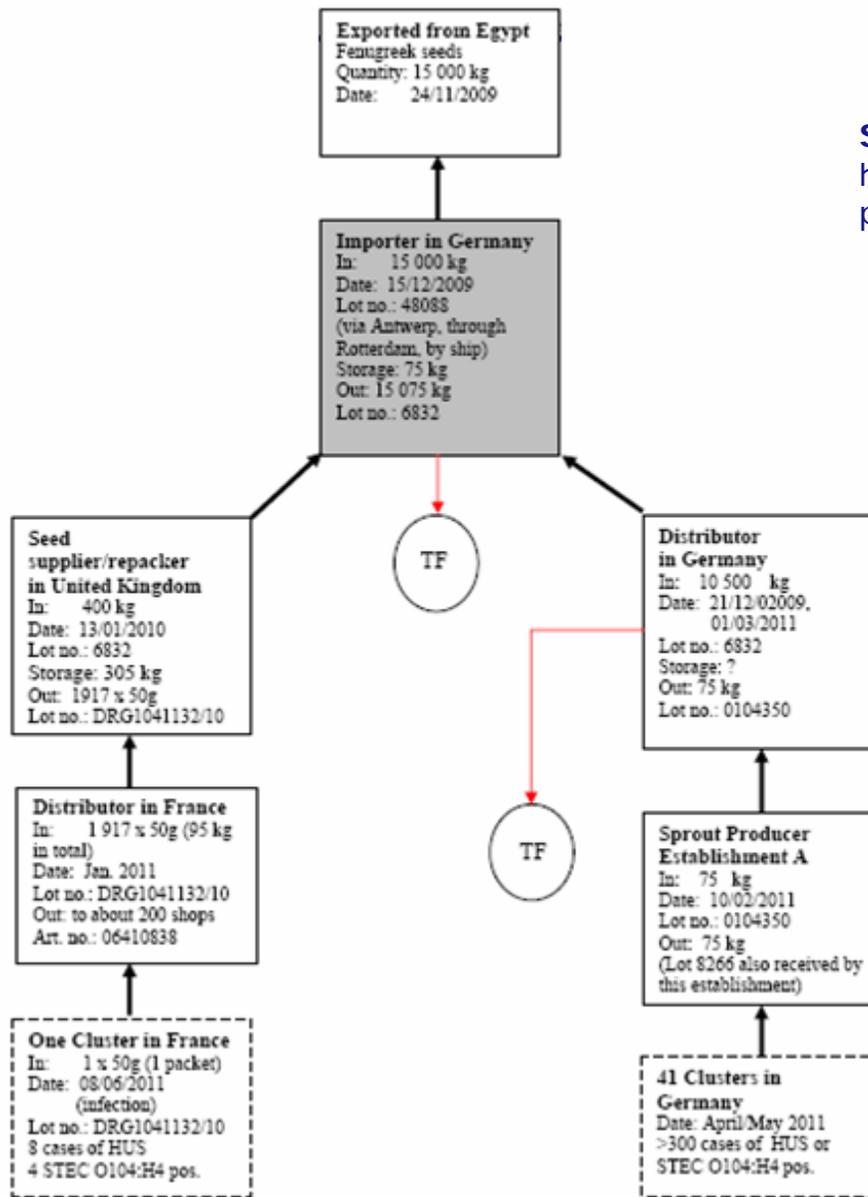
- A cohort study of those attending the event was initiated and preliminary results revealed a significant association between consumption of **sprouted seeds** (fenugreek, rocket and white mustard) and infection.

Table 1: Summary of seeds linked to *E. coli* STEC O104:H4 outbreaks in France and Germany, during the investigation.

English seed name	Scientific name	Other names	Mixture type in German trace back	Identified in French Outbreak	Focus for EU trace back
alfalfa	<i>Medicago sativa</i>	Luzerne (DE) luzerne (FR)	Mild*		
fenugreek	<i>Trigonella foenum-graecum</i>	Bockshornklee (DE), Fénu grec (FR)	Mild* & Spicy	Yes	Yes
lentils (black beluga, brown mountain)	<i>Lens culinaris</i>	Linsen (DE) lentilles (FR)	Mild* & Spicy		
adzuki beans	<i>Vigna angularis</i>	Azukibohnen (DE) haricots adzuki (FR)	Mild*		
radish (red, daikon)	<i>Raphanus sativus</i>	Rettich (DE) radis (FR)	Spicy		
mustard	<i>Sinapis alba</i>	senf (DE) Moutarde blanche (FR)		Yes	
rocket	<i>Eruca sativa</i>	Roquette (FR)		Yes	

*Keimspross-Mischung

EFSA Task Force: Link between German and French outbreaks



Source:

<http://www.efsa.europa.eu/en/suporting/doc/176e.pdf>

Investigation completed without positive bacteriology

- The outbreak strain was not isolated from seeds or sprouted seeds.
- The outbreak strain has not been isolated from foods where the possibility of cross-contamination could be excluded.
- The lack of positive microbiological results is not unexpected:
 - Test sensitivity for very low levels of contamination,
 - Sampling volumes/strategies for low contamination levels,
 - Possibly heterogeneously distributed in large lots,
 - Specific physiological considerations due to the seed matrix; soaking seeds prior to testing may aid recovery of contaminants (ANSES and EU-RL).

9th June

EFSA has published its fast track risk assessment on consumer exposure to STEC/VTEC through the consumption of raw vegetables and provided advice on options to mitigate the risks of possible food contamination and human infection.

5th July

Based on the findings, EFSA recommends:

- to the European Commission that all efforts be made to prevent any further consumer exposure to the suspect seeds and that forward tracing be carried out in all countries which may have received seeds from the concerned lots.
- to the consumers not to grow sprouts for their own consumption and not to eat sprouts or sprouted seeds unless they have been cooked thoroughly.

3rd October

EFSA is no longer advising consumers “not to grow sprouts for their own consumption and also not to eat sprouts or sprouted seeds unless they have been cooked thoroughly”. EFSA recommends that consumers refer to national food safety agencies for any specific advice regarding sprout consumption. 18

- Lot 48088 of fenugreek seeds imported from Egypt was the common link for both outbreaks. Possible implication of other lots. **Import ban**
- While the trace-forward activities were ongoing, consumers were advised not to grow sprouted seeds for consumption and not to eat sprouts or sprouted seeds, unless they were cooked thoroughly. When the trace-forward was completed and the implicated lot(s) removed from the market, such advise was revised (3rd October, EFSA website)
(<http://www.efsa.europa.eu/en/press/news/111003a.htm>)
- Contamination with STEC O104:H4 with faecal material of human and/or animal origin during production or distribution process. Typically, such contamination occurs during production at farm level. **Mandate to BIOHAZ panel on a risk assessment on the EU production chain for sprouts and sprouting seeds.**

- European Centre for Disease Prevention and Control and European Food Safety Authority. Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104. Stockholm: ECDC; 2011
(<http://www.efsa.europa.eu/en/supporting/pub/166e.htm>)
- European Food Safety Authority; Urgent advice on the public health risk of Shiga-toxin producing *Escherichia coli* in fresh vegetables. EFSA Journal 2011; 9(6):2274
(<http://www.efsa.europa.eu/en/efsajournal/pub/2274.htm>)
- European Food Safety Authority; Tracing seeds, in particular fenugreek (*Trigonella foenum-graecum*) seeds, in relation to the Shiga toxin-producing *E. coli* (STEC) O104:H4 2011 Outbreaks in Germany and France.
(<http://www.efsa.europa.eu/en/supporting/pub/176e.htm>)
- European Food Safety Authority; Shiga toxin-producing *E. coli* (STEC) O104:H4 2011 outbreaks in Europe: Taking Stock. EFSA Journal 2011;9(10):2390
(<http://www.efsa.europa.eu/en/efsajournal/pub/2390.htm>)