

## TECHNICAL REPORT OF EFSA

# 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<sup>1</sup>

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### KEY WORDS

Shiga toxin-producing *E. coli* (STEC), VTEC, EHEC, sprouts, seeds, trace-back, trace-forward.

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## SUMMARY

On the 21<sup>st</sup> of May 2011, Germany reported an ongoing outbreak of Shiga-toxin producing *Escherichia coli*-bacteria (STEC<sup>45</sup>), serotype O104:H4 (Frank et al., 2011). In Germany, between the 1<sup>st</sup> of May and the 28<sup>th</sup> of June 2011, 838 Haemolytic Uremic Syndrome (HUS) cases and 3 091 STEC cases with diarrhea have been reported, of which 47 persons have died (RKI, 2011).

On Friday the 24<sup>th</sup> of June, France reported<sup>6</sup> a cluster of patients with bloody diarrhoea, after having participated in an event in the Commune of Bègles near Bordeaux on the 8<sup>th</sup> of June. As of 28 June, eight cases of bloody diarrhoea and a further eight cases with HUS have been identified. Eleven of these patients, seven women and four men, between 31 and 64 years of age, had attended the same event in Bègles. Infection with *E. coli* O104:H4 has been confirmed for four patients with HUS.

Six of the cases reported having eaten sprouts at the event on the 8<sup>th</sup> of June, and leftovers are being analysed. Outbreak investigation revealed that the suspected sprouts of fenugreek, rocket and mustard had been privately produced in small quantities by the organiser of the event from seeds bought at an approved garden centre, and were not imported from the sprout producer implicated in the outbreak in Germany (INVS, 2011). An analytical epidemiological study is ongoing with the persons that attended the event on 8<sup>th</sup> of June. Local trace back investigations in France suggested that the seeds for sprouting were distributed to the approved garden centre by a UK based company.

EFSA was urgently requested by the Commission to initiate a comprehensive tracing back exercise (followed by tracing forward) to identify the source of the two outbreaks and contribute to identifying appropriate risk mitigating measures regarding potential further outbreaks. These further investigations particularly aimed at determining whether the origin of the suspected sprout-seeds from the French cluster were linked to the large outbreak in northern Germany. This report documents the steps taken in the trace back process. Any activities already undertaken by the Task Force with regard to tracing forward are also described.

A trace back investigation is the method used to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a food-borne illness investigation. A trace forward investigation aims to find the distribution of the suspected food products along the food chain from the origin in the direction of the consumer.

Using this approach for this investigation, at each step of the delivery/production chain identified in the trace back, further investigation was initiated to try and account for all seeds in any suspect lots. The objective was to identify critical lots and their current location. To this end, detailed information on each lot of seeds was established for each step of the delivery/production chain back to the importation into the EU.

The comparison of the back tracing information from the French and German outbreaks leads to the conclusion that lot # 48088 of fenugreek seeds imported by the Importer, from Egypt, is the most likely common link, although it cannot be excluded that other lots may be implicated.

Given the possible severe health impact of exposure to a small quantity of contaminated material, and, in the absence of information regarding the source and means of contamination and possible cross-contamination, it seems appropriate to consider all lots of fenugreek from the identified exporter as

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<sup>4</sup> 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. [50 pp.]

<sup>5</sup> In the EU and as reflected in EFSA's work on zoonoses, Shiga-toxin producing *Escherichia coli*-bacteria is referred to as VTEC (verotoxin-producing *E. coli*) but the term STEC is used for this outbreak as it is in line with terminology used by WHO and other organisations.

<sup>6</sup> RASFF Alert Notification 2011.0842

suspect. In this regard, the thus far negative test results from the microbiological tests carried out on seeds cannot be interpreted as proof that a batch is not contaminated with STEC O104:H4 since these results depend on and may be limited by both the analytical and diagnostic performance characteristics as well as by the nature of the sampling plan.

The number of Member States that have received parts of the suspected lots is much larger than previously known and it cannot be excluded that other Member States and third countries were supplied. The trace forward operation is becoming complex and widespread and may take weeks.

This report is one of many elements contributing to the investigation of the cause of this outbreak, and should not be considered in isolation. The findings of this study are consistent with other investigations conducted thus far. Specifically, it supports the hypothesis that the outbreaks in Germany and France are linked, and are due to the import of fenugreek seeds, which became contaminated with STEC O104:H4 at some point prior to leaving the Importer. The contamination of seeds with the STEC O104:H4 strain reflects a production or distribution process which allowed contamination with faecal material of human and/or animal origin. Where exactly this took place is still an open question. Typically such contamination could occur during production at the farm level. While contamination at subsequent steps in, up to, and including at the Importer can not be excluded, it is highly unlikely that contamination could have taken place during transport of the sealed container.

The following several recommendations are made. In the short term, all efforts have to be made to prevent any further exposure of the consumer to seeds from the lots of concern. As a consequence, it seems important that a trace back investigation be initiated on the incriminated lots of fenugreek seeds in the third country from which they were exported to the EU. In addition, it appears essential that Member States and third countries initiate or complete forward tracing of companies receiving the suspect lots. In the medium term, and using the experience of the back tracing of sprout seeds in Europe, appropriate tools for the generic methodology of trace back should be developed and validated at the EU level.

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## **BACKGROUND AS PROVIDED BY EFSA ON 26 JUNE .**

Since May 2011, an outbreak of Shiga-toxin producing *Escherichia coli*- bacteria (STEC), serotype O104:H4 is ongoing in Germany. Currently available epidemiological information from Germany on this outbreak suggests that STEC-contaminated sprouts produced at a sprout farm in Niedersachsen are the vehicle of infection. Epidemiological investigations in Germany have now entered a second phase in order to identify the origin of the O104 STEC contamination in the sprout farm.

On the 24<sup>th</sup> of June, the French authorities informed about an *E. coli* outbreak in the region of Bordeaux. Although the investigations in France are still ongoing six of the cases reported having eaten sprouts at the event on the 8<sup>th</sup> of June; if confirmed, seeds could be seen as the common factor between the two outbreaks in France and Germany. The seeds were supplied by a company in the UK and a RASFF alert was launched.

Only a comprehensive tracing back and tracing forward may allow the identification of the source of the two outbreaks enabling recommendations to be made to Risk Managers that would allow them to take the necessary and appropriate risk mitigating measures.

## **TERMS OF REFERENCE AS PROVIDED BY EFSA.**

EFSA is asked to support the Member States and coordinate the tracing back and tracing forward exercise to investigate the source of the two outbreaks in France and Germany in order to allow Risk Managers to take the necessary and appropriate risk mitigating measures towards potential further outbreaks.

In particular, EFSA should:

- Set up a task force composed of experts from the European Commission, relevant EU Member States, the ECDC and the WHO, as well as EFSA staff members.
- Provide data collection, data management and data analysis support to the Member States.
- Provide a scientific report on the tracing back of seeds in relation to the O104:H4 Shiga toxin-producing *E. coli* (STEC) 2011 outbreak by Thursday 30 June 2011.
- Depending on the outcome of the trace-back exercise, propose an action plan for further tracing forward activities to the EFSA Executive Director. The proposal is to be produced within one week after the publication of the tracing back report.

## ASSESSMENT

### 1. INTRODUCTION

On the 21<sup>st</sup> of May 2011, Germany reported an ongoing outbreak of Shiga-toxin producing *Escherichia coli*- bacteria (STEC<sup>78</sup>), serotype O104:H4 (Frank et al., 2011). In the past STEC O104:H4 had been isolated in humans twice in Germany in 2001 (Mellmann et al., 2008) and once in Korea in 2005 (Bae et al., 2006). In addition, according to the information reported to the European Centre for Disease Prevention and Control (ECDC), a total of 10 persons were infected with other STEC O104 types in the European Union (EU) Member States from 2004 to 2009 (ECDC/EFSA, 2011). In Germany, between the 1<sup>st</sup> of May and the 28<sup>th</sup> of June 2011, 838 Haemolytic Uremic Syndrome (HUS) cases and 3 091 STEC cases with diarrhea have been reported, of which 47 persons have died (RKI, 2011). The last date of onset of disease reported from Germany was on the 23<sup>rd</sup> of June for all EHEC or HUS cases reported, while for confirmed STEC O104:H4 cases the last date of disease onset was the 12<sup>th</sup> of June. Up to the 29<sup>th</sup> of June, 13 EU/EEA<sup>9</sup> countries reported cases associated with the outbreak in Germany for a total of 885 HUS and 3 170 non-HUS STEC cases (ECDC, 2011). Until a recent outbreak in the Bordeaux area in France, with a rare exception, these cases in other European countries had all been linked to travel to northern Germany, where the outbreak had occurred. Updated figures on the epidemiological situation are regularly published on the ECDC website<sup>10</sup>:

Investigations carried out by the German EHEC Task Force started with 5 major clusters. The trace back studies carried out by the German EHEC Task Force ([http://www.bvl.bund.de/EN/01\\_Food/06\\_Task\\_Force\\_EHEC/Task\\_Force\\_EN\\_node.html](http://www.bvl.bund.de/EN/01_Food/06_Task_Force_EHEC/Task_Force_EN_node.html)) and the authorities of Lower Saxony identified one sprout-producing establishment in Niedersachsen (Establishment A) as being the most likely source of STEC O104 contaminated sprouts. In a second step, forward tracing established that all 41 case clusters identified in the outbreak were linked to Establishment A by consumption of sprouts originating from there (Report from BfR, in progress).

The epidemiological information currently available on this STEC outbreak in Germany suggests that STEC O104-contaminated sprouts are the vehicle of infection. This link is based on the results of a cohort study which is corroborated by analysis of trace-back and trace-forward studies carried out by the German EHEC Task Force and the authorities of Lower Saxony. The cohort study carried out by the Robert Koch Institute (RKI 2011b) involved guests of a restaurant which had been established as the place of exposure to the hazard for several cases. The food consumption of restaurant customers during the period of concern was ascertained not only through interviews, but also by checking food delivery lists and receipts. It established a high relative risk to develop bloody diarrhoea related to consumption of sprouts.

The German EHEC Task Force extensively investigated the possible source of infection in Establishment A, in particular water, personnel, and seeds. They showed that personnel were infected. Whereas this may have contributed to the spread of the contamination, there was no indication that personnel had introduced the outbreak strain of *E. coli*. Analyses of water and seeds have all proved negative to date.

The trace forward investigation on seeds carried out by the German EHEC Task Force<sup>11</sup> started at the sprout producing Establishment A in Germany and aimed at establishing the origin of seeds used at

<sup>7</sup> 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. [50 pp.]

<sup>8</sup> In the EU and as reflected in EFSA's work on zoonoses, Shiga-toxin producing *Escherichia coli*-bacteria is referred to as VTEC (verotoxin-producing *E. coli*) but the term STEC is used for this outbreak as it is in line with terminology used by WHO and other organisations.

<sup>9</sup> European Economic Area

<sup>10</sup> [http://ecdc.europa.eu/en/activities/sciadvise/Pages/Epidemiological\\_Updates.aspx](http://ecdc.europa.eu/en/activities/sciadvise/Pages/Epidemiological_Updates.aspx)

<sup>11</sup> [http://www.bvl.bund.de/EN/01\\_Food/06\\_Task\\_Force\\_EHEC/Task\\_Force\\_EN\\_node.html](http://www.bvl.bund.de/EN/01_Food/06_Task_Force_EHEC/Task_Force_EN_node.html)

Establishment A in the period of concern and linked to the German outbreak. On June 13<sup>th</sup>, 41 outbreak clusters could be linked with the Establishment A and the trace back investigations from the 41 identified outbreak clusters confirmed Establishment A as being the source of the EHEC outbreak in Germany.

On Friday the 24<sup>th</sup> of June, France reported<sup>12</sup> a cluster of patients with bloody diarrhoea, after having participated in an event in the Commune of Bègles near Bordeaux on the 8<sup>th</sup> of June. As of 28<sup>th</sup> June, eight cases of bloody diarrhoea and a further eight cases with HUS have been identified. Eleven of these patients, seven women and four men, between 31 and 64 years of age, had attended the same event in Bègles. Infection with *E. coli* O104:H4 has been confirmed for four patients with HUS (ECDC, 2011).

Six of the cases reported having eaten sprouts at the event on the 8<sup>th</sup> of June, and leftovers are being analysed. Outbreak investigation revealed that the suspected sprouts of fenugreek, rocket and mustard had been privately produced in small quantities by the organiser of the event from seeds bought at an approved garden centre, and were not imported from the sprout producer implicated in the outbreak in Germany (INVS, 2011). An analytical epidemiological study is ongoing with the persons that attended the event on 8 June. Local trace back investigations in France suggested that the seeds for sprouting were distributed to the approved garden centre by a UK based company.

The German outbreak strain is a Shiga toxin producing *Escherichia coli* (STEC) that belongs to serotype O104:H4, and has been microbiologically characterised in detail (Bielaszewska, M. et al., 2011; EFSA, 2011). Preliminary information on the microbiological characterisation of the isolates implicated in the French outbreak indicate that many characteristics (*stx2* positive, *eae* negative, *hlyA* negative, multi-resistance pattern to antimicrobials) are common with the German outbreak strain. In addition, the two molecular techniques (Repetative sequence based Polymerase Chain Reaction (Rep-PCR) and pulsed-field gel electrophoresis (PFGE)) used to fully characterise and compare the outbreak strains in France and Germany showed the genetic relatedness of the strains (Gault et al., 2011).

A comprehensive tracing back exercise (followed by tracing forward) should allow the identification of the source of the two outbreaks and contribute to identifying appropriate risk mitigating measures regarding potential further outbreaks. These further investigations particularly aimed at determining whether the origin of the suspected sprout-seeds from the French cluster were linked to the large outbreak in northern Germany. This report documents the steps taken in the trace back process. Any activities already undertaken by the Task Force with regard to tracing forward are also described.

## 2. MATERIALS AND METHODS

### 2.1. Trace back and trace forward investigations

A trace back investigation is the method used to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a food-borne illness investigation. A trace forward investigation aims to find the distribution of the suspected food products along the food chain from the origin in the direction of the consumer.

Using this approach for this investigation, at each step of the delivery/production chain identified in the trace back, further investigation was initiated to try and account for all seeds in any suspect lots. The objective was to identify critical lots and their current location. To this end, detailed information on each lot of seeds was established for each step of the delivery/production chain back to the importation into the EU.

To get precise information, it is necessary to gather data from each step of the supply chain separately. Within a company, the information on the ingredients, their processing and the resulting products are

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<sup>12</sup> RASFF Alert Notification 2011.0842

available. Data on the characteristics, such as incoming and outgoing product names, their lot numbers, arrival and departure dates are normally given on delivery notes and invoices. The data on the quantity of material allows verification that the information on incoming material corresponds with the outgoing and actual stored material. Missing quantities should be identified in a tracing forward step.

## 2.2. Seeds investigated

From the outbreak investigation in Germany, five seed types used for sprouting in Establishment A were postulated as the possible source of the STEC O104:H4. These were alfalfa, fenugreek, lentils (2 different kinds), adzuki beans and radish (see table 1 below). The sprouts were packaged in Establishment A for distribution to customers in two different mixture types “Spicy mixture” and Keimspross-Mischung (called herein “Mild mixture”). Only fenugreek sprouts and lentil sprouts were included in both mixtures. Taking into account the investigation and results of the German EHEC Task Force, there was some evidence already that the fenugreek seeds from Egypt could be involved in the EHEC outbreak (this was the main hypothesis of the German EHEC Task Force).

In France three seed types used for sprouting were implicated in the outbreak investigation, fenugreek, mustard and rocket (Gault et al., 2011).

As fenugreek seeds were identified in both outbreaks, these became the primary focus for the EU trace back. Trace back information from the German outbreak investigation was available on June 13<sup>th</sup> (personal communication from German EHEC Task Force) and for completeness trace back information for mustard and rocket was also requested.

**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), Fénugrec (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>Sinapsis alba</i>	senf (DE) Moutarde blanche (FR)		Yes	
rocket	<i>Eruca sativa</i>	Roquette (FR)		Yes	

\*Keimspross-Mischung

## 2.3. Request for information to the Member States involved

In response to an urgent request from the European Commission, EFSA scientists initiated immediate scientific assistance and were joined by experts from the European Commission, EU Member States, in particular from Austria, France, Germany, Italy, Spain, Sweden, The Netherlands and the United Kingdom, and scientists from the European Centre for Disease Prevention and Control (ECDC), the



World Health Organisation (WHO) and Food and Agriculture Organisation (FAO). Such scientific cooperation proved useful in investigating the recent German outbreak<sup>13</sup>.

The participants in the Task Force are listed below:

- Austria: Bundesministerium für Gesundheit (BMG)
- France: Direction générale de la concurrence, de la consommation et de la répression des fraudes, (DGCCRF) and Direction générale de l'alimentation, (DGAL).
- Germany: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL).
- Italy: Ministero della Salute and Istituto Superiore di Sanità (ISS).
- Spain: Agencia Española de Seguridad Alimentaria y Nutrición (Ministerio de Sanidad , Política Social e Igualdad)
- Sweden: Livsmedelsverket
- The Netherlands: Voedsel en Waren Autoriteit (VWA).
- United Kingdom: Food Standards Agency (FSA) and Health Protection Agency (HPA).
- World Health Organisation (WHO)
- European Centre for Disease Prevention and Control (ECDC)
- Food and Agriculture Organization (FAO)

Technical assistance was received from the BfR. Recognising the importance of harmonising of methods and tools to enable the swift exchange of back tracing results, close cooperation has indeed been established through the mutual exchange of staff between the EFSA Task Force and the German EHEC Task Force.

The concepts developed by the German EHEC Task Force were adapted and used by the EFSA Task Force for collecting the data at a European level, and the method was transferred to EFSA by visiting staff from BfR and EFSA staff visiting BfR. An excel *pro forma* was translated from German to English and modified for use in the EU trace back. The required data items and definitions can be found in appendix 1. To ensure fast and efficient processing, EFSA initially completed the excel *pro forma*.

Information provided by the Rapid Alert System for Food and Feed (RASFF) system was used as the initial source of data. For each business identified in the delivery chain associated with the outbreaks a Microsoft Excel *pro forma* was pre-filled and information about suppliers and customers was requested. Information relating to delivery dates, lot numbers, product names and company names was of particular importance. Where repackaging, mixing, etc. had occurred additional rows were added to the table and information on packing units was required. The Excel request form was then sent to the Member State where the identified business was located, for checking and completion, and supporting documentation i.e. delivery receipts and invoices, were requested. All the documents requested were sent via the RASFF to the EFSA Task Force.

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<sup>13</sup> The process was explained in a letter to the MS from the European Commission referenced REF.Ares(2011)703472 – 29/06/2011.

## 2.4. Data processing

The system developed for the tracing back and the tracing forward for the investigation of the source of the sprouts is as follows:

- After the identification of a food item (i.e. type of seed), it is followed through the specific supply chain. Companies in the supply chains are identified by names, addresses and where available identification number, such as value added tax (VAT) number (this data is not shown in this report).
- In a further revision, several criteria for consistency checking are used, i.e. checking the lot numbers, seed names, quantities, expiration dates and delivery timelines through the supply chain. These criteria restrict the number of food supply chains for the selected food item to the consistent (valid) ones.
- Only those supply chains linked to outbreak clusters are selected in order to identify any common characteristics that would lead to a suspected source (e.g. the same lot number for the food items or potential cross contamination occurring at the same time). Products which are still in storage are considered to be an endpoint of the food supply chain.

Data on single parts of the food supply chain were gathered using spreadsheets (MS Excel) for each company. A relational database (HSQLDB version 2.2.4) was used to manage the data/information from the tracing. Additional processing was done using the statistical package SAS version 9.2.

## 2.5. Analysis

Summaries of quantities of seeds traded for any suspected lot are presented by country and number of companies.

The data collected on each specific transfer allows the investigation of the relationship between seed suppliers, distributors and recipients and sprout producers and recipients i.e. a trace back and a trace forward for each type of seed. These relationships can be plotted in distribution networks to show their complexity and the number of companies involved. The primary interest is in identifying common links between the clusters of cases and the source of the suspected seeds.

A graphical presentation of the relationships between suppliers, distributors and sprout producers aided the assessment of the information gathered from the back and forward tracing. Each supplier, distributor and sprout producer is represented as a node (point). If any transfer (sale) of seeds occurred then these are represented by an arrow linking the two appropriate nodes indicating the direction in which the seeds were transferred. By visualising the networks, it was possible to see if there are any common nodes between the clusters of cases. The analysis was conducted using the “network” package (Butts, 2008) from R (R Development Core Team, 2010).

In the data analysis the different parts of the chain were combined to visualise the flow of the potentially contaminated material through the food chain. A given business can be both a receiver and a supplier.

### 3. RESULTS

#### 3.1. Analysis of data provided by the concerned Member States on tracing back

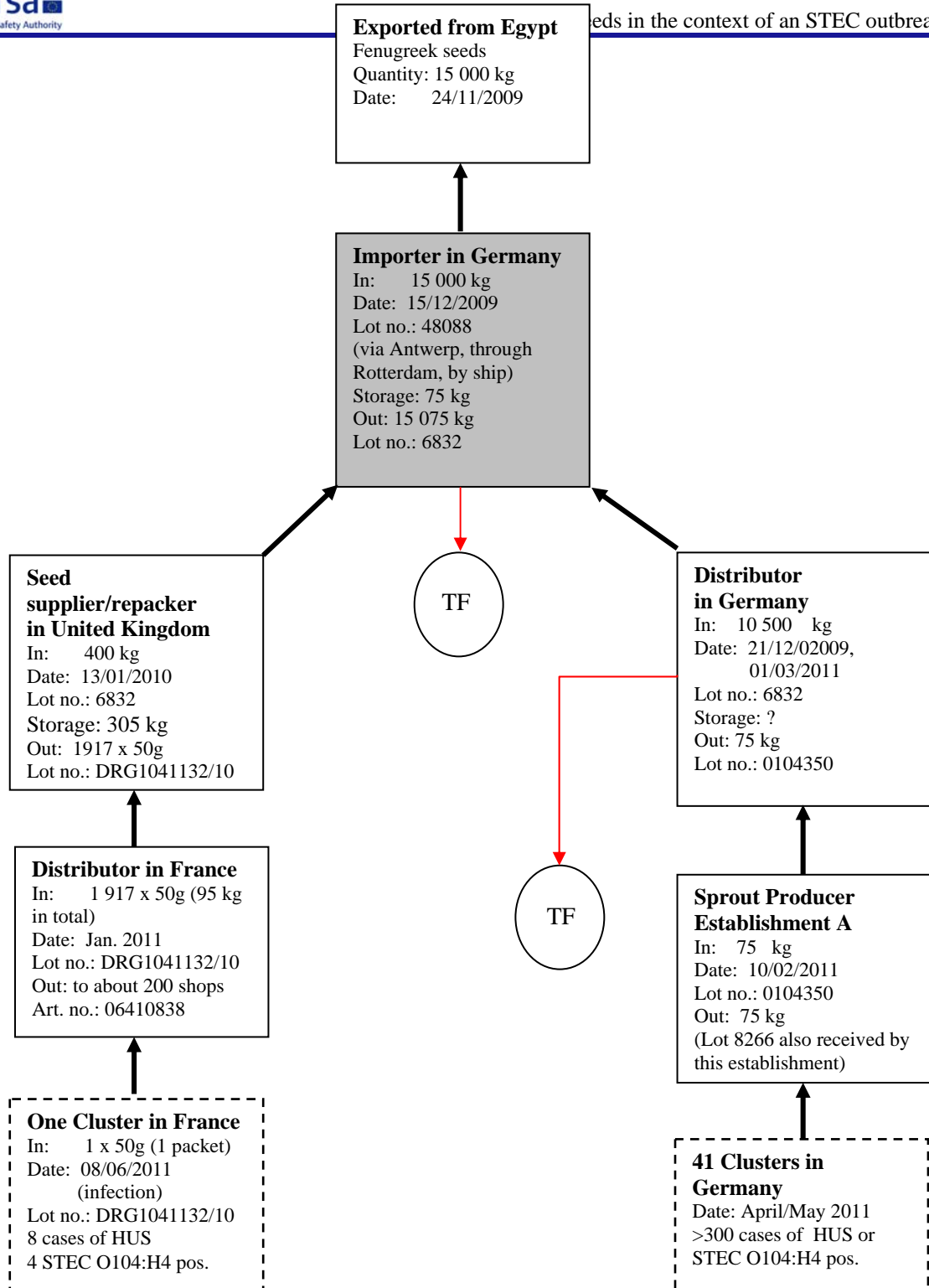
The sprout producer in Germany (Establishment A), that was linked to 41 clusters (German EHEC Task Force report in preparation), received 75 kg fenugreek seeds which could be traced back to the import of a consignment (# 48088) of 15 000 kg which left Egypt by boat on the 24<sup>th</sup> of November 2009 (port of loading was Damietta). The consignment was sent in a customs' sealed container. The boat arrived at Antwerp (port of discharge) and was sent by barge to Rotterdam (port of delivery) where the customs formalities took place. The customs' sealed container was sent by truck in the afternoon of 14<sup>th</sup> of December to a company in Germany (The Importer), arriving there in the morning of the 15<sup>th</sup> of December. In Germany, the container was 'customs cleared for free circulation'. The Importer redistributed 14 925 kg and retained 75 kg in storage.

Other imports of fenugreek seeds from the same exporter in Egypt by the Importer in Germany took place (see appendix B for the period 2008-2011). There were also other imports by the Importer in Germany of fenugreek during this period, through another company in Egypt. It is noteworthy that during this period substantial quantities (about 3 000 tonnes in 2010) of fenugreek were imported into the EU from different countries (see Appendix C).

In particular, the Importer received another lot (# 8266) of 10 000 kg exported by the same company in Egypt in October 2010. It should be noted that at the time of the outbreak in Germany both of these lots were possibly in use at Establishment A (i.e. the sprout producer). From this lot, Establishment A received 75 kg on the same day as it received the 75 kg from lot 48088. There is no clarity as to whether these deliveries were mixed and when exactly each was used. Hence, both lots are investigated as it is not possible to determine if only one of these lots was implicated in the German outbreak.

As indicated, the outbreak investigation in France revealed that the suspected sprouts of fenugreek had been privately produced in small quantities from a **single 50 g packet** by the organiser of the event from seeds bought at an approved garden centre, and were not imported from the sprout producer implicated in the outbreak in Germany (INVS, 2011). The seeds were supplied to French garden centers from a UK seed supplier/repacker as 1 917 packets of 50 g (total of some 95 kg). These were disseminated in small batches of 5 to 125 seed packets to more than 200 branches in France. The RASFF alert notification (2011.0842-add03) reported that these seeds also came from lot # 48088 and were received by the UK seed supplier/repacker from the Importer based in Germany on the 13<sup>th</sup> of January 2010. This UK seed supplier/repacker sent this consignment to France from January 2011 onwards. The UK seed supplier still has 305 kg in storage that have been retained. In the time period 01/07/10 to 27/06/11, 1 013 packets from a different lot were also supplied to the French garden centre chain. Further information on this shipment is currently being sought.

Figure 1 graphically presents the outcome of the back tracing to lot # 48088 of fenugreek seeds imported from Egypt. It links the outbreaks in Germany (41 clusters) and France (1 cluster). It is recognised that there is a difference between what was declared to have been imported and delivered to the Importer versus what was recorded to have left this establishment plus what is still in storage (about 1%). It should be noted that the weight of the packaging material was estimated to represent in itself an additional 1.2% (approximately 180 kg) of the gross weight. According to the documents provided at import, the net weight of the consignment was 15 000 kg (gross weight 15 180 kg). The consignment was composed of 600 paper bags (net weight 25 kg each).



**Figure 1:** Network graphic showing the trace back (black thick arrows) (incl. lot no., quantities and dates) of fenugreek seeds lot no. 48088 from the two clusters in Germany and France via all identified distributors/producers to the company in Egypt. The red thin arrows indicate the ongoing tracing forward work done and are discussed in chapter 3.2. TF=Trace forward, see section 3.2

### 3.2. Analysis of data provided by the concerned Member States on tracing forward

The forward tracing for lot # 48088 (as well as other lots) imported from Egypt is ongoing, however the information gathered to date shows that the Importer in Germany distributed this lot as follows:

- 10 500 kg were received by a single large distributor in Germany
- 3 550 kg were received by 9 other companies in Germany
- 400 kg were received by one company in the UK
- 250 kg were forwarded via an Austrian distributor and received by one company in Austria
- 375 kg were received by one company in Spain

This represents a total of 15 075 kg. For all the suspected lots, the BVL is currently checking on 17 companies that were supplied by the Importer. For one of them, a single large distributor, information has already been received. It shows that it in turn sold fenugreek seeds from this lot to 70 different companies, of which 54 are based in Germany and 16 in 11 other European countries.

It was not possible for Germany and other involved Member States to provide exhaustive trace forward information for timely inclusion in this report.

#### 4. DISCUSSION

An EFSA Task Force composed of experts from the European Commission, relevant EU Member States, the ECDC, the WHO and the FAO, as well as EFSA staff members was set up.

The analysis and discussion in this report focuses primarily on data obtained from the back tracing process to identify the source of the seeds suspected of causing the STEC O104:H4 outbreaks. The German EHEC Task Force trace back methodology was successfully extended to support the investigations involving five other European Member States.

The comparison of the back tracing information from the French and German outbreaks leads to the conclusion that lot # 48088 of fenugreek seeds imported by the Importer, from Egypt, is the common link for these two outbreaks. The implication is that the seeds became contaminated with STEC O104:H4 at some point prior to leaving the Importer. Such contamination typically reflects a production or distribution process which allowed contamination by faecal material of human and/or animal origin. The results show that from this Importer, seeds were sold to many businesses in Germany and many other countries in Europe. As the case of the UK shows, the seeds may pass through many Member States before being used or consumed. Many of the seeds bought by the Importer may already have been used. However it is noted that some are still present in the supply chain.

Uncertainties on the origin and number of batches involved can be linked to possible incorrect information about the seeds under suspicion. A major difficulty and source of possible errors is that the items, their naming and/or identification numbers might change at each step of the whole supply chain, or errors might have occurred in the reporting. In addition, missing information on possible cross contamination due to handling such as repackaging and mixing, need to be taken into account when doing further trace forward. This becomes even more evident considering that several lots from the same exporter were handled by the Importer during the same period and that, at least in Germany, it could be demonstrated that more than one lot of fenugreek seeds was used for the production of sprouts by Establishment A during the likeliest time of exposure to the consumer. The same scenario is possible for the UK distributor to France but this is still under investigation.

#### 5. CONCLUSIONS

The comparison of the back tracing information from the French and German outbreaks leads to the conclusion that a lot (# 48088) of fenugreek seeds imported from Egypt, is the most likely common link, although it cannot be excluded that other lots coming through the same production/supply chain may be implicated.

Given the possible severe health impact of exposure to a small quantity of contaminated material, and, in the absence of information regarding the source and means of contamination and possible cross-contamination, it seems appropriate to consider all lots of fenugreek for the period 2009-2011 from the identified exporter as suspect (Appendix B). In this regard, the thus far negative test results from the microbiological tests carried out on seeds cannot be interpreted as proof that a batch is not contaminated with STEC O104:H4 since these results depend on and may be limited by both the analytical and diagnostic performance characteristics as well as by the nature of the sampling plan.

The number of Member States that have received parts of the suspected lots is much larger than previously known and it cannot be excluded that other Member States and third countries were supplied. The trace forward operation is becoming complex and widespread and may take weeks.

This report is one of many elements contributing to the investigation of the cause of this outbreak, and should not be considered in isolation. The findings of this report are consistent with other investigations conducted thus far. Specifically, it supports the hypothesis that the outbreaks in Germany and France are linked, and are due to the import of fenugreek seeds from Egypt, which became contaminated with STEC O104:H4 at some point prior to leaving the Importer. The

contamination of seeds with the STEC O104:H4 strain reflects a production or distribution process which allowed contamination with faecal material of human and/or animal origin. Where exactly this took place is still an open question. Typically such contamination could occur during production at the farm level.

## RECOMMENDATIONS

### Short term

- All efforts have to be made to prevent any further exposure of the consumer to seeds from the lots of concern. As a consequence, it seems important that a trace back investigation be initiated on the incriminated lots of fenugreek seeds in the third country from which they were exported to the EU.

In addition, it appears essential that Member States and third countries initiate or complete forward tracing of companies receiving the suspect lots.

### Medium term

- Using the experience of the back tracing of sprout seeds in Europe, appropriate tools for the generic methodology of trace back should be developed and validated at the EU level.



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## APPENDIX/APPENDICES

### A. FORM DEVELOPED TO BE USED IN TRACE BACK INVESTIGATIONS

<b>Serial number</b>	Identification of your entry in the table for later queries. Identification with abbreviation and serial number (e.g. AAW1).
<b>Contact Region</b>	Notifying member state, province
<b>Contact person for questions (Name/ Tel./ E-mail)</b>	Name and telephone for urgent on-site queries (inspector)
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) Name</b>	Name. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) Address</b>	Address. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) Zip Code</b>	Postcode. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) City/Town</b>	Town/city. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) Federal state/ Province/ [...]</b>	E.g. Federal German 'Land' responsible. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Customer/ Destination/ Purchaser of the article/ product from the business concerned (deliverer) VAT number</b>	if available, please state company number and/or VAT No. For clarity and retrieval purposes.
<b>Processing of the article delivered to the customer/purchaser</b>	Processing of the "business concerned (deliverer)" to produce the article delivered to the customer/purchaser, e.g. mixture, repacking etc.
<b>To the customer/ purchaser delivered article Intended use</b>	Use of the product intended by the "business concerned (deliverer)", e.g. for food etc.
<b>To the customer/ purchaser delivered article Name</b>	Name of the article/ product which was delivered by the "business concerned (deliverer)" to the customer/ purchaser. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>To the customer/ purchaser delivered article Article number</b>	Number of the articles/ products which were delivered by the "business concerned (deliverer)" to the customer/ purchaser. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Date of delivery (arrival) to the customer/ purchaser</b>	Arrival/ delivery date of the articles/ products at the customer/ purchaser location.

If <b>Number of the largest packing unit</b> (e.g. cardboard box, boxing pallet and the like., which contain smaller packing units)	true: Number of the largest packing unit (e.g. pallet) which consists of smaller packing units (e.g. bags).
If <b>Name of the largest packing unit</b> (e.g. cardboard box, boxing pallet and the like., which contain smaller packing units)	true: Name of the largest packing unit (e.g. pallet) which consists of smaller packing units (e.g. bags).
<b>Number of smaller packing unit</b> (e.g. sack, bag, tray, and the like)	Number of the smaller packing unit (e.g. bags) which contains the article/ product.
<b>Name of smaller packing unit</b> (e.g. sack, bag, tray, and the like)	Name of the smaller packing unit (e.g. bags) which contains the article/ product.
<b>Amount (Content of the smaller packing unit)</b>	Amount of articles/ products within the smaller packing unit.
<b>Unit (e.g. g/kg/l )</b>	Unit for the amount of articles/ products within the smaller packing unit.
<b>Lot-/ Charge number</b>	Appropriate specification of the food disposed of, e.g. lot number, batch number, order number. These details serve to trace the ingredients back in the case of suppliers. In the case of a restaurant, the menu numbers could be given here.
<b>Expiration date</b>	Date of minimum durability. These details serve to trace the ingredients back in the case of suppliers.
<b>Additional information: e.g. invoice number to customer/ purchaser</b>	Please describe the source of your information, e.g. delivery receipt number, telephone call with contact, personal observation, etc.
<b>Business concerned (deliverer) Name</b>	Name of the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Business concerned(deliverer) Address</b>	Address of the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Business concerned(deliverer) Zip Code</b>	Postcode of the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Business concerned (deliverer) City/ Town</b>	City/ town of the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Business concerned (deliverer) Federal state/ Province/ [...]</b>	E.g. Federal German 'Land' responsible of the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Business concerned(deliverer) VAT number</b>	If available, please state company number and/or VAT No. For clarity and retrieval purposes.
<b>Product name of the supplier (pre-deliverer) of the Business concerned (deliverer)</b>	Name of the article/ product which was delivered by supplier (pre-deliverer) to the the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Article number of the supplier (pre-deliverer) of the Business concerned (deliverer)</b>	Number of the Articles/ products which were delivered by supplier (pre-deliverer) to the "business concerned (deliverer)". Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Date of delivery (arrival) from the supplier (pre-deliverer) to the Business concerned (deliverer)</b>	Arrival/ delivery date of the articles/ products at the location of the business concerned (deliverer).

If <b>Number of the largest packing unit</b> (e.g. cardboard box, boxing pallet and the like., which contain smaller packing units) true:	Number of the largest packing unit (e.g. pallet) which consists of smaller packing units (e.g. bags).
If <b>Name of the largest packing unit</b> (e.g. cardboard box, boxing pallet and the like., which contain smaller packing units) true:	Name of the largest packing unit (e.g. pallet) which consists of smaller packing units (e.g. bags).
<b>Number of smaller packing unit</b> (e.g. sack, bag, tray, and the like)	Number of the smaller packing unit (e.g. bags) which contains the article/ product.
<b>Name of smaller packing unit</b> (e.g. sack, bag, tray, and the like)	Name of the smaller packing unit (e.g. bags) which contains the article/ product.
<b>Amount (Content of the smaller packing unit)</b>	Amount of articles/ products within the smaller packing unit.
<b>Unit (e.g. g/kg/l )</b>	Unit for the amount of articles/ products within the smaller packing unit.
<b>Lot-/ Charge number</b>	Appropriate specification of the food disposed of, e.g. lot number, batch number, order number. These details serve to trace the ingredients back in the case of suppliers. In the case of a restaurant, the menu numbers could be given here.
<b>Expiration date</b>	Date of minimum durability. These details serve to trace the ingredients back in the case of suppliers.
<b>Additional information: e.g. invoice number to customer/ purchaser</b>	Please describe the source of your information, e.g. delivery receipt number, telephone call with contact, personal observation, etc.
<b>Supplier Name (pre-deliverer)</b>	Name. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Supplier Address (pre-deliverer)</b>	Address. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Supplier Zip Code (pre-deliverer)</b>	Postcode. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Supplier City/ Town (pre-deliverer)</b>	Town/city. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Supplier Federal state/ Province/ [...] (pre-deliverer)</b>	E.g. Federal German 'Land' responsible. Please ensure correct spelling since these entries are needed for sorting and comparison purposes.
<b>Supplier VAT number (pre-deliverer)</b>	if available, please state company number and/or VAT No. For clarity and retrieval purposes.
<b>Additional information: Delivery chain end? (yes/ no)</b>	Has the end of the chain been reached? Yes, No
<b>Additional information: Reason for end of delivery chain (e.g. producer, importer, and the like)</b>	If YES (supplier is not being traced further), please give reason, e.g. supplier unknown, supplier abroad (importer), no upstream supplier, since producer. If NO: please complete 'lists still to be requested'. (Note that the supplier still has to be written to and has to report its upstream suppliers.)

<b>Additional information: General remarks</b>	Please make a note here of general irregularities in the business concerned, e.g. workers sick (with EHEC).
<b>Additional information Country of origin/ Producing country</b>	Country of origin of the seeds.
<b>Additional information Source of information</b> (e.g. delivery orders, invoice, and the like)	Please describe the source of your information, e.g. delivery receipt number, telephone call with contact, personal observation, etc.
<b>File location of the information source</b>	Where is the source stored? e.g. FIS-VL file
<b>Questions/ comments of the person who enters the data (e.g. to the controller)</b>	Question to the controller? For recording purposes and also as a checklist for return calls to the controller.
<b>Ordering of further delivery orders (e.g. from the pre-supplier)</b> (yes/ no)	Is a further trace-back order started? Yes, No.

**B. FENUGREEK IMPORTS FROM EGYPT TO THE GERMAN IMPORTER 2008-2011**

<i>Product name</i>	<i>Import date</i>	<i>Expiry date</i>	<i>Egyptian lot number</i>	<i>Import number</i>	<i>Importer lot number</i>	<i>Amount (kg)</i>
Organic fenugreek "Bockshornklee"	2008			542/08	5161	
Organic fenugreek "Bockshornklee"	15.12.2009	11/2011	48088	512/09	6832	15,000
Organic fenugreek "Bockshornklee"	28.10.2010	09/2012	8266	345/10	8223	10,000
Organic fenugreek "Bockshornklee"	14.02.2011	12/2014	2660002	51/11A	8710	12,000

**C. 2010 EU IMPORTS OF “FENUGREEK SEED”**

<b>Importer</b>	EU27_Extra	India	Egypt	Turkey	Thailand	Morocco	Australia	Sri Lanka	China	Singapore	Brazil	Pakistan	Israel	Jordan	Syria	Lebanon	Barbados	Malaysia
<b>EU27</b>	2861	2496	77	67	58	53	44	14	13	7	7	4	4	4	4	3	3	1
<b>United Kingdom</b>	950	800	14	2	57	36		14	10			3	4	3			3	1
<b>Germany</b>	635	551	52	28				0	3			2						
<b>France</b>	491	457	1	12		3				7	7					3		
<b>Netherlands</b>	477	411	4	15			44								3			
<b>Austria</b>	68	65		3														
<b>Belgium</b>	62	39	6	2		14								1		0		
<b>Spain</b>	44	44								0								
<b>Poland</b>	44	44																
<b>Italy</b>	32	32																
<b>Greece</b>	20	20																
<b>Estonia</b>	14	14																
<b>Bulgaria</b>	8	7		1														
<b>Sweden</b>	7	7		0	0													
<b>Denmark</b>	4	3	0		0			0										
<b>Romania</b>	4			4														
<b>Cyprus</b>	3	2						0							1			
<b>Finland</b>	1	1													0			
<b>Portugal</b>	1	1																
<b>Ireland</b>	0	0																
<b>Slovenia</b>	0	0																

Notes: Product by CN: 09109910-fenugreek seed; Quantities in tonnes; data extracted on 29/6/2011 from Eurostat Comext database. EU27\_Extra: total imports from third countries