TECHNICAL REPORT

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Type E botulism associated with fish product consumption – Germany and Spain

European Food Safety Authority

European Centre for Disease Prevention and Control

Abstract

Five cases of botulism caused by botulinum neurotoxin type E (BoNT E) have been diagnosed in November 2016 in two countries: three cases in males in Germany and two cases in partners (one male and one female) in Spain. Two German and two Spanish cases had symptom onset in early November and the third German case at the end of November. All five cases have a Russian background and they had all consumed dried and salted roach. Two samples taken from products at one of the patient's homes have been confirmed to contain the BoNT E gene. This product was distributed to 15 European Union (EU) and European Economic Area (EEA) countries, including stores specialising in eastern European food. A sixth patient with a Kazakh background was reported by Germany with onset of illness on 11 December 2016. This patient had consumed dried and salted roach. Household leftovers of the fish product consumed by the patient were reported to be positive for BoNT E gene. For this outbreak, the populations at greatest risk are those who traditionally consume salted and dried roach ('vobla'). The risk for other population groups is very low in EU/EEA. Extensive recalls of the implicated food product have been undertaken in the EU/EEA since 25 November 2016. Targeted public warnings have also been issued in Germany, Spain and the other countries where the implicated fish product was distributed. In view of the rapid initiation of recalls and targeted public warnings of the risk, the risk that new cases linked to the outbreak will appear in the EU/EEA is considered to be very low. The main potential residual risk of exposure relates to consumers still keeping the product at home who may not been made aware of the public warnings, or stores that may not have received notification of the recall and are continuing to sell the implicated fish product. There is no risk of person-to-person transmission. This cross-border botulism outbreak highlights the importance of rapid information exchange between food safety and public health authorities so that control measures can be implemented without delay.

Key words: Botulism, botulinum neurotoxin type E, fish product, Germany, Spain

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RAPID OUTBREAK ASSESSMENT

Type E botulism associated with fish product consumption – Germany and Spain

20 December 2016

Main conclusions and options for response

Five cases of botulism caused by botulinum neurotoxin type E (BoNT E) have been diagnosed in November 2016 in two countries: three cases in males in Germany and two cases in partners (one male and one female) in Spain. Two German and two Spanish cases had symptom onset in early November and the third German case at the end of November. All five cases have a Russian background and they had all consumed dried and salted roach. Two samples taken from products at one of the patient's homes have been confirmed to contain the BoNT E gene. This product was distributed to 15 European Union (EU) and European Economic Area (EEA) countries, including stores specialising in eastern European food. A sixth patient with a Kazakh background was reported by Germany with onset of illness on 11 December 2016. This patient had consumed dried and salted roach. Household leftovers of the fish product consumed by the patient were reported to be positive for BoNT E gene.

For this outbreak, the populations at greatest risk are those who traditionally consume salted and dried roach ('vobla'). The risk for other population groups is very low in EU/EEA. Extensive recalls of the implicated food product have been undertaken in the EU/EEA since 25 November 2016. Targeted public warnings have also been issued in Germany, Spain and the other countries where the implicated fish product was distributed.

In view of the rapid initiation of recalls and targeted public warnings of the risk, the risk that new cases linked to the outbreak will appear in the EU/EEA is considered to be very low. The main potential residual risk of exposure relates to consumers still keeping the product at home who may not been made aware of the public warnings, or stores that may not have received notification of the recall and are continuing to sell the implicated fish product. There is no risk of person-to-person transmission.

This cross-border botulism outbreak highlights the importance of rapid information exchange between food safety and public health authorities so that control measures can be implemented without delay.

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Source and date of request

European Centre for Disease Prevention and Control (ECDC) and European Food Safety Authority (EFSA) decision, 1 December 2016.

Public health issue

This document assesses the risk to human health posed by a multi-country incident of botulism neurotoxin type E, possibly associated with consumption of a commercially-available dried and salted fish product.

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Disease background information

Botulism is a serious and potentially fatal paralytic illness caused by a nerve toxin that is produced by anaerobic clostridia bacteria, most often *Clostridium botulinum*. Clostridia occur commonly in soil, dust, the aquatic environment and in the intestines of animals. Consequently, *C. botulinum* can be present in a wide range of foods. Foodborne botulism is caused by the consumption of food where germination and multiplication of *C. botulinum* has occurred, accompanied by neurotoxin production. Botulism from commercially prepared food is usually associated with a failure during the preparation process, or a problem with container/pack integrity. Historically a high percentage of botulism outbreaks have been associated with home-preserved foods [1].

There are three forms of disease depending on the site of toxin production: foodborne (ingestion of pre-formed toxin); infant and wound botulism. Botulism is not spread from one person to another [2]. The botulinum neurotoxin (BoNT) produces descending, flaccid paralysis without fever. Patients typically present with difficulty in speaking, seeing and swallowing. If untreated, paralysis may progress to the arms, legs, trunk and respiratory muscles, requiring mechanical ventilation. Treatment includes antibiotics (wound botulism) and the administration of antitoxins, usually bivalent AB or trivalent ABE antitoxin [3]. The case–fatality rate is around 5 to 10% for adequately treated patients.

The botulinum neurotoxins have traditionally been divided into seven toxin types (A to G) according to their antigenic properties [4]. A new toxin type H has been discovered recently in the US [5]. *C. botulinum* exhibits phenotypic and genetic heterogeneity, and group I (proteolytic, able to produce BoNT A, B and F) and group II (non-proteolytic, able to produce BoNT B, E or F) are responsible for food-borne botulism [6]. Foodborne botulism outbreaks involving Group II BoNT E have been frequently associated with the consumption of fish and fish products [6,7], probably due to temperature abuse as this group of bacteria is psychrotrophic and grows well in anaerobic, chilled environments [4,6]. While *C. botulinum* is the most common species producing botulinum neurotoxins, rare cases of BoNT E have been caused by *C. butyricum* [8].

Botulism is a rare disease in the EU/EEA, with 85 to 137 confirmed cases having been reported to ECDC annually during the period 2010–2015. Italy accounted for 28% of the cases, followed by Romania (19%). Cases have been reported in all age groups, with most cases among those aged 25–44 years (32%) and 45–64 years (31%). Cases have been more common among men than women (male/female ratio 1.3:1). The majority (98%) of infections were domestically acquired. Neurotoxin type was introduced in the data collection from 2013 and only four cases of type E and four cases with neurotoxin type B were reported in the period 2013–2014 (no neurotoxin type E cases reported in 2015).

More information about botulism is available on ECDC's website: http://ecdc.europa.eu/en/healthtopics/botulism/Pages/index.aspx

Reported foodborne outbreaks due to *Clostridium botulinum* toxins

In 2015, 24 outbreaks caused by *C. botulinum* toxins were reported by 10 EU Member States, involving 60 cases, 43 of which were hospitalised [9]. Although the reporting rate of outbreaks caused by *C. botulinum* toxins was low (0.01 per 100 000 population), toxins produced by *C. botulinum* were associated with the highest proportion of cases hospitalised. The number of outbreaks reported in 2015 increased compared with 2014, when nine outbreaks were reported. The majority of outbreaks caused by *C. botulinum* toxins were reported to be household outbreaks.

In 2015, the evidence supporting the implication of the food vehicle was reported to be strong for 15 outbreaks (out of 24), which were mainly associated with the consumption of 'pig meat and products thereof' (four outbreaks), other meat and meat products (four outbreaks) and 'canned food products' (three outbreaks). The detailed frequency distribution of the food vehicles reported in strong-evidence foodborne-outbreaks caused by *C. botulinum* toxins in 2015 and over the previous five years is presented in Table 1.

During the period 2010–2014, a total of 62 foodborne outbreaks caused by *C. botulinum* toxins were reported by 13 EU Member States. For 36 of these foodborne outbreaks, the evidence supporting the implication of the food vehicle was reported to be strong. During this five-year period, the most frequently reported food vehicles were 'vegetables and juices and other products thereof' (seven outbreaks) and 'canned food products' (six outbreaks), followed by 'pig meat and products thereof' (five outbreaks), 'other meat and meat products' (three outbreaks) and 'fish and fishery products' (two outbreaks). Detailed information on the implicated food vehicle was not provided for 13 of the 36 strong-evidence outbreaks (reported as 'other foods').

Information on the type of BoNT associated with the outbreaks has rarely been reported to EFSA. During the period 2010–2015, this information was only available for seven out of 86 foodborne outbreaks reported to be caused by *C. botulinum* toxins. No outbreaks due to BoNT E were reported among the seven outbreaks for which this information was provided.

Table 1. Reported strong-evidence foodborne outbreaks caused by *Clostridium botulinum* toxins, EU Member States, 2010–2015

Implicated food vehicle	No. of outbreaks in 2010	No. of outbreaks in 2011	No. of outbreaks in 2012	No. of outbreaks in 2013	No. of outbreaks in 2014	No. of outbreaks in 2015	Total outbreaks 2010-2015
Canned food products		1	1	2	2	3	**9**
Pig meat and products thereof	3	2				4	**9**
Vegetables and juices and other products thereof	1	3	1		2		**7**
Other meat and meat products [(a)]		1		2		4	**7**
Fish and fishery products	1			1			**2**
Cereal products including rice and seeds/pulses (nuts, almonds)						1	**1**
Mixed food						1	**1**
Other foods	2	5	3	2	1	1	**14**
Unknown						1	**1**
Total outbreaks	**7**	**12**	**5**	**7**	**5**	**15**	**51**

Note: information summarised in this table is based on Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC.

(a): Other meat and meat products include information on 'other meat and meat products' and 'other, mixed or unspecified poultry meat and products thereof'.

Threat description

The European outbreak case definition

A confirmed outbreak case:

- A resident in EU/EEA with a clinical symptoms compatible with botulism and disease onset on or after 1 November 2016

  AND
- Detection of botulinum neurotoxin (BoNT) E or BoNT E- coding gene in a clinical sample

  AND
- Exposure to salted and dried roach.

A probable outbreak case:

- A resident in EU/EEA with a clinical symptoms compatible with botulism and disease onset on or after 1 November 2016

  AND

- Exposure to salted and dried roach.

Event background information

On 22 November 2016, Germany reported two laboratory-confirmed cases of foodborne botulism BoNT -type E in adult males from two neighbouring states with onset dates in early November to the Epidemic Intelligence Information System for Food- and Waterborne Diseases and Zoonoses (EPIS-FWD). Both patients had clinical symptoms compatible with botulism and their stool samples were confirmed positive for gene-encoding BoNT E in the German Consultant Laboratory for botulism. Both patients had eaten 'dried and salted roach' (*Rutilus rutilus*). On 28 November 2016, Germany posted an alert in the Early Warning and Response System (EWRS). On 7 December, Germany updated EWRS with information on an additional case, later confirmed, from a third German state with clinical symptoms of botulism and disease onset 24 November 2016. The patient had eaten dried and salted roach (*Rutilus rutilus*). Analyses of faecal samples were initiated in order to verify the botulism. The three German patients have a Russian background. On 19 December 2016, Germany reported a fourth confirmed case of foodborne botulism in a female with a Kazakh background through EWRS. She had consumed dried and salted roach and fell ill on 11 December 2016.

On 25 November 2016, Spain reported two probable cases of botulism in partners (one male and one female). The cases were Russian nationals with residence in Spain who consumed dried and salted fish 'Plötze Salz' (*Rutilus rutilus*) and developed symptoms on 5 and 6 November 2016. The results of the clinical samples tested were negative.

Microbiological and environmental investigations of the food

This section summarises the information on traceability and microbiological investigations on food related to this outbreak that has been reported to the Rapid Alert System for Food and Feed (RASFF) (last update: 15 December 2016), as well as additional information reported by the competent authorities of the interested Member States to EFSA in the context of this outbreak (last update: 19 December 2016). The graphical representation of the traceability information available in RASFF is illustrated in Figure 1.

On 25 November 2016, Germany issued a RASFF message (2016.1621) pertaining to the recall of 'dried and salted roach (*Rutilus rutilus*)' distributed within Germany and to other EU/EEA Member States. Two fish samples taken from a patient's home were tested with real-time PCR and found to be positive for the BoNT E -gene. Colonies of *Clostridium botulinum* isolated from these samples were also tested and found positive to BoNT E -gene. The two samples were negative when tested with mouse-bioassay. The first two German cases bought and consumed the fish product of concern from separate locations of the same chain of grocery stores belonging to wholesaler A, which received the product from a producer in the Netherlands (Producer A) (Figure 1). The German wholesaler A also received 'dried and salted roach (*Rutilus rutilus*)' from another two producers in Lithuania. Additional epidemiological investigations and analyses were carried out by the Lithuanian authorities. Based on the current state of available information, there is no evidence of their involvement in the outbreak cases. Wholesaler A further distributed the fish product originating from Producer A to Germany, France, Italy and two wholesalers in Spain (including wholesaler G, mentioned below). The Dutch producer A also delivered fish to additional wholesalers in Germany (wholesalers B, C, D and E) and the United Kingdom (wholesaler F). Each of these German wholesalers further distributed the fish product to Germany and other countries, including Austria, Belgium, the Czech Republic, Denmark, Ireland, Portugal, Slovenia, Sweden, and Switzerland, as indicated in Figure 1. Sweden further distributed the product originating from the German wholesaler E to Norway (Figure 1). The third German case consumed 'dried and salted roach (*Rutilus rutilus*)' that he had bought in a store to which the implicated product (as indicated in the RASFF notification) was delivered from wholesaler A (Figure 1). According to the information available, it was not possible to trace this product further back to the producer level. According to the information reported by Germany in EWRS on 19 December, the leftover dried and salted roach consumed by the fourth German case was reported to be PCR-positive for BoNT E gene. The consumed dried fish was bought on 12 November 2016, before the recall of the implicated products. Since no traceability information on the fish product consumed by the fourth German case is currently available in RASFF, this case has not been included in Figure 1.

Both Spanish cases had ingested dried and salted roach (*Rutilus rutilus*) and according to the label, the product was distributed from a Spanish wholesaler (wholesaler G) and was manufactured by the Dutch producer A (Figure 1).

The competent authorities in the Netherlands reported that Producer A has collected single samples from different batches of the implicated product to test for the presence of the BoNT gene using real-time PCR. All tested samples were reported to be negative for the gene coding for botulinum neurotoxins A, B, E and F. Producer A did not distribute the implicated product further within the Dutch market.

Restrictive measures were taken (i.e. recall from consumer, withdrawal from the market) and targeted public warnings issued in Germany, Spain and the other countries where the fish product concerned by the RASFF notifications was distributed.

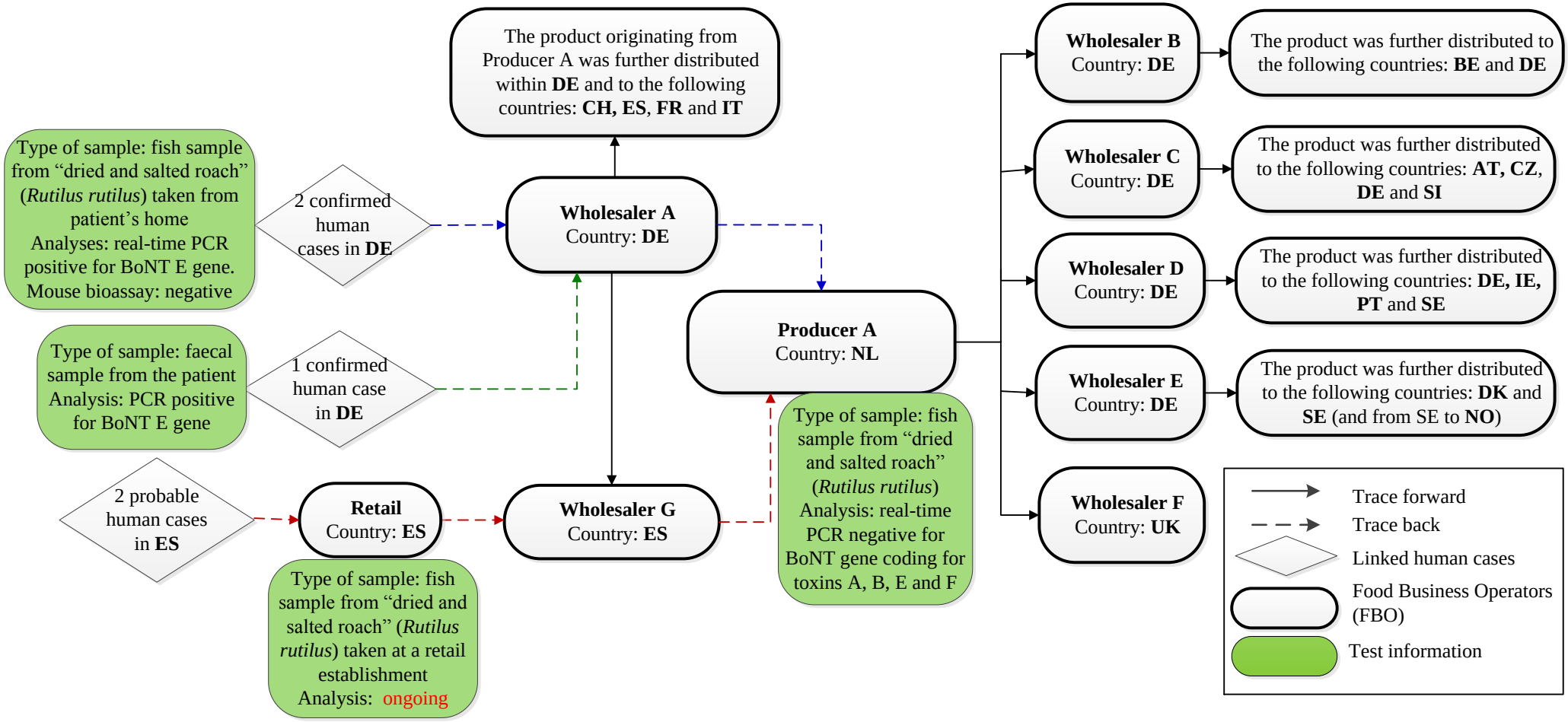
ECDC and EFSA threat assessment for the EU/EEA

There are four confirmed botulism E cases in Germany and two probable cases in Spain. The clustering in time and very likely link to the consumption of commercially available dried and salted roach (*Rutilus rutilus*) indicates that this fish product may be a common source. Five human cases have a Russian background and one case has a Kazakh background. The implicated fish product has been distributed to several EU/EEA Member States and intensive recall measures have been initiated in the countries concerned following the German RASFF notification (2016.1621) on 25 November 2016.

Botulism neurotoxin type E is not an uncommon contamination in fish products, which have been poorly eviscerated and/or self-salted at home [1]. Contamination in commercial fish products has also been reported [10].

For this outbreak, the populations at the greatest risk are those who traditionally consume salted and dried roach ('vobla'). The risk for other population groups is very low in EU/EEA. In view of the rapid initiation of recalls and targeted public warnings, the risk that new cases linked to the outbreak will appear in the EU/EEA is considered to be very low. The main potential residual risk of exposure relates to consumers still keeping the product at home who may not been made aware of the public warnings, or stores that may not have received notification of the recall and are continuing to sell the implicated fish product. There is no risk of person-to-person transmission.

Figure 1. Graphical representation of traceability information available in RASFF[(a)]



(a) This graph includes traceability information reported in RASFF (last update 15 December 2016), as well as information on human cases and investigations in food reported by the national authorities to EFSA (last update 19 December 2016). Different colours (blue, green and red) have been used to trace-back the fish product associated with the human cases in Germany and Spain.

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