Main conclusions and options for response

A human case of *Bacillus anthracis* (*B. anthracis*) infection in an individual in contact with a sick cow in an anthrax enzootic area of Bulgaria is not an unexpected event.

Although distribution of contaminated and possibly contaminated meat to food outlets and food-processing plants occurred, the official recall of implicated food has significantly reduced the risk of additional cases with cutaneous or gastro-intestinal anthrax. Currently, no cases other than the initial one have been reported and considering that most cases have onset of illness within seven days of exposure, it seems unlikely that new cases associated with this event will arise, taking into account the recall of contaminated products.

Bulgarian authorities implemented control measures minimising the risk of further spread of the infection. Exposure to the infected animal or its meat occurred only at a local level, and international distribution of possibly contaminated meat has not been reported. Thus it is considered that this event represents a negligible risk to other European Union/European Economic Area (EU/EEA) countries.

Source and date of request

Following the Early Warning and Response System (EWRS) messages posted by Bulgaria on 27 and 28 July 2015, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) decided on 28 July to update the rapid risk assessment 'Fatal human case of *Bacillus anthracis* infection and bovine meat contamination in Bulgaria, July 2015' requested by the European Commission on 23 July 2015 and published in EWRS on 24 July 2015.

Public health issue

Assessment of the cross-border risk associated with consumption by international tourists and international distribution of meat possibly contaminated with *B. anthracis* in eastern Bulgaria.

Consulted experts

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The external experts submitted declarations of interest that revealed no conflicts of interest.

**Disease background information**

Anthrax is a zoonotic disease caused by the gram-positive spore-forming and toxin-producing bacterium *B. anthracis*. Anthrax most commonly occurs in wild and domestic herbivores that ingest or inhale the spores while grazing. The spores can persist in soil for many decades even under harsh conditions. Anthrax is enzootic in several parts of the world including Southern and Eastern Europe. Humans almost invariably contract the natural disease directly or indirectly from animals or animal products. In most industrialised countries, anthrax is a rare disease, and infection in humans is usually due to occupational exposure to infected animals or their products [1,2]. Infection with *B. anthracis* has also been reported at injection sites among injecting drug users [3]. The risk of person-to-person transmission is generally extremely low, but could result from direct contact with infected open wounds [1,2]. The infection can also be spread through the deliberate release of *B. anthracis*.

Human anthrax occurs in three forms: cutaneous (about 95% of all cases occurring), pulmonary with severe atypical pneumonia, and gastro-intestinal. Symptoms of disease vary depending on how the disease was contracted. The incubation period is usually 1 to 7 days, but can be as long as 60 days [1,2]. Untreated, the case–fatality rates range from 5 to 20% for cutaneous anthrax, to more than 85% for pulmonary and gastro-intestinal anthrax. Antibiotic treatment is effective and can prevent most deaths in cutaneous cases. However, mortality in pulmonary and gastro-intestinal cases remains high even with treatment [1,2].

*B. anthracis* spores can persist in the soil for many years and humans can become infected by handling products from infected animals or by inhaling spores from contaminated animal products. *B. anthracis* infection can also be acquired by eating contaminated meat from an infected animal. The symptoms of gastro-intestinal anthrax are similar to food poisoning but can worsen to severe abdominal pain, vomiting of blood and severe diarrhoea. The case-fatality ratio in untreated gastro-intestinal anthrax patients can be high [2].

Anthrax is a rare disease in the EU/EEA countries. From 2008 to 2014, 74 confirmed cases were reported via the European Surveillance System (TESSy) by EU/EEA countries, ranging from 1 to 32 per year. A large proportion of these cases were reported in people who inject drugs and were part of a European outbreak affecting consumers of contaminated heroin in western and northern European countries. During the same period, Bulgaria reported nine confirmed cases (range per year: 0–3). All cases were reported in individuals in contact with infected livestock [4].

In 2011, two cases of human anthrax who had been exposed to a *B. anthracis* infected cow via consumption of its meat or being involved in its slaughter in a private backyard in Romania were reported [5]. Cases of gastro-intestinal anthrax have resulted from the ingestion of beef from infected animals [6]. The persisting occurrence of human gastro-intestinal anthrax can be due to (i) uncontrolled slaughtering of sick livestock without prior veterinary examination and laboratory testing as well as (ii) the distribution of meat and by-products from such dead and slaughtered sick animals [7].

The occurrence of *B. anthracis* infection outbreaks in domestic animals is uncommon in the EU with 67 outbreaks having been reported during the period 2011-2014 [8].

Control measures include the correct disposal of dead animals: disinfection, decontamination and disposal of contaminated materials and decontamination of the environment. Protective equipment must be used by workers undertaking such measures. Vaccination of exposed animals and humans is required [1,2].

In areas prone to the disease, particularly those that experience outbreaks or sporadic cases in livestock, annual vaccination of susceptible animals is commonly performed. The usually peracute clinical symptoms observed in unvaccinated animals lead to a rapid death and make it very unlikely that meat derived from such animals enters the food chain [9]. Meat-borne transmission of anthrax in the EU has been a very rare event [10].

**Event background information**

On 21 July 2015, Bulgaria posted an Early Warning Response System (EWRS) message to report a fatal case of anthrax in a 53-year-old male. The man owned and bred sheep and cows in a village in the municipality of Vetrinto, administrative district of Varna. The area is known as enzootic for anthrax. On 7 July, the man and two of his friends slaughtered a sick cow without informing the Regional Food Safety Directorate (RFSD). Initial reports suggested that the meat was illegally cut, processed and consumed only by family members and acquaintances of the farmer. On 10 July, the man fell ill with fever and displayed wounds on both hands consistent with a toxic infectious syndrome. The man sought medical care on 14 July and was transported to the emergency care unit of the University Hospital in Varna where he died on 17 July. The patient tested positive for anthrax on 16 July.
The Regional Health Inspectorate and the RFSD in Varna implemented joint control measures after the case was notified. The Regional Health Inspectorate identified 30 contacts who had been exposed to the sick cow or to its carcass or meat derived from it. All contacts were prescribed antibiotic prophylaxis and are currently under medical observation. RFSD started immunisation against anthrax in livestock of the affected area.

On 18 July, after notification of the human fatal case was received by the RFSD, an alert on the illegal introduction of meat from the sick cow into an authorised meat processing plant was launched. The meat processing plant has permission for international distribution. However, during the time this event occurred, all production was distributed only on the Bulgarian market. Statements by the business operator indicated that meat from the sick cow had not entered the premises. Despite these statements, initial data showed that the plant had processed part of the meat to produce a meat preparation (‘nadenitsa’) intended for private consumption within the close circle of the owner of the sick cow. No data on the total yield of meat recovered and processed from this cow were provided. Subsequent investigations showed that between the 8 and 18 July, the plant had processed and dispatched meat preparations within the country to 25 retail and catering sites located in the district of Varna and two in the neighbouring district of Dobrich, some of which are located in areas of the Black Sea coast visited by tourists. At the time of the inspection, there were no ready-to-dispatch products available that had been manufactured within the period of 8 to 18 July. Thus, investigations throughout the wholesale, retail and catering networks were carried out.

During the period 18-22 July, three sets of samples were collected and analysed: i) two samples from a total of 5 kg of ‘nadenitsa’ suspected to have been produced by or with meat from the sick cow and confiscated from two private persons were positive on testing for anthrax spores; ii) four out of eight environmental samples (smears) from the working environment, food-contact surfaces and equipment of the processing plant were positive on testing for anthrax spores; iii) two additional samples of meat preparations produced on 14 July were collected in a retail food market were negative on testing for anthrax spores.

As a consequence of these laboratory results, several measures were undertaken by the competent authorities: i) suspension of operations and confiscation of all raw and processed meat products in the processing plant; ii) suspension of operations in the 27 retail and catering sites that received meat preparations from the processing plant, followed by disinfection with appropriate disinfecting agent (spore-killing) and confiscation of all meat preparations produced by the incumbent processing plant and all others that had been in contact with them. After the initial disinfection of these sites, ten of the 116 samples analysed resulted positive for anthrax spores; iii) an initial recall of 1 519 kg of raw and processed meat products from the processing plant (1 059 kg) and retail market (460 kg) that were confiscated and sent to a rendering plant in compliance with the EU legislation (Regulation (EC) 142/2011).

As a consequence of the laboratory results of the environmental sampling at retail and catering sites, several measures were undertaken by the competent authorities in the ten sites where samples resulted positive for anthrax spores: i) a second recall of 3 321 kilos of raw and processed meat products that were confiscated and sent to a rendering plant; ii) a second disinfection and sampling and suspension of operation. All the 50 samples collected and analysed after the second disinfection tested negative for anthrax spores.

The individuals who had traded or consumed the possibly contaminated meat were identified, tested, prescribed antibiotic prophylaxis and are under medical observation [11]. Currently, no human cases of anthrax other than in the 53-year-old male have been reported associated with this event.

**Threat assessment for the EU**

A fatal human case of anthrax in a farmer in contact with livestock in an anthrax enzootic area is rare but not an unexpected event. Bulgaria report human anthrax cases on an annual basis and the area where the event took place is known as an anthrax enzootic area. Slaughtering sick animals and processing/consuming their meat is a well-known risk factor for *B. anthracis* infection [1].

It is recognised that, in individuals accidentally exposed to contaminated meat, eating well-cooked meat lowers the risk of severe gastro-intestinal anthrax [6,9], while this risk is increased in the case of eating raw or undercooked contaminated meat. As the incubation period generally ranges from 1 to 7 days, and since control measures were put in place on 21 July, the absence of new reports of clinical cases offers supportive evidence that consumers are no longer exposed to contaminated meat. The likelihood of occurrence of new human cases associated with this event keeps decreasing as time passes by.

The risk of person to person transmission is extremely low.

Local authorities in Bulgaria implemented appropriate control measures in order to limit the risk of spread of the infection: individuals exposed to the sick animal, its meat and possibly contaminated meat in the food processing plant have been traced and put under medical observation.

Exposure to the anthrax-infected animal or its meat occurred only at a local level and there are no reports of international distribution of products from the meat-processing plant involved. The possibility that contaminated
meat or meat products were internationally distributed is minimal. Thus it is considered that this event represents a negligible risk to other EU/EEA countries.

**Conclusions**

A human case of *B. anthracis* infection in an individual in contact with a sick cow in an anthrax enzootic area of Bulgaria is not an unexpected event.

Although distribution of contaminated and possibly contaminated meat to food outlets and food-processing plants occurred, the official recall of implicated food has significantly reduced the risk of additional cases with cutaneous or gastro-intestinal anthrax. Currently no cases other than the initial one have been reported and considering that most cases have onset of illness within seven days of exposure, it seems unlikely that new cases associated with this event will arise, taking into account the recall of contaminated products.

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**References**