





International Food Safety Authorities Network (INFOSAN)

12 February 2007 INFOSAN Information Note No. 01/2007 - *E. coli* in spinach

Escherichia coli O157:H7 outbreak in spinach

SUMMARY NOTES

- *E. coli* O157:H7 is an Enterohaemorrhagic *Escherichia coli* strain that causes severe illness in humans.
- *E. coli* O157:H7 can be transmitted to humans through contaminated food.
- In September 2006, the United States of America experienced an *E. coli* O157:H7 outbreak involving fresh, bagged spinach with 205 cases of illness including 104 hospitalizations, 31 cases of kidney failure and 3 deaths.
- Primary distribution of the product to three countries was confirmed. Because another country received the product through secondary distribution, an INFOSAN Emergency Alert was issued to all INFOSAN members.
- All the contaminated spinach in the outbreak was traced back to one company in California.
- National Emergency Contact Points assisted INFOSAN Emergency by notifying the INFOSAN secretariat (<u>infosan@who.int</u>) of the events and providing updates throughout the investigation, thus enabling the rapid exchange of information to other members of INFOSAN.
- Although food contamination events can not be completely eliminated, this example demonstrates that action at the national and international level can prevent further spread of the contaminated product and illness.

Introduction

Escherichia coli (E. coli) is a bacterium that is commonly found in the gut of humans and animals. Most strains of *E. coli* are harmless. Some strains, such as the Enterohaemorrhagic *Escherichia coli* (EHEC) which includes *E. coli* O157:H7, can cause severe diarrhoea that is often bloody and accompanied by abdominal cramps. Fever may be absent or mild. Symptoms usually occur within 2-3 days following consumption of contaminated food, but may occur as soon as 1 day or up to 1 week after consumption of contaminated food. Healthy adults typically recover completely from *E. coli* O157:H7 illness within a week. However, in some people, especially young children and the elderly, the illness can progress to Haemolytic uraemic syndrome (HUS): a condition that can lead to serious kidney damage and even death¹.

The incidence of EHEC varies by country. In 2004 the number of laboratory confirmed cases in the European Union (17 Member States) and Norway was 1.3 cases per 100 000 population while in the same year the incidence in the USA was 0.9 cases per 100 000 people. In 2001 the incidence in New Zealand was reported to be 2 cases per 100 000 and 0.2 cases per 100 000 in Australia. The frequency of EHEC, and more specifically HUS, appears to be the highest in Argentina with estimates of approximately 22 cases of HUS per 100 000 children aged 6 to 48 months. While EHEC infections have also been reported for other parts of the world, including a number of African countries, specific incidence data is not always collected or readily available. EHEC infection and associated diseases can occur in any age group, however it seems that illness occurs most often in young children. For example, in Japan the median age for EHEC illness has been reported to be 8 years².

EHEC's have been isolated from various domestic animals and wildlife, including cattle, sheep, swine, goats and deer. Ruminants, and in particular cattle, are considered the primary reservoir of EHEC. It is, however, unclear to what extent EHEC can be considered ubiquitous in cattle and the reasons for the sporadic nature of EHEC in cattle and the variation in prevalence in different regions of the world. While multiple sources and routes of transmission are now recognized, data based on outbreaks and sporadic infections indicate beef and beef products as the most frequently identified source of foodborne EHEC infection. In particular, undercooked ground beef products have emerged as the single most frequently identified source of foodborne EHEC infection. Dry fermented meats as well as cooked and fermented sausages have also been implicated in reported outbreaks of EHEC infection. Other foodborne sources include milk and dairy products (e.g. unpasteurized milk, cheese from raw milk), fresh produce (e.g. sprouts, salads), drinks (e.g. apple cider/juice) and water. In recent months, dozens of new outbreaks have been reported implicating different sources and illustrating the multifaceted epidemiology of EHEC infections. In particular, an increasing number of outbreaks have been associated with the consumption of raw or minimally processed fruits and vegetables. Leafy green vegetables are the second most identified cause of human foodborne illness cases of EHEC as they are subject to contamination and eaten raw.

The present INFOSAN information note describes an outbreak of *E. coli* O157:H7 that occurred in the United States of America (USA) in September 2006. This case serves as an example of how prompt risk-based decision-making and open communication can be used to lessen the public health impact of contaminated food.

Outbreak Identification and Communication

On 8 September 2006, public health officials in one state in the USA notified the United States Center of Disease Control and Prevention (CDC) of a cluster of *E. coli* O157:H7 infections. Shortly thereafter public health officials in two other states, not in close proximity to the first state, reported similar disease clusters. On 12 September, CDC's PulseNet (the USA network of public health laboratories that sub-type bacteria using pulse-field gel electrophoresis)³ confirmed by DNA analysis that the *E. coli* O157:H7 strains from all the infected patients were the same. On 13 September, the state public health officials notified CDC that the results of their epidemiological investigations suggested the infections were associated with the consumption of fresh spinach⁴.

On the 14 September, the United States Food and Drug Administration (USFDA) alerted consumers about the multi-state outbreak of *E. coli* O157:H7, summarized the preliminary epidemiological evidence suggesting bagged fresh spinach may be the cause of the outbreak, and advised consumers to avoid this product⁵. The USFDA also notified their counterparts in Canada and Mexico of the outbreak. Although the USFDA had no knowledge of export of the recalled product to those two countries, given that many of the initial cases came from states that border on Canada and Mexico and that thousands of people cross the border every day, it seemed probable that a person could be infected in the USA and develop signs and symptoms of disease in Canada or Mexico. On 15 September, an INFOSAN Emergency Contact Point for the USA informed INFOSAN about the outbreak and noted that the USA had already informed officials in Mexico and Canada, so that an INFOSAN Emergency Alert would not be necessary.

As the outbreak continued to unfold, on 16 September the USFDA advised consumers to avoid all raw spinach and raw spinach-containing products⁶. This advisory remained in effect until 22 September when the USFDA concluded that the contaminated spinach was grown in three counties in California and advised consumers that spinach from outside these counties was safe to eat⁷. During the outbreak, the USFDA, CDC and the State of California kept the public informed in an attempt to limit the spread of the outbreak.

On 18 September, by reviewing company records USFDA investigators confirmed that the implicated product had also been distributed to Canada, Mexico and Taiwan, China. This information was

immediately relayed to the food safety and human health counterparts in these countries and INFOSAN. INFOSAN immediately sent Emergency Alerts to the INFOSAN Emergency Contact Points in the affected countries to make sure they were aware of actions taken by the USA.

On 22 September the INFOSAN Emergency Contact Point for the USA informed INFOSAN about the possibility of secondary and tertiary distribution of the implicated product. Since it was not possible to trace this distribution to specific countries, an INFOSAN Emergency Alert was sent to the entire network the same day stating that there was a possibility that the product may have been imported into their country. At present, international distribution of the implicated product has been reported for Canada, Iceland, Mexico and China (limited to Hong Kong, Special Administrative Region and Province of Taiwan).

On 29 September, USFDA announced that based on epidemiological and laboratory evidence obtained by multiple states it appeared that all spinach implicated in the outbreak traced back to one company⁸. The company voluntarily recalled all spinach products. Similarly farmers in the affected area voluntarily stopped growing spinach or stopped producing ready-to-eat spinach.

Illnesses associated with the outbreak

The DNA of the outbreak strain of *E. coli* O157:H7 from ill persons was analysed (fingerprinted) at public health laboratories around the country, as part of PulseNet. All *E. coli* O157:H7 strains associated with this outbreak had the same DNA pattern. A total of 204 cases of illness due to *E. coli* O157:H7 infection were reported to CDC from 26 states, including 31 cases involving HUS, 104 hospitalizations and 3 deaths, 2 elderly women and a two-year-old child. In addition, Canada has one confirmed case.

The 204 cases represent culture confirmed cases, i.e. individuals that were confirmed as ill from the contaminated product. However, this number may not include all the individuals who became ill from eating the contaminated product. Individuals that became ill but 1) did not seek medical attention; 2) did not provide a faecal sample; or 3) received antibiotic therapy prior to the faecal culture would not be included as a culture confirmed case. It is essential the health care providers be made aware of disease outbreaks so that patients are properly treated and epidemiological information is collected.

Traceback Investigation

The USFDA, the State of California, CDC, and the U.S. Department of Agriculture (USDA) conducted a traceback investigation. Traceback investigations follow the contaminated food product backwards along the food chain to identify the possible source(s) of the contamination. Factors that can cause *E. coli* O157 contamination include contaminated agricultural water, the use of manure as fertilizer, and the presence of animals in fields or packing areas.

The multidisciplinary field team assessed and took samples from the production establishments and the growing fields; and studied the animal management, water use, and the environment in the growing area. In this area of California, large tracks of land, called ranches, are divided into several fields which are rented out for different farming activities. The traceback investigation implicated four fields on four different ranches as the source of contamination. While *E. coli* bacteria were found on all the ranches, only one of the ranches had the outbreak strain of *E. coli* O157:H7. Testing of other environmental samples from all four ranches is in progress to determine how the cattle faeces contaminated the spinach.

Although the focus of this outbreak has narrowed to these four fields in the USA, the history of *E. coli* O157:H7 outbreaks linked to leafy greens indicates an ongoing problem globally. In the USA alone, there have been 19 outbreaks of foodborne illness caused by *E. coli* O157:H7 for which lettuce or leafy greens were implicated as the outbreak vehicle.

Control and prevention methods

The modern food control system shifts the focus of food safety strategies from response and recovery, following a contaminated food product reaching consumer markets, to strategies of prevention. Effective prevention strategies require the involvement of all stakeholders and the integration of risk-based programmes addressing the sources of hazards. National governments are responsible for developing food safety standards and primary preventive programmes, such as Good Agricultural Practices (GAPs) and Hazard Analysis and Critical Point Control (HACCP) system, and ensuring that these programmes are implemented and that safety standards are met. For example, in 2004 the USFDA developed a Produce Safety Action Plan⁹ to minimize the incidence of foodborne illness associated with the consumption of fresh produce. The overarching goal of this Action Plan is to minimize the incidence of foodborne illness associated with the consumption of fresh produce. To achieve this goal, the Action Plan has four general objectives: 1) Prevent contamination of fresh produce with pathogens; 2) Minimize the public health impact when contamination of fresh produce occurs: 3) Improve communication with producers, preparers, and consumers about fresh produce; and 4) Facilitate and support research relevant to fresh produce. For each objective, USFDA's Action Plan identifies steps that could contribute to the achievement of the objective and many specific milestones to address produce safety, including educational activities. The primary responsibility for implementing prevention strategies falls to industry.

The Codex Alimentarius Commission has developed a Code of Hygienic Practice for Fresh Fruits and Vegetables to help national government develop a risk-based GAPs programme. This code covers general hygienic practices for the primary production and packing of fresh fruits and vegetables cultivated for human consumption, particularly for those intended to be consumed raw. Specifically, this code is applicable to fresh fruits and vegetables grown in the field or in protected facilities¹⁰. In 2007, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) will provide scientific advice on pathogens in produce as requested by the Codex Committee on Food Hygiene to further develop this code to cover product-pathogen combinations and provide practical guidance for developing GAP programmes.

Summary

Effective prevention strategies throughout the entire farm-to-fork continuum are the most efficient way to produce safe food. Foodborne disease surveillance data from several countries shows that these preventive measures are reducing the total incidence of foodborne illness. Unfortunately, it is not possible to completely eliminate food contamination events. Dealing with these events requires the rapid access and exchange of food safety information at both the national and international level. Clear, reliable and authoritative information on food safety is essential not only for prevention and response measures but also for maintaining international food trade and consumer confidence in the food supply. By issuing frequent, timely and accurate information about the type of contamination, distribution of the product, and number of persons affected, the USFDA was able to prevent the further spread of the product and disease. In addition, once the international distribution was confirmed, the USFDA worked closely with INFOSAN Emergency to identify and notify countries that had received contaminated product. INFOSAN Emergency, through an Emergency Alert informed countries of the potential for secondary and tertiary distribution of the product.

¹ More information on *E. coli* sources of infection and control and prevention methods is available from a World Health Organization (WHO) fact sheet available at: http://www.who.int/mediacentre/factsheets/fs125/en/

² 2007. Joint Food and Agriculture Organization of the United Nations and World Health Organization technical meeting on: Enterohaemorrhagic *Escherichia coli* in raw meat and meat products: Approaches for the provision of scientific advice. Microbiological Risk Assessment Series. [In Press]

³ More information about PulseNet is available at <u>http://www.cdc.gov/pulsenet/index.htm</u>

⁴ More information about the Outbreak is available at: <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d926al.htm</u>

⁵ The full text of the press release is available at: <u>http://www.fda.gov/bbs/topics/NEWS/2006/NEW01450.html</u>

⁶ Full text of the 16 September Advisory: <u>http://www.fda.gov/bbs/topics/NEWS/2006/NEW01452.html</u>.

⁷ Consumer Advisory of 22 September: <u>http://www.fda.gov/bbs/topics/NEWS/2006/NEW01462.html</u>

⁸ Result of trace back analysis: <u>http://www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html</u>

⁹ The outline of the 2004 Produce Safety Action Plan: <u>http://www.cfsan.fda.gov/~dms/prodpla2.html</u>

¹⁰ The Codex Alimentarius Code of Hygienic Practice for Fresh Fruits and Vegetables, CAC/RCP 53 2003 is available at: <u>http://www.codexalimentarius.net/download/standards/10200/cxp_053e.pdf</u>

INFOSAN serves as a vehicle for food safety authorities and other relevant agencies to exchange food safety information and to improve collaboration among food safety authorities at both the national and international level.

INFOSAN Emergency, embedded in INFOSAN, links official national contact points to address outbreaks and emergencies of international importance and allows for the rapid exchange of information. INFOSAN Emergency is intended to complement and support the existing WHO Global Outbreak Alert and Response Network (GOARN).

INFOSAN is operated/managed by WHO, Geneva. It currently includes 152 Member States.

More information is available at: <u>www.who.int/foodsafety</u>