

## Imported food risk statement

### Uncooked ready-to-eat spreadable sausages and Shiga toxin-producing *Escherichia coli*

**Commodity:** Uncooked spreadable sausages that are ready-to-eat (RTE). An example of this type of product includes some varieties of teewurst. Ambient stable sealed packages are not covered by this risk statement.

**Microorganism:** Shiga toxin-producing *Escherichia coli* (STEC)

Recommendation and rationale
<p>Is STEC in uncooked RTE spreadable sausages a medium or high risk to public health:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Uncertain, further scientific assessment required</p> <p><b>Rationale:</b></p> <ul style="list-style-type: none"><li>• Consumption of uncooked RTE spreadable sausages has been epidemiologically associated with human illness due to STEC and infections can have severe consequences</li><li>• Ruminants are the main animal reservoir for STEC, however, STEC can also be found in other animals and birds</li><li>• International surveillance data have shown detections of STEC in uncooked RTE spreadable sausages</li></ul>

General description
<p><b>Nature of the microorganism:</b></p> <p><i>E. coli</i> are facultative anaerobic, Gram-negative, rod-shaped bacteria. They are found in warm-blooded animals and humans as part of the normal intestinal flora (FSANZ 2013). The majority of <i>E. coli</i> are harmless, however some have acquired specific virulence attributes, such as Shiga toxin-producing <i>E. coli</i> (STEC), which can cause severe diarrheal disease in humans (FDA 2012). Major foodborne pathogenic STEC strains include O26, O45, O103, O111, O121, O145, O157 (FDA 2012) and O104 (ECDC/EFSA 2011). The major animal reservoir of STEC is ruminants. STEC can also colonise other animals and birds, although the incidence of STEC is lower than in ruminants (FSANZ 2013; Meng et al. 2013).</p> <p>Growth of <i>E. coli</i> can occur at temperatures between 7 – 46°C, pH of 4.4 – 10.0 and a minimum water activity of 0.95 when other conditions are near optimum. Some STEC strains are able to survive at pH 2.5 – 3.0 for over 4 hours. STEC is able to survive frozen storage at -20°C, however, it is readily inactivated by cooking (FSANZ 2013; Meng et al. 2013).</p>
<p><b>Adverse health effects:</b></p> <p>STEC is a severe hazard as it can cause life threatening illness or substantial chronic sequelae (ICMSF 2002). People of all ages are susceptible to infection with STEC. However, the young and the elderly are more susceptible and are more likely to develop serious symptoms (FSANZ 2013).</p> <p>Symptoms include diarrhoea, abdominal pain, vomiting and fever. The onset of illness is typically 3 – 8 days after infection and most patients recover within 10 days of the initial onset of symptoms. Acute STEC infections (haemorrhagic colitis) are characterised by severe abdominal cramps and bloody diarrhoea. In some cases, patients develop haemolytic uraemic syndrome (HUS) which can lead to kidney failure. HUS can also have neurological effects and cause seizures, stroke and coma. Approximately 3 – 7% of haemorrhagic colitis cases develop HUS. The fatality rate of HUS is 3 – 5% (FDA 2012; FSANZ 2013).</p> <p>It is generally accepted that very low levels (10 – 100 cells) of STEC can cause illness. However, depending on the food matrix and strain of STEC, illness may occur at exposure to even lower levels of STEC (FSANZ 2003; FDA 2012).</p>

FSANZ provides risk assessment advice to the Department of Agriculture on the level of public health risk associated with certain foods. For more information on how food is regulated in Australia refer to the [FSANZ website](#) or for information on how imported food is managed refer to the [Department of Agriculture website](#).

**Consumption pattern:**

Uncooked RTE spreadable sausages were not identified as being consumed by any of the respondents (2 years and over) in the 1995 National Nutrition Survey (McLennan and Podger 1999) or the respondents (2-16 years) in the 2007 Australian National Children's Nutrition and Physical Activity Survey (DOHA 2008).

**Key risk factors:**

Key risk factors during production for uncooked RTE spreadable sausage being contaminated with STEC include but are not limited to; STEC contamination in the raw ingredients, incorrect time and temperature combination applied to the fermentation process and incorrect time and temperature combination applied to the maturation process (MLA 2003). Using raw meat of ruminant origin in which STEC prevalence is high for the manufacture of uncooked RTE sausages presents a higher risk than using raw meat of other animal species such as pig in which STEC prevalence is low (Meng et al. 2013).

Uncooked spreadable sausages are typically low in acid content and high in moisture content (Brown 2000). These conditions favour the growth of STEC.

**Risk mitigation:**

To minimise STEC contamination in the production of uncooked RTE spreadable sausages, source raw meat that has been produced such that the potential for STEC contamination is minimised. Good manufacturing practices, good hygienic practices to prevent cross contamination and good temperature control in food manufacturing and handling play an important role in minimising STEC contamination and proliferation in uncooked RTE spreadable sausages.

Curing agents like salt and nitrite, and correct application of curing temperature and time combinations contribute to the inhibition and inactivation of STEC present in raw ingredients. Growth of STEC in uncooked RTE spreadable sausages is negatively affected by a high level of lactic acid bacteria in the product (Birzele et al. 2005).

In Australia Division 3 of [Standard 4.2.3 of the Australia New Zealand Food Standards Code](#) (the Code) states that RTE meat must be produced under a food safety management system which identifies, evaluates and controls food safety hazards. Clause 5 includes additional requirements for uncooked comminuted fermented meat for the fermentation, maturation and smoking processes and for recording the number of *E. coli* organisms for the raw meat ingredients, the product after fermentation and any subsequent process. [Standard 1.6.1 of the Code](#) has a microbiological limit for all comminuted fermented meat which has not been cooked during the production process for *E. coli* of n=5, c=1, m=3.6, M=9.2 per g.

**Compliance history:**

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture indicated that during the period of January 2007 – June 2013 there were no imports of uncooked RTE spreadable sausages.

There have been no notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for STEC in uncooked RTE spreadable sausages during the period of January 2007 – June 2013. There were four notifications for STEC or excessive levels of generic *E. coli* (levels up to 18,000 CFU/g) in sausages from multiple countries and one notification of STEC in several undisclosed beef products from Belgium, however, it was not stated if these products were uncooked RTE spreadable sausages.

There have been no food recalls in Australia due to the presence of STEC or excessive levels of *E. coli* in imported or domestically produced uncooked RTE spreadable sausages from January 2007 – June 2013.

### Surveillance information:

Infection with STEC is a notifiable disease in all Australian states and territories. The incidence of STEC infections notified in Australia in 2012 was 0.5 cases per 100,000 population (112 cases), which includes both foodborne and non-foodborne cases. This is the same as the previous five year mean of 0.5 cases per 100,000 population per year (ranging from 0.4 – 0.6 cases per 100,000 population per year). The most common STEC serotype identified in Australia in 2010 was O157 (58.8% of cases), O111 was the next most common serotype (FSANZ 2013).

### Illness associated with consumption of uncooked RTE spreadable sausages contaminated with STEC

There are limited reports of STEC outbreaks associated with consumption of uncooked RTE spreadable sausages.

- Outbreak in Germany in 1995 – 1996, 28 children developed HUS related to STEC including 3 fatalities. Case control studies showed a relationship between consumption of teewurst (an uncooked RTE spreadable sausage) and mortadella (a cooked RTE sausage) and illness (Ammon et al. 1999)
- A matched case-control study in Germany that examined risk factors for sporadic illness associated with STEC infection in the period of 2001-2003 found that consumption of uncooked RTE spreadable sausages was significantly associated with illness in persons aged 10 years or older (Werber et al. 2007)

### Prevalence of STEC in uncooked RTE spreadable sausages

- Routine food surveillance activities in Germany from 2005 – 2007 detected STEC in uncooked RTE spreadable sausages (Werber et al. 2008)
- Survey in Germany from 1997 – 2002, STEC was detected in 1.5% of uncooked RTE spreadable sausages (n=2748) (Werber et al. 2007)
- Survey in Germany from 1997 – 1998, STEC was detected in 8.8% of shortly ripened uncooked RTE sausages sampled at retail (n=158). The majority of STEC positive samples (13 of 14) were uncooked RTE spreadable sausages, however, the total proportion of samples that were uncooked RTE spreadable sausages was not reported (Timm et al. 1999)

### Other relevant standard or guideline

- Codex general principles of food hygiene *CAC/RCP 1 – 1969* follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage (Codex 2003)
- Codex code of hygienic practice for meat *CAC/RCP 58-2005* covers additional hygienic provisions for raw meat, meat preparations and manufactured meat from the time of live animal production up to the point of retail sale (Codex 2005)

### Approach by overseas countries

Many countries, such as the European Union, the United States and Canada, have HACCP-based regulatory measures in place for meat products.

Health Canada has published [guidance](#) for the production of fermented RTE sausages containing beef as an ingredient. This requires interventions such as temperature/time combinations, validation of process to achieve a 5 log<sub>10</sub> reduction of STEC O157:H7, end product testing and implementation of HACCP systems.

In the United States the production of RTE meat products should achieve at least a 5 log<sub>10</sub> reduction in *E. coli* O157:H7 for products containing beef (FSIS 2012).

### Other considerations

Generic *E. coli* is commonly used as an indicator of process hygiene (ICMSF 2011).

Quarantine restrictions apply to certain products under this commodity classification. Refer to the [ICON database](#).

**This Risk Statement was compiled by FSANZ in:** August 2014

### References

Ammon A, Petersen LR, Karch H (1999) A large outbreak of hemolytic uremic syndrome caused by an unusual sorbitol-fermenting strain of *Escherichia coli* O157:H-. The Journal of Infectious Diseases 179:1274–1277

Birzele B, Djordjevic S, Kramer J (2005) A study of the role of different nitrite concentrations on human pathogenic bacteria in fresh spreadable ham and onion sausage. Food Control 16:695–699

Brown MH (2000) Processed meat products. Ch 18 In: Lund BM, Baird-Parker TC, and Gould GW (eds) The microbiological safety and quality of food, vol.1. Aspen Publishers, Gaithersburg, p. 389–419

Codex (2003) General principles of food hygiene (CAC/RCP 1 - 1969). Codex Alimentarius Commission, Geneva

Codex (2005) Code of hygienic practice for meat (CAC/RCP 58 - 2005). Codex Alimentarius Commission, Geneva

DOHA (2008) 2007 Australian national children's nutrition and physical activity survey - Main findings.

Department of Health and Ageing, Canberra.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-food-monitoring.htm#07survey>. Accessed 6 August 2014

ECDC/EFSA (2011) Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104. European Centre for Disease Prevention and Control, Stockholm.

<http://www.efsa.europa.eu/en/supporting/doc/166e.pdf>. Accessed 11 April 2014

FDA (2012) Bad bug book: Foodborne pathogenic microorganisms and natural toxins handbook, 2nd ed. US Food and Drug Administration, Silver Spring.

<http://www.fda.gov/Food/FoodbornenessContaminants/CausesOfIllnessBadBugBook/ucm2006773.htm>. Accessed 27 March 2013

FSANZ (2003) Review of processing requirements for uncooked comminuted fermented meat (UCFM) products. Food Standards Australia New Zealand, Canberra.

<http://www.foodstandards.gov.au/code/proposals/documents/P251%20UCFM%20FAR.pdf>. Accessed 18 July 2013

FSANZ (2013) Agents of foodborne illness. 2nd ed, Food Standards Australia New Zealand, Canberra.

[http://www.foodstandards.gov.au/publications/Documents/FSANZ\\_Foodborneness\\_2013\\_WEB.pdf](http://www.foodstandards.gov.au/publications/Documents/FSANZ_Foodborneness_2013_WEB.pdf). Accessed 4 September 2013

FSIS (2012) *Salmonella* compliance guidelines for small and very small meat and poultry establishments that produce ready-to-eat (RTE) products.

[http://www.fsis.usda.gov/wps/wcm/connect/2ed353b4-7a3a-4f31-80d8-20262c1950c8/Salmonella\\_Comp\\_Guide\\_091912.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/2ed353b4-7a3a-4f31-80d8-20262c1950c8/Salmonella_Comp_Guide_091912.pdf?MOD=AJPERES). Accessed 12 March 2014

ICMSF (2002) Microorganisms in Food 7: Microbiological testing in food safety management.

Kluwer Academic/Plenum Publishers, New York

ICMSF (2011) Meat products. Ch 8 In: Microorganisms in food 8: Use of data for assessing process control and product acceptance. Springer, New York, p. 75–93

McLennan W, Podger A (1999) National nutrition survey. Foods eaten. Australia. 1995. ABS Catalogue number 4804.0. Australian Bureau of Statistics and Commonwealth Department of Health and Family Services, Canberra.

<http://www.abs.gov.au/ausstats/abs@.nsf/PrimaryMainFeatures/4804.0?OpenDocument>. Accessed 6 August 2014

Meng J, LeJeune JT, Zhao T, Doyle MP (2013) Enterohemorrhagic *Escherichia coli*. Ch 12 In: Doyle MP, Beuchat LR (eds) Food microbiology: Fundamentals and frontiers. 4th ed, ASM Press, Washington D.C., p. 287–309

MLA (2003) Guidelines for the safe manufacture of smallgoods. Meat & Livestock Australia, Sydney

Timm M, Klie H, Richter H, Gallien P, Perlberg KW, Lehmann S, Protz D (1999) Detection and prevalence of verotoxin-producing *Escherichia coli* (VTEC) in raw sausages. Berliner und Muenchener tieraerztliche Wochenschrift 112:395–389

Werber D, Beutin L, Pichner R, Stark K, Fruth A (2008) Shiga toxin-producing *Escherichia coli* serogroups in food and patients, Germany. Emerging Infectious Diseases 14(11):1803–1806

Werber D, Behnke C, Fruth A, Merle R, Menzler S, Glaser S, Kreienbrock L, Prager R, Tschape H, Roggentin P, Bockemuhl J, Ammon A (2007) Shiga toxin-producing *Escherichia coli* infection in Germany - Different risk factors for different age groups. American Journal of Epidemiology 165(4):425–434