Imported food risk statement
Uncooked ready-to-eat sausages and Shiga toxin-producing *Escherichia coli*

Commodity: Uncooked ready-to-eat (RTE) sausages. Examples of this type of product include salami, cacciatore, chorizo, dried sausages and semi-dried sausages. Spreadable sausages and sausages in ambient stable sealed packages are not covered by this risk statement.

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

Recommendation and rationale
Is STEC in uncooked RTE sausages a medium or high risk to public health: ☑ *Yes* ☐ *No* ☐ *Uncertain, further scientific assessment required* **Rationale:** • Human illness has been associated with uncooked RTE sausages contaminated with STEC and infections can have severe consequences • Ruminants are the main animal reservoir for STEC, however, STEC can also be found in other animals and birds • International compliance data have shown detections of STEC in uncooked RTE sausages

General description
Nature of the microorganism: *E. coli* 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 *E. coli* are harmless, however some have acquired specific virulence attributes, such as Shiga toxin-producing *E. coli* (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). Growth of *E. coli* 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).
Adverse health effects: 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). 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). 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).

Consumption pattern:

One percent of children (aged 2-16 years), 2% of adults (aged 17-69 years) and 1% of people aged 70 and above reported consumption of uncooked RTE sausages in the 1995 National Nutrition Survey (McLennan and Podger 1999). In the 2007 Australian National Children's Nutrition and Physical Activity Survey, 5% of children (aged 2-16 years) reported consumption of uncooked RTE sausages (DOHA 2008).

Key risk factors:

Key risk factors of STEC contamination in the finished product include but are not limited to (1) a high level of STEC contamination in the raw ingredients, (2) incorrect time and temperature combination applied to the fermentation process, and (3) 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 animal species such as pig in which STEC prevalence is low (Meng et al. 2013).

Risk mitigation:

To manage STEC contamination in the production of uncooked RTE 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 these products.

Curing agents like salt and nitrite, and correct application of curing temperature and time combination contribute to the inhibition and inactivation of STEC present in raw ingredients.

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 sausages.

There have been five notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for STEC in uncooked RTE sausages during the period of January 2007 – June 2013. Products notified included cured fermented sausage, mettwurst, salami, and smoked sausage. These detections occurred from multiple countries. There were no notifications for excessive levels of generic *E. coli* in uncooked RTE sausages during this period. There were an additional 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 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 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 sausages contaminated with STEC

There are a number of reported outbreaks caused by STEC associated with consumption of uncooked RTE sausages. Examples are listed below:

- Outbreak in the United States in 2011, 14 cases of illness associated with consumption of Lebanon bologna, a type of uncooked RTE sausage, contaminated with STEC strain O157:H7 (CDC 2011)
- Outbreak in Norway in 2006, 16 cases of illness with 10 HUS cases and one fatality associated with consumption of Morrpølse, a type of uncooked RTE sausage manufactured in Norway, contaminated with STEC strain O103. The outbreak STEC strain was isolated from unopened packages of Morrpølse and was traced to the mutton production plant, mutton slaughterhouse and sheep farms (Schimmer et al. 2008)
- Outbreak in Australia (South Australia) in 1995, over 200 cases of illness with 23 HUS cases and the death of a 4 year old associated with consumption of mettwurst contaminated with STEC O111:NM. The outbreak STEC strain was isolated from the mettwurst (FSANZ 2003)

Prevalence of STEC in uncooked RTE sausages

Surveys of uncooked RTE sausages have not isolated pathogenic STEC. Examples of surveys are listed below:

- Surveys conducted by the New South Wales Food Authority from 2001 – 2011, *E. coli* counts exceeding 10 CFU/g were detected in 12.2% of uncooked fermented meat samples (n=172) (New South Wales Food Authority, pers. com.)[1]; it is not known if any of the *E. coli* was STEC
- Surveys conducted by the Department of Health of Western Australia from 2002 – 2004, *E. coli* at 100 CFU/g was isolated from one sample of uncooked RTE sausages and non-Shiga toxin producing *E. coli* O157 was isolated from another sample (n=587) (Department of Health of Western Australia, pers. com.)[2]
- Surveys across England, Wales and Northern Ireland in 1996, STEC strain O157:H7 was not detected in RTE dried and fermented RTE meat and meat products (n=2,304) (Little 1998)
- Surveys conducted by the Food Safety and Inspection Service of the United States from 1995 – 1999, STEC strain O157:H7 was not detected in domestically produced dry and semi-dry sausages (n=3,445) (Levine et al. 2001)

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 have 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 $\log_{10}$ reduction of STEC O157:H7, end product testing and implementation of HACCP systems.

[1] New South Wales Food Authority, personal communication 9th October 2013
[2] Department of Health of Western Australia, personal communication 20th September 2013

In the United States the production of RTE meat products should achieved at least a 5.0 $\log_{10}$ reduction in *E. coli* O157:H7 for products containing beef (FSIS 2012). In the United States it is recommended that the pH of the product reaches a pH of 5.3 within a defined number of hours at a defined temperature in order to control the growth of *E. coli* O157:H7 in fermented dry and semi-dry sausage products (AMIF 1997; FSIS 2013)

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.

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