Imported food risk statement
Marinara mix and Shiga toxin-producing *Escherichia coli*

Commodity: Marinara mix. This is a composite product that contains a variety of different types of seafood, such as crustaceans, fish and molluscs and is not a ready-to-eat product. Marinara mix in ambient stable sealed packages is not covered by this risk statement.

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

Recommendation and rationale
Is STEC in marinara mix a medium or high risk to public health: ☐ *Yes* ☑ *No* ☐ *Uncertain, further scientific assessment required* **Rationale:** • STEC is a severe hazard as it can cause life threatening illness or substantial chronic sequelae. • There is no evidence of STEC related human illness attributed to marinara mix. • Marinara mix requires cooking prior to consumption which will inactivate STEC. • Post-cooking contamination is unlikely if good food handling practices are followed. • International and Australian compliance and recall data has shown limited evidence of STEC associated with marinara mix.

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, such as Shiga toxin-producing *E. coli* (STEC), have acquired specific virulence attributes which can cause severe diarrhoeal disease in (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 ranging 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 four 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 exposure to an infectious dose 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. Approximately 3 – 7% of haemorrhagic colitis cases subsequently develop haemolytic uraemic syndrome (HUS). HUS is characterised by acute kidney injury, thrombocytopenia and haemolytic anaemia. Children under five years of age are more susceptible to developing HUS following STEC infection. About 30% of patients with HUS develop minor sequelae such as proteinuria, and 5% of patients develop severe sequelae such as stroke and kidney failure. The fatality rate of HUS is 3 – 5% (Meng and Schroeder 2007; 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 (FDA 2012; FSANZ 2013).

Consumption patterns:

In the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey) no children (aged 2 – 16 years), <1 % of adults (aged 17 – 69 years) and <1% of people aged 70 and above reported consumption of marinara mix (Australian Bureau of Statistics 2011). Survey data was derived from one day of dietary recall data.

Key risk factors:

Marinara mix consists of a range of different seafood, therefore, key risk factors for the various types of seafood will be considered.

A key risk factor for the production of bivalve molluscs is microbiological contamination of the waters in which they grow. As bivalve molluscs are filter feeders, they can accumulate bacteria such as STEC from polluted aquatic environments. In marine environments STEC typically only survives for short periods of time, but STEC maintain viability for much longer when ingested by oysters and can multiply quickly under conditions which allow growth (i.e. higher temperatures). Contamination with STEC can also occur during the bivalve mollusc shucking process or during further handling (FSANZ 2005; Codex 2013).

Fish may be contaminated with STEC as a result of near-shore harvest water contamination, poor sanitary practices during post-harvest handling and processing and poor aquacultural practices (FSANZ 2005; FDA 2011). Crustaceans trapped in estuarine or inshore marine waters may be contaminated with potentially pathogenic bacteria from sewage, such as STEC. Post-harvest handling and processing has the potential to introduce pathogens, such as STEC (ICMSF 2000; FSANZ 2005).

Temperature abuse during handling, transport and/or storage may allow the growth of STEC (FSANZ 2005). However, illness may occur with exposure to low levels of STEC.

Risk mitigation:

To manage STEC contamination, seafood should be sourced and produced under conditions where the potential for STEC contamination is minimised (i.e. from quality shellfish harvest areas or fishing grounds). The shellfish control authority (government agencies) classifies shellfish harvest areas, based in part on an assessment of water quality. All growing water and/or molluscan flesh should be monitored for the presence of indicators for the presence of faecal contamination. As a result of harvest area classifications, shellfish harvesting is restricted to certain waters and may also be subject to specific conditions. For example depuration can be used in which live animals are placed in clean water to slowly rid themselves of pathogens, although efficacy varies depending on pathogen. Some pathogens, for instance viruses, may stay in the animals even during depuration (FDA 2011; ICMSF 2011; Codex 2013; ASQAAC 2016).

Use of low temperatures (<5°C) during processing, transport and storage will reduce the rate of growth for most microbial pathogens (FSANZ 2005; Codex 2013). Good hygienic practices in food manufacturing and food handling will minimise STEC contamination of marinara mix.

Marinara mix requires cooking prior to consumption. Cooking food to an internal temperature of at least 68.3°C for several seconds will inactivate STEC (Meng et al. 2013).

In Australia, Division 2 of Standard 4.2.1 in the Australia New Zealand Food Standards Code (the Code) states that a seafood business must systematically examine all of its primary production and processing operations to identify potential seafood safety hazards and implement controls that are commensurate with the food safety risk, and must take all necessary steps to prevent the likelihood of seafood being or becoming contaminated. Specifically, Division 3 requires businesses engaging in the primary production, processing, or manufacturing activities concerning bivalve molluscs to implement a documented food safety management system that effectively controls the hazards. The food safety management system incorporates the conditions of the ASQAP Manual for managing risk in the harvesting, relaying, depuration and wet storage of shellfish.

Schedule 27 of the Code has a microbiological limit for bivalve molluscs, other than scallops for *E. coli* of n=5, c=1, m=2.3/g, M=7/g.

Compliance history:

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture and Water Resources for January 2007 – May 2016 showed that of the 138 generic *E. coli* tests applied to marinara mix there were four fails, a 2.9% failure rate. The failed samples were marinara mix imported from China and Vietnam. Foods were not specifically tested for STEC.

There were no notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for STEC or excessive levels of generic *E. coli* in marinara mix from January 2007 – May 2016.

There have been no food recalls in Australia due to the presence of STEC or excessive levels of *E. coli* in imported or domestic marinara mix from January 2007 – May 2016.

Surveillance information:

Infection with STEC is a notifiable disease in all Australian states and territories, with a reported incidence rate in 2015 of 0.6 cases per 100,000 population (137 cases), which includes both foodborne and non-foodborne cases. This is an increase from the previous five year mean of 0.5 cases per 100,000 population per year (ranging from 0.4 – 0.8 cases per 100,000 population per year). The most common STEC serotype identified in Australia in 2011 was O157 (38% of cases), followed by O111 (17% of cases). There were seven cases of STEC-associated HUS reported in Australia in 2011 (OzFoodNet 2015; NNDSS 2016).

Illness associated with consumption of marinara mix contaminated with STEC

A search of the scientific literature via Web of Science, PubMed, Scopus, CAB abstracts, US CDC Foodborne Online Database and other publications during the period 1990 – April 2016 failed to identify any STEC outbreaks associated with consumption of marinara mix.

Prevalence of STEC in marinara mix

A search of the scientific literature via Web of Science, PubMed, Scopus, CAB abstracts and other publications during the period 1990 – April 2016 did not find any data on the prevalence of STEC in marinara mix.

Other relevant standards or guidelines

- 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 practice for fish and fishery products *CAC/RCP 52-2003* applies to the growing, harvesting, handling, production, processing, storage, transportation and retail of fish, shellfish and aquatic invertebrates and products thereof from marine and freshwater sources that are intended for human consumption. Section seven, eight, 13A, 13B, 14 and 15 of *CAC/RCP 52-2003* is specific to the processing of live and raw bivalve molluscs; fresh, frozen and minced fish; lobsters; crabs; shrimps and prawns; and cephalopods, respectively, and describes controls at individual processing

steps (Codex 2013).

- Codex standard for quick frozen lobsters *CODEX STAN 95-1981* covers the production and processing of quick frozen lobsters, including cooked squat lobsters (red and yellow) (Codex 2014a).
- Codex standard for quick frozen shrimps or prawns *CODEX STAN 92-1981* covers the production and processing of quick frozen shrimps or prawns, including fully cooked shrimps or prawns (Codex 2014b).
- Codex standard for live and raw bivalve molluscs *CODEX STAN 292-2008* covers the production and processing of live and raw bivalve molluscs. This standard states that growing area monitoring programs must ensure that live bivalve molluscs meet the *E. coli* limit of n=5, c=1, m=230, M=700. Raw bivalve molluscs should also meet this *E. coli* limit (Codex 2015).
- Codex standard for fresh and quick frozen raw scallop products *CODEX STAN 315-2014* covers production and processing of fresh and quick frozen raw scallop products, including those intended for further processing (Codex 2016).

Approach by overseas countries

Many countries and regions, such as the United States, Canada and the European Union, have HACCP-based regulatory measures in place for production of this commodity.

In Europe, shelled and shucked products of cooked crustaceans and molluscan shellfish have a *E. coli* limit of n=5, c=2, m=1/g, M=10/g for products at the end of the manufacturing process (European Commission 2007).

Other considerations

Generic *E. coli* can be used as an indicator of faecal contamination in water and shellfish (European Commission 2007; Codex 2013).

Biosecurity restrictions apply to products under this commodity classification. Refer to the BICON database.

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References

ASQAAC (2016) Australian shellfish quality assurance program. Australian Shellfish Quality Assurance Advisory Committee. http://safefish.com.au/wp-content/uploads/2016/07/Australian-Shellfish-Quality-Assurance-Program-Operations-Manual-2016.pdf. Accessed 31 August 2016

Australian Bureau of Statistics (2011) National Nutrition and Physical Activity survey, 2011-2012, Basic CURF, CD-ROM. Findings based on ABS Curf data.

Codex (2003) General principles of food hygiene (CAC/RCP 1 - 1969). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 5 August 2016

Codex (2013) Code of practice for fish and fishery products (CAC/RCP 52-2003). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 2 September 2016

Codex (2014a) Standard for quick frozen lobsters (CODEX STAN 95-1981). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 2 September 2016

Codex (2014b) Standard for quick frozen shrimps or prawns (CODEX STAN 92-1981). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 2 September 2016

Codex (2015) Standard for live and raw bivalve molluscs (CODEX STAN 292-2008). Codex Alimentarius, Rome. http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 2 September 2016

Codex (2016) Standard for fresh and quick frozen raw scallop products (CODEX STAN 315-2014). Codex Alimentarius, Rome.
http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/. Accessed 2 September 2016

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

European Commission (2007) Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. Official Journal of the European Union 7.12.2007:L322/12–L322/29

FDA (2011) Fish and fishery products hazards and controls guidance - fourth edition. US Food and Drug Administration, Silver Spring.
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm#sampling. Accessed 31 August 2016

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/foodborneillnesscontaminants/causesofillnessbadbugbook/default.htm. Accessed 23 July 2015

FSANZ (2005) Proposal P265: Primary production and processing standard for seafood - Final assessment report. Food Standards Australia New Zealand, Canberra.
http://www.foodstandards.gov.au/code/proposals/documents/P265_Seafood_PPPS_FAR.pdf. Accessed 7 September 2016

FSANZ (2013) Agents of foodborne illness. 2nd ed, Food Standards Australia New Zealand, Canberra.
http://www.foodstandards.gov.au/publications/Documents/FSANZ_FoodborneIllness_2013_WEB.pdf. Accessed 4 September 2013

ICMSF (2000) Fish and seafood products. Ch 3 In: Microorganisms in food 6: Microbial ecology of food commodities. Aspen Publishers, Gaithersburg, p. 130–189

ICMSF (2002) Selection of cases and attributes plans. Ch 8 In: Microorganisms in food 7: Microbiological testing in food safety management. Kluwer Academic/Plenum publishers, London, p. 145–172

ICMSF (2011) Fish and seafood products. Ch 10 In: Microorganisms in food 8: Use of data for assessing process control and product acceptance. Springer, New York, p. 107–133

Meng J, Schroeder CM (2007) *Escherichia coli*. Ch 1 In: Simjee S (ed) Foodborne Diseases. Humana Press, Totowa, p. 1–25

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

NNDSS (2016) Notifications of a selected disease by State and Territory and year. National Notifiable Disease Surveillance System, Department of Health and Ageing, Canberra.
http://www9.health.gov.au/cda/source/rpt_4_sel.cfm. Accessed 19 May 2016

OzFoodNet (2015) Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the OzFoodNet Network, 2011. Communicable Diseases Intelligence 39(2):E236–E264