

Imported food risk statement
Marinara mix and staphylococcal enterotoxin

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.

Microbial enterotoxin: Staphylococcal enterotoxin (SE)

Recommendation and rationale
<p>Is SE in marinara mix a medium or high risk to public health:</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Uncertain, further scientific assessment required</p> <p>Rationale:</p> <ul style="list-style-type: none"> • SE is a moderate hazard as it generally causes illness of short duration and usually no sequelae. • No evidence of staphylococcal food poisoning attributed to marinara mix. • Marinara mix requires cooking prior to consumption which will inactivate <i>Staphylococcus aureus</i>. • Post-cooking contamination can occur due to poor food handling. • <i>S. aureus</i> can grow in the product if temperature abuse occurs but large numbers of <i>S. aureus</i> are required for SE production to occur. • International and Australian compliance and recall data show no evidence for marinara mix being contaminated with high levels of <i>S. aureus</i> or the presence of SE.
General description
<p>Nature of the microbe and enterotoxin:</p> <p><i>Staphylococcus</i> spp. are facultative anaerobic Gram-positive, non-spore forming spherical-shaped bacteria. They are commonly found in the environment, humans (nose and skin) and animals. Although several <i>Staphylococcus</i> species can produce SEs, including both coagulase-negative and coagulase-positive isolates, the majority of staphylococcal food poisoning (SFP) is attributed to SE produced by coagulase-positive <i>S. aureus</i> in the contaminated food (FDA 2012; FSANZ 2013).</p> <p>Growth of <i>S. aureus</i> can occur at temperatures ranging between 7 – 48°C, pH of 4.0 – 10.0 and a minimum water activity of 0.83 when other conditions are near optimum. SEs are produced during the exponential phase of <i>S. aureus</i> growth. SEs are resistant to heat inactivation and cannot be destroyed by cooking. SEs remain stable under frozen storage (FSANZ 2013).</p>
<p>Adverse health effects:</p> <p>SE is a moderate hazard as it generally causes illness of short duration and usually no sequelae (ICMSF 2002). People of all ages are susceptible to SFP. However, the severity of symptoms may vary depending on the amount of SE consumed and the general health status of individuals. The young and elderly are more likely to develop more serious symptoms (FSANZ 2013).</p>

SFP is characterized by rapid onset gastroenteritis that appears around three hours after ingestion of preformed SE (normal range of 1 – 6 hours). Common symptoms of SFP include nausea, vomiting, abdominal cramps and diarrhoea. Recovery is usually between 1 – 3 days (FSANZ 2013).

People become ill after exposure to very small quantities of SE (less than 1 µg). These levels of toxin are generally observed when *S. aureus* populations exceed 10⁵ CFU/g in food (FDA 2012).

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.

The key risk factor for *S. aureus* contamination for all marinara components is post-harvest handling and processing (e.g. the shucking process for bivalve molluscs and hand-peeling of shrimp). Temperature abuse during handling, transport and/or storage may then allow the growth of *S. aureus* to levels where potential for production of SE exists (ICMSF 2000; FSANZ 2005; ICMSF 2011).

Risk mitigation:

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 manufacturing practices, good hygienic practices and temperature control will minimise *S. aureus* contamination and growth.

Marinara mix is generally cooked prior to consumption. Cooking is lethal to *S. aureus*, but not to SE. Avoiding time and temperature abuse of food products is essential in preventing the proliferation of staphylococci and subsequent production of SE. Levels of SE likely to cause illness are generally observed when *S. aureus* populations exceed 10⁵ CFU/g in food (FDA 2012).

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 cooked crustacea for coagulase-positive staphylococci of n=5, c=2, m=10²/g and M=10³/g and a microbiological limit for raw crustacea for coagulase-positive staphylococci of n=5, c=2, m=10²/g and M=10³/g.

Compliance history:

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture for January 2007 – May 2016 showed that there were no fails for the 116 coagulase positive staphylococci tests applied to marinara mix.

There were no notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for SE or *S. aureus* in marinara mix from January 2007 – May 2016.

There have been no food recalls in Australia due to the presence of SE or *S. aureus* in imported or domestic marinara mix from January 2007 – May 2016.

Surveillance information:

SFP is not a notifiable disease in Australia. There was one reported outbreak in Australia in 2013, one reported outbreak in 2012 and two reported outbreaks in 2011. Factors that may have contributed to the outbreaks include the role of infected food handlers, poor food handling practices and temperature abuse of food. It is generally recognised that there may be significant under reporting of SFP due to the short duration of illness and self-limiting symptoms. In Australia, it is estimated that *S. aureus* accounts for 1% of foodborne illness caused by known pathogens (FSANZ 2013; Pillsbury et al. 2013; OzFoodNet 2014; OzFoodNet 2015).

Illness associated with consumption of marinara mix contaminated with SE

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 SFP outbreaks associated with consumption of marinara mix.

Prevalence of coagulase positive *S. aureus* 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 *S. aureus* in marinara mix.

Other relevant standards or guidelines

- [FSANZ compendium of microbiological criteria for food](#) has a satisfactory level for coagulase positive staphylococci of $<10^2$ CFU/g. Food is deemed potentially hazardous if levels are $>10^4$ CFU/g or staphylococcal enterotoxin is detected.
- 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 (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 coagulase-positive staphylococci limit of $n=5$, $c=2$, $m=100$ CFU/g, $M=1000$ CFU/g for products at the end of the manufacturing process (European Commission 2007).

Other considerations

Testing for high levels of coagulase-positive staphylococci is an indicator test for the presence of SE.

Biosecurity restrictions apply to products under this commodity classification. Refer to the [BICON database](#).

This risk statement was compiled by FSANZ in: November 2016

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