Imported food risk statement

Bivalve molluscs and norovirus

Commodity: Bivalve molluscs (e.g. oysters, mussels, clams, cockles and scallops) and seafood mixes containing bivalve molluscs (e.g. marinara mix). Retorted shelf stable product is not covered by this risk statement.

Recommendation and rationale
Is norovirus (NoV) in bivalve molluscs a medium or high risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • NoV is a moderate hazard as it generally causes illness of short duration and usually no sequelae. • NoV has been isolated from bivalve molluscs; areas of higher sanitary classification show less contamination. • NoV is a frequent cause of foodborne illness associated with consumption of bivalve molluscs. • Bivalve molluscs bioaccumulate NoV from their environment (i.e. surrounding growing waters). • The risk can be mitigated by harvesting bivalve molluscs from approved areas and ensuring producers follow a verified sanitation program. This will reduce but not eliminate the risk. • Bivalve molluscs do not usually receive a heat treatment that is sufficient to inactivate NoV (internal temperature of 90°C for 90 seconds) as this can make the product unpalatable.

General description
Nature of norovirus: Norovirus (NoV) belongs to the *Caliciviridae* family of viruses. It is a small (27 – 40nm) non-enveloped icosahedral virus with a single stranded RNA viral genome (Green 2013). NoV cannot grow in food; however the virus can survive in food and still be present at the point of consumption. The virus can also survive in the environment, including water (Zainazor et al. 2010; Codex 2012). In humans NoV is typically spread via person-to-person transmission (faecal-oral or vomit-oral route). Infection can occur through consumption of contaminated food or water, direct person-to-person contact, or contact with contaminated surfaces (Karst 2010; Barclay et al. 2014). Resistance of NoV to heating is variable and highly dependent on the initial level of contamination, time and temperature of heating, virus strain, and type of food matrix. Cooking bivalve molluscs to an internal temperature of 90°C for 90 seconds is considered adequate to inactivate NoV (studies were performed using surrogates as NoV is non-culturable). Cooling and freezing processes do not reduce NoV infectivity to levels considered safe (Hewitt and Greening 2006; Sow et al. 2011; Codex 2012; Flannery et al. 2014; Cook et al. 2016). NoV is generally resistant to detergents and ethanol-based reagents used to clean environmental surfaces and fomites, so additional chemical disinfection is required (Green 2013). The viral distribution pattern within an animal will differ based on the viral genotype, type of virus and bivalve mollusc. In oysters NoV can accumulate in the gills, adductor muscle and digestive tissues. Some NoV strains bind specifically to receptor sites in the digestive tissues. These strains are more efficiently concentrated than other viral strains and generally persist after depuration procedures (le Guyader et al. 2012; Araud et al. 2016).

General description
NoV has a winter seasonality in temperate climates, with higher concentrations of NoV in oysters collected from cooler waters (Campos et al. 2017). Testing food for any virus is challenging and requires matrix-dependent extraction, concentration techniques and viral RNA detection (however, this does not discriminate between infectious and non-infectious virus particles)(Codex 2012).
Adverse health effects: NoV is a moderate hazard as it generally causes illness of short duration and usually no sequelae (ICMSF 2002). Symptoms include explosive/projectile vomiting, diarrhoea, abdominal cramps and nausea. Onset of illness is typically 24 – 48 hours after infection, but can be as short as 12 hours, with duration of illness generally 12 – 60 hours. NoV is shed in large amounts during illness, but this may also occur before the onset of symptoms, and continues for several weeks afterwards. Asymptomatic infection can also occur with these individuals also shedding large amounts of NoV (Codex 2012; FDA 2012). The infective dose for NoV is very low (estimated at 10 – 100 viral particles) and people of all ages are susceptible to infection. The elderly, infants and immunocompromised individuals can have more severe and prolonged disease (Karst 2010; Zainazor et al. 2010; FDA 2012).
Consumption patterns: In the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey), <1% of children (aged 2 – 16 years), <1% of adults (aged 17 – 69 years) and <1% of people aged 70 and above reported consumption of bivalve molluscs (Australian Bureau of Statistics 2011). Mixed foods that contained bivalve molluscs and canned product were excluded from the analysis.
Risk factors and risk mitigation A key risk factor for NoV in bivalve molluscs is human faecal contamination of the production environment (growing waters). To mitigate this risk, bivalve molluscs should be grown in waters of good sanitary quality. The growing and harvest waters are classified under appropriate quality assurance programs, along with requirements for through-chain good hygienic practices, post-harvest handling, storage, relaying and depuration (Codex 2012; ASQAAC 2016). Sanitary surveys of growing areas should be conducted prior to the commencement of growing and/or harvesting operations. These surveys evaluate all actual and potential pollution sources and environmental factors which may affect harvest area water quality, to determine the appropriate harvest area classification. The classification of a harvest area is re-evaluated at least annually (Codex 2012; ASQAAC 2016). Classifications may restrict appropriate end use of the product, for example: suitable for direct human consumption, requiring depuration or relaying, or unsuitable for growing or harvesting. The competent authority is responsible for classifying the harvest waters, including closing or reopening the waters. Classifications require ongoing assessment of the quality of the growing waters, with growing areas opened or closed to harvest based on analytical results. *Escherichia coli*/faecal coliforms or total coliforms may be used as an indicator of possible faecal contamination, but cannot guarantee the animals are free of NoV (Codex 2012; Codex 2016; ASQAAC 2016). Viruses present in the growing waters can bioaccumulate in the tissues of bivalve molluscs. Depuration and relaying processes involve moving live animals into clean water to allow them to slowly be purged of pathogens. Depuration is a short process (usually 24 – 48 hours) and utilises tanks of clean water, while relaying involves transferring the bivalve molluscs to new seabeds with clean water for up to several weeks. NoV can remain in bivalve molluscs after depuration and while long-term relay of bivalve molluscs can reduce the viral load, it is often impractical due to added costs or lack of clean areas in the proximity of the contaminated harvest site (ICMSF 2005; Codex 2012; le Guyader et al. 2012; Woods and Burkhardt 2013). Virus levels will generally decline slowly over time through relaying. However, neither depuration nor relaying alone are reliable risk mitigation steps. Contagious food handlers present a risk of contaminating bivalve molluscs with NoV. Seafood businesses should ensure good hygienic practices are implemented throughout the supply chain to prevent contamination

General description
from food handlers during growing, harvest and post-harvest activities. Good manufacturing practices, such as ensuring water and ice used to process bivalve molluscs come from an uncontaminated source will also help mitigate the risk of NoV (ICMSF 2011; Codex 2012). Traditionally bivalve molluscs are consumed raw or lightly cooked and as such there is no kill step that inactivates NoV.
Surveillance information: NoV is not a notifiable disease in Australia. It has been estimated that 276,000 cases of foodborne gastroenteritis are associated with NoV annually in Australia (Kirk et al. 2014). **Illness associated with consumption of bivalve molluscs contaminated with NoV** A search of the scientific literature via Web of Science, PubMed, Scopus, US CDC Foodborne Outbreak Online Database and other publications from 2000 – February 2017 identified there have been over 100 international NoV outbreaks associated with consumption of bivalve molluscs from 2000 onwards. A selection of outbreaks are listed below: • Australia (2013) – 525 NoV cases linked to consumption of Tasmanian oysters associated with a sewerage pipe leaking into the harvest area (Lodo et al. 2014). • Canada (2010) – 36 NoV cases linked to consumption of raw oysters, epidemiologically associated with ill harvest workers (McIntyre et al. 2012). • USA (2009) – 177 NoV cases epidemiologically linked to steamed oysters; cooking temperatures (21 – 74°C) inadequate to inactivate NoV (Alfano-Sobsey et al. 2012). • New Zealand (2006) – 115 NoV cases epidemiologically linked to consumption of raw oysters imported from Korea. Labelling recommended cooking prior to consumption, however the product was consumed raw (Simmons et al. 2007) • Italy (2002) – 103 NoV cases linked to consumption of raw and cooked mussels (Prato et al. 2004). **Data on the prevalence of bivalve molluscs contaminated with NoV** A search of the scientific literature via Web of Science, PubMed, Scopus and other publications from 2000 – February 2017 identified that surveys of bivalve molluscs have isolated NoV in <2 to >75% of samples (dependent on classification area)(Lowther et al. 2012; Brake et al. 2014): • Australia (2010 – 2011) – NoV was detected in <2% of oysters (n=115) collected from harvest areas. The oyster samples had *E. coli* levels <230 MPN/100g so complied with the Class A classification (Brake et al. 2014). • Italy (2008 – 2012) – NoV was detected in 22.1% of bivalve molluscs (mussels and clams)(n=68) collected from Class A classified areas and 66.3% of bivalve molluscs (mussels, clams and oysters)(n=184) from Class B classified areas (Suffredini et al. 2014). • United Kingdom (2009 – 2011) – NoV was detected in 76.2% of oyster samples collected from harvest areas (n=844). Of the oysters from Class A, B or C classified harvesting areas the proportion that were positive for NoV was approximately 65% (n=130), >75% (n=669) and >85% (limited sample size, n=41), respectively (Lowther et al. 2012). • Italy (2003 – 2011) – NoV was detected in 4.7% of mussels (n=2310), 3.8% of clams (n=1517) and 2.4% of oysters (n=510) collected from the market or Class A classified harvesting areas (Pavoni et al. 2013).

Standards or guidelines
• Division 3 of Standard 4.2.1 in the Australia New Zealand Food Standards Code requires bivalve molluscs businesses to implement a documented food safety management system that effectively controls the hazards and incorporates the Australian shellfish quality assurance program (ASQAP) Manual conditions. • ASQAP require a sanitary survey to determine the appropriate harvest area classification. The water of

Standards or guidelines
approved areas must have a median thermotolerant faecal coliform most probable number (MPN) ≤14/100mL and an estimated 90th percentile MPN ≤43/100mL (five tube MPN test)(ASQAAC 2016). • Codex Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food *CAC/GL 79-2012* provides guidance on how to minimise the presence of NoV in food (Codex 2012). • Section seven of the Codex Code of Practice for Fish and Fishery Products *CAC/RCP 52-2003* applies to the pre-harvest and primary production of bivalve molluscs and describes control measures (Codex 2016). • Codex Standard for Live and Raw Bivalve Molluscs *CODEX STAN 292-2008* covers the production and processing of live and raw bivalve molluscs. For the edible parts of bivalve molluscs the *E.coli* limit is n=5, c=1, m=230 and M=700 (Codex 2015).

Management approaches used by overseas countries
• The European Commission regulation (EC) No 854/2004 classifies the different harvesting areas (A to C). Live bivalve molluscs in Class A areas may be collected for human consumption. Regulation (EC) 2073/2005 specifies an *E. coli* limit of n=1, c=0, m=230 MPN/100g for live bivalve molluscs placed on the market. As per Regulation (EC) No 854/2004 Class B areas (*E. coli* limit <4600 MPN/100g) require purification treatment and Class C areas (*E. coli* limit <46000 MPN/100g) require relaying over a long period (European Commission 2004; European Commission 2007). • New Zealand includes bivalve molluscan shellfish and products containing bivalves as food of high regulatory interest. These foods must be from a permitted country or geographic region and food must meet the clearance limits (*E. coli* limit <7cfu/g for bivalve molluscs)(MPI 2016). • The US National Shellfish Sanitation Program (NSSP) requires a sanitary survey. The water of approved areas must have median faecal coliform MPN ≤14/100mL and an estimated 90th percentile MPN ≤43/100mL (five tube MPN test). All commercial shellfish harvested or imported into the US must meet the NSSP safety standards set for raw molluscan shellfish (FDA 2015; NACMCF 2016). • The Canadian Shellfish Sanitation program requires a comprehensive survey to assess all environmental factors. The water of approved areas must have median faecal coliform MPN ≤14/100mL, with ≤ 10% of samples with an MPN >43/100mL. Live or raw molluscan shellfish can only be imported into Canada if the shellfish were harvested in an authorised country, are an approved species, and were handled and processed by an authorised shipper/establishment (CFIA 2012).

This risk statement was compiled in: July 2017

References

Alfano-Sobsey E, Sweat D, Hall A, Breedlove F, Rodriguez R, Greene S, Pierce A, Sobsey M, Davies M, Ledford SL (2012) Norovirus outbreak associated with undercooked oysters and secondary household transmission. Epidemiology and Infection 140:276–282

Araud E, DeCaprio E, Ma Y, Lou F, Gao Y, Kingsley D, Hughes JH, Li J (2016) Thermal inactivation of enteric viruses and bioaccumulation of enteric foodborne viruses in live oysters (*Crassostrea virginica*). Applied and Environmental Microbiology 82(7):2086–2099

ASQAAC (2016) Australian shellfish quality assurance program. Australian Shellfish Quality Assurance Advisory Committee.
http://safefish.com.au/About/Partners. Accessed 19 July 2017

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

Barclay L, Park GW, Vega E, Hall A, Parashar U, Vinje J, Lopman B (2014) Infection control for norovirus. Clinical Microbiology and Infection 20:731–740

Brake F, Ross T, Holds G, Kiermeier A, McLeod C (2014) A survey of Australian oysters for the presence of human noroviruses. Food Microbiology 44:264–270

Campos CJA, Kershaw S, Morgan OC, Lees DN (2017) Risk factors for norovirus contamination of shellfish water catchments in England and Wales. International Journal of Food Microbiology 241:318–324

CFIA (2012) Canadian Shellfish Sanitation program - Manual of operations. Canadian Food Inspection Agency, Ottawa.
http://www.inspection.gc.ca/food/fish-and-seafood/manuals/canadian-shellfish-sanitation-program/eng/1351609988326/1351610579883. Accessed 27 February 2017

Codex (2012) Guidelines on the application of general principles of food hygiene to the control of viruses in food (CAC/GL 79 - 2012). 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) 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 29 March 2017

Cook N, Knight A, Richards GP (2016) Persistence and elimination of human norovirus in food and on food contact surfaces: A critical review. Journal of Food Protection 79(7):1273–1294

European Commission (2004) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Official Journal of the European Union 30.4.2004:L155/206-L155/320

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 (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

FDA (2015) National Shellfish Sanitation Program - Guide for the control of molluscan shellfish. US Food and Drug Administration, Silver Spring.
https://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754. Accessed 27 February 2017

Flannery J, Rajko-Nenow P, Winterbourn JB, Malham SK, Jones DL (2014) Effectiveness of cooking to reduce norovirus and infectious F-specific RNA bacteriophage concentrations in *Mytilus edulis*. Journal of Applied Microbiology 117:564–571

Green KY (2013) *Caliciviridae:* The noroviruses. Ch 20 In: Knipe DM, Howley PM (eds) Fields virology. 6th ed, Lippincott Williams and Wilkins, Philadelphia, p. 582–608

Hewitt J, Greening GE (2006) Effect of heat treatment on hepatitis A virus and norovirus in New Zealand Greenshell mussels (*Perna canaliculus)* by quantitative real-time reverse transcription PCR and cell culture. Journal of Food Protection 69(9):2217–2223

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 (2005) Fish and fish products. Ch 3 In: Microorganisms in food 6: Microbial ecology of food commodities. 2nd ed, Kluwer Academic/Plenum Publishers, New York, p. 174–249

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

Karst SM (2010) Pathogenesis of noroviruses, emerging RNA viruses. Viruses 2:748–781

Kirk M, Glass K, Ford L, Brown K, Hall G (2014) Foodborne illness in Australia: Annual incidence circa 2010. Australian Government Department of Health, Canberra

le Guyader FS, Atmar RL, Le Pendu J (2012) Transmission of viruses through shellfish: When specific ligands come into play. Current Opinion in Virology 2:103–110

Lodo KL, Veitch MGK, Green ML (2014) An outbreak of norovirus linked to oysters in Tasmania. Communicable Diseases Intelligence 38(1):E16–E19

Lowther JA, Gustar NE, Powell AL, Hartnell RE, Lees DN (2012) Two-year systematic study to assess norovirus contamination in oysters from commercial harvesting areas in the United Kingdom. Applied and Environmental Microbiology 78(16):5812–5817

McIntyre L, Galanis E, Mattison K, Mykytczuk O, Buenaventura E, Wong J, Prystajecky N, Ritson M, Stone J, Moreau D, Youssef A, Outbreak Investigation Team (2012) Multiple clusters of norovirus among shellfish consumers linked to symptomatic oyster harvesters. Journal of Food Protection 75(9):1715–1720

MPI (2016) Food notice - Importing food. New Zealand Ministry for Primary Industries, Wellington

NACMCF (2016) Response to the questions posed by the Food Safety and Inspection Service, the Centers for Disease Control and Prevention, the National Marine Fisheries Services, and the Defense Health Agency Veterinary Services activity regarding control strategies for reducing foodborne norovirus infections. Journal of Food Protection 79(5):843–889

Pavoni E, Consoli M, Suffredini E, Arcangeli G, Serracca L, Battistini R, Rossini I, Croci L, Losio MN (2013) Noroviruses in seafood: A 9-year monitoring in Italy. Foodborne Pathogens and Disease 10(6):533–539

Prato R, Lopalco PL, Chironna M, Giovanna B, Germinario C, Quarto M (2004) Norovirus gastroenteritis general outbreak associated with raw shellfish consumption in South Italy. BMC Infectious Diseases 4(37):doi:10.1186/1471-2334-4-37

Simmons G, Garbutt C, Hewitt J, Greening G (2007) A New Zealand outbreak of norovirus gastroenteritis linked to the consumption of imported raw Korean oysters. The New Zealand Medical Journal 120(1264):66–72

Sow H, Desbiens M, Morales-Rayas R, Ngazoa SE, Jean J (2011) Heat inactivation of hepatitis A virus and a norovirus surrogate in soft-shell clams (*Mya arenaria)*. Foodborne Pathogens and Disease 8(3):387–393

Suffredini E, Lanni L, Arcangeli G, Pepe T, Mazzette R, Ciccaglioni G, Croci L (2014) Qualitative and quantitative assessment of viral contamination in bivalve molluscs harvested in Italy. International Journal of Food Microbiology 184:21–26

Woods JW, Burkhardt W (2013) Preventing and controlling viral contamination of shellfish. Ch 14 In: Cook N (ed) Viruses in food and water - Risks, surveillance and control. Woodhead Publishing, Cambridge, p. 281–292

Zainazor T, Hidayah MSN, Chai LC, Tunung R, Ghazali FM, Son R (2010) The scenario of norovirus contamination in food and food handlers. Journal of Microbiology and Biotechnology 20(2):229–237