FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Imported food risk statement

Bivalve molluscs and hepatitis A

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 hepatitis A virus (HAV) in bivalve molluscs a medium or high risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • HAV is a serious hazard as it causes incapacitating, though not usually life threatening, illness of moderate duration. • HAV has been isolated from bivalve molluscs; areas of higher sanitary classification show less contamination. • HAV is a common cause of foodborne illness associated with consumption of bivalve molluscs. • Bivalve molluscs bioaccumulate HAV 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 HAV (internal temperature of 90°C for 90 seconds) as this can make the product unpalatable.

General description
Nature of hepatitis A: Hepatitis A (HAV) belongs to the *Picornaviridae* family of viruses. It is a small (25 – 28 nm) non-enveloped icosahedral virus with a single stranded RNA genome. HAV 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 (Codex 2012; FSANZ 2013). In humans, HAV is transmitted via the faecal-oral route by either person-to-person contact or consumption of contaminated food or water (FSANZ 2013). Resistance of HAV to heating is variable and highly dependent on the initial level of contamination, time and temperature of heating, virus strain and the type of food matrix. Cooking bivalve molluscs to an internal temperature of 90°C for 90 seconds will inactivate HAV. Cooling and freezing processes do not reduce HAV infectivity to levels considered safe (Hewitt and Greening 2006; Codex 2012; FSANZ 2013; Sanchez 2015). The viral distribution pattern within an animal will differ based on the bivalve mollusc and virus type. In oysters, HAV can accumulate in the gills, adductor muscle and digestive tissues (Araud et al. 2016). 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).

General description
Adverse health effects: HAV is a serious hazard as it causes incapacitating but not usually life threatening illness of moderate duration. However, sequelae are rare (ICMSF 2002). Symptoms include fever, nausea, anorexia, malaise, vomiting, diarrhea, muscular pain and often jaundice. Jaundice generally occurs five to seven days after the onset of gastrointestinal symptoms. Illness typically occurs 15 – 50 days after infection, with duration generally one to two weeks (in a minority of patients prolonged disease or relapses may occur). HAV is shed in the faeces up to two weeks before, and for several weeks after, onset of illness. Peak shedding occurs prior to the onset of symptoms when most individuals are unaware they have a HAV infection. Asymptomatic infection can also occur with these individuals also shedding HAV (Wasley et al. 2010; FDA 2012; FSANZ 2013). The infective dose for HAV is unknown, however, it is thought to be 10 – 100 viral particles (FDA 2012). People of all ages are susceptible to HAV infection (unless they have immunity from a previous infection or vaccination). The disease is milder in children under six years, with many cases being asymptomatic. Infection in older people and those with underlying chronic liver disease can have a more severe disease outcome (Codex 2012; FSANZ 2013).
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 HAV 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 HAV (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. HAV 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; McLeod et al. 2009; Codex 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 HAV. Seafood businesses should ensure good hygienic practices are implemented throughout the supply chain to prevent contamination 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 help

General description
mitigate the risk of HAV (ICMSF 2011; Codex 2012). Traditionally bivalve molluscs are consumed raw or lightly cooked and as such there is no kill step that inactivates HAV.

Surveillance information:

HAV is a notifiable disease in all Australian states and territories with a notification rate in 2016 of 0.6 cases per 100,000 population (144 cases). This was a decrease from the previous five year mean of 0.8 cases per 100,000 population per year (ranging from 0.6 – 1.0 cases per 100,000 population per year)(NNDSS 2017). In Australia in 2011, 28% of HAV cases were locally acquired (OzFoodNet 2015).

HAV vaccination is effective at reducing the incidence of HAV disease. HAV vaccination is included as part of the National Immunisation Program Schedule for Aboriginal and Torres Strait Islander children (introduced in 2005 across jurisdictions with high disease incidence) and is also recommended for travellers to endemic areas and those at increased risk because of lifestyle or occupation (DOHA 2016a; DOHA 2016b; Thompson et al. 2017)

Seroprevalence data provides an important measure of the level of immunity to HAV infection in a population due to vaccination or past exposure. An Australian national HAV seroprevalence survey across 46 laboratories in 1998 found 41.1% of serum samples were seropositive for HAV (n=3,043)(Amin et al. 2001). A seroprevalence study over a 20 year period in Victoria found HAV seroprevalence had increased over time from 34.3% in 1988 (n=753), to 40.0% in 1998 (n=1091), and 55.1% in 2008 (n=791)(Heywood et al. 2012).

Illness associated with consumption of bivalve molluscs contaminated with HAV

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 at least seven international HAV outbreaks associated with consumption of bivalve molluscs from 2000 onwards. A selection of outbreaks are listed below:

- US (2016) – 292 hepatitis A cases linked to consumption of raw scallops (adductor muscle) imported from the Philippines (FDA 2016; Hawaii DOH 2017).
- Netherlands and United Kingdom (2012) – 12 primary hepatitis A cases epidemiologically linked to consumption of cooked mussels. One patient with travel history to a HAV endemic country visited near the harvesting area (Class B classification). Mussels were exported from the UK to the Netherlands (Boxman et al. 2016).
- France (2007) – 111 hepatitis A cases linked to consumption of raw shellfish (mainly oysters) from one French farm and surrounding area (Guillois-Becel et al. 2009).
- United States (2005) – 39 hepatitis A cases epidemiologically linked to consumption of raw oysters from two Louisiana harvest areas (Bialek et al. 2007).

Data on the prevalence of HAV in bivalve molluscs

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 HAV in 0 to >40% of samples (dependent on classification area)(Manso et al. 2010; Prato et al. 2013):

- Spain (2011 – 2012) – HAV was detected in 10.1% of bivalve mollusc samples (mussels, clams and cockles)(n=168) collected from Class B classified areas (Polo et al. 2015).
- Spain (2009 – 2010) – HAV was detected in 8.5% of bivalve molluscs (mussels and clams)(n=281) collected at retail. The samples all had *E. coli* levels <230 MPN/100g so complied with the Class A classification (Moreno Roldan et al. 2013).
- Italy (2007) – no HAV was detected in blue mussels (n=200) collected from Class A classified harvest areas (Prato et al. 2013).
- Spain (2004 – 2006) – HAV was detected in 42.6% of mussels (n=68) collected from Class B classified harvesting areas and in 43.5% of bivalve molluscs (clams, cockles, mussels)(n=92) collected from Class C classified harvesting areas (Manso et al. 2010).

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 approved areas must have a median thermotolerant faecal coliform most probable number (MPN) ≤14/100mL and an estimated 90^{th} 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 HAV 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 90^{th} 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).

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