Imported food risk statement

Dried ready-to-eat pomegranate arils and hepatitis A virus

Scope: Ready-to-eat (RTE) dried arils (and seeds) of pomegranate (*Punica granatum*). Retorted, fresh and frozen product is not covered by this risk statement.

Recommendation and rationale
Does hepatitis A virus (HAV) in imported dried RTE pomegranate arils present a potential medium or high risk to public health: ☐ *High* ☑ *Medium* ☐ *No* FSANZ concludes that hepatitis A virus (HAV) in imported dried RTE pomegranate arils presents a potential medium risk to public health. **Rationale**: • HAV is a serious hazard as it causes incapacitating illness of moderate duration which, in rare cases, can be life threatening. It is very infectious, with small quantities likely to cause infection. • No outbreaks of foodborne illness associated with dried RTE pomegranate arils and HAV have been reported. There is a lack of data on the prevalence of HAV in dried RTE pomegranate arils. • The method of primary production and processing can introduce contamination, and there is also the potential for post-processing contamination of the food. The drying process is likely to reduce but not eliminate HAV contamination of pomegranate arils. • Although HAV cannot replicate in food, it is a robust virus, and is likely to survive for extended periods of time in dried RTE pomegranate arils and so could be present at the time of consumption. • In Australia hepatitis A is uncommon and, while vaccination is available, there is a low overall seroprevalence in the population. This means a significant proportion of the Australian population are susceptible to foodborne transmission of HAV.

General description

Nature of the microorganism:

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. Like all viruses, HAV can multiply in living host cells but cannot replicate 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 and is considered to be extremely stable under a wide range of environmental conditions, including drying, freezing and heating (Codex 2012; FDA 2012; FSANZ 2013; Hollinger and Martin 2013).

The host range of HAV is limited to humans and non-human primates (Hollinger and Martin 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).

HAV replicates in the liver before being released into the small intestine via the bile duct and is subsequently shed in highest concentrations in faeces. Peak levels of HAV shedding in faeces occurs in the two weeks prior to the onset of clinical symptoms (up to 10^9 infectious HAV particles per gram of faeces: (Hollinger and Martin 2013; Wasley et al. 2010). Asymptomatic and symptomatically infected persons are generally unaware they present a hazard at the time most virus is being shed (FSANZ 2013).

Resistance of HAV to heating is variable and highly dependent on the virus strain, initial level of contamination, time and temperature of heating and the type of food matrix (Bidawid et al. 2000; Codex 2012; FSANZ 2013). Also, increasing the concentration of sugar increases the resistance of HAV to heating (Deboosere et al. 2004). Cooling and freezing processes are not considered suitable for the control of viruses as they do not reduce virus infectivity to levels considered safe. In studies on

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enteric viruses on berries and herbs, Butot et al. (2008; 2009) showed that both freeze-drying and frozen storage for up to 90 days at -20°C had negligible effect on the infectivity of HAV, with less than 1 Log reduction achieved on most products. In addition, HAV is not readily inactivated by drying or desiccation (Cliver 2009; Sanchez and Bosch 2016). Studies on blueberries have shown that HAV was still detectable after osmotic dehydration at 23°C (15 hours) followed by air drying at 100°C (1 hour), with a 2.6 Log reduction in HAV (Bai et al. 2020). Very high temperatures—e.g. dry heat treatment of freeze-dried berries at 120°C for 20 min—was required to inactivate HAV (Butot et al. 2009).
Adverse health effects: HAV is a serious hazard as it causes incapacitating illness of moderate duration which, in rare cases, can be life threatening. Symptoms associated with HAV infection include fever, nausea, anorexia, malaise, vomiting, diarrhoea, 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, and HAV is shed in the faeces up to two weeks before—and for several weeks after—onset of illness. The duration of illness is typically one to two weeks, although prolonged or relapsing cases may continue for up to six months in a minority of patients (FDA 2012; FSANZ 2013). People of all ages are susceptible to HAV infection unless they have immunity from a previous infection (which provides lifelong protection against reinfection) or vaccination (after which, anti-HAV antibodies persist for at least 20 years) (CDC 2019) and references therein). The disease is milder in young children under six years, with many cases being asymptomatic. HAV infection in people over 40 years can have a more severe disease outcome. In rare cases, HAV infection can lead to acute liver failure, which can be fatal (Codex 2012; FDA 2012; FSANZ 2013). The infectious dose of HAV is considered to be 10–100 viral particles (FDA 2012).
Consumption patterns: In the 2011–2012 Australian National Nutrition and Physical Activity Survey (part of the 2011–2013 Australian Health Survey), no respondents reported consumption of dried RTE pomegranate arils when eaten as is (i.e. excluding mixed dishes and processed foods). Less than 1% of children (aged 2–16 years), <1% of adults (aged 17-69 years) and <1% of people aged 70 years and above reported consumption of dried RTE pomegranate arils in mixed or processed foods or when eaten as is (ABS 2014). The reported percentages are based on single day of consumption information from the nutrition survey, and do not indicate the frequency of consumption of dried RTE pomegranate arils. It is likely that consumption of pomegranate has increased in the years since the 2011–2013 Australian Health Survey was conducted, driven by changing food consumption trends and evidenced by the existence of a small but growing Australian pomegranate production sector in Australia (AgriFutures Australia 2017).
Risk factors and risk mitigation Pomegranate arils can potentially be contaminated with HAV at many points in the supply chain, from primary production through to the point of consumption. To minimise contamination of pomegranate arils with HAV, effective control measures are necessary during primary production and processing, e.g. through application of Good Agricultural Practices (GAP) on-farm and Good Hygienic Practices (GHP) at critical points in the supply chain (Codex 2017). During the primary production of pomegranates, risk factors include the use of contaminated water for irrigation or the application of water-soluble fertilisers and agricultural chemicals, and potential contact with human biosolids used as fertiliser. Risks can be managed by application of GAP, including the use of clean or potable water (free of human faecal contamination); and minimising the contact of fruit with irrigation water and soil-borne contaminants (Codex 2012, 2017; Fiore 2004). Harvesting by hand can lead to transfer of HAV from the hands of infected workers to the surface of the fruit. In countries where HAV is endemic, workers who are asymptomatic or have unsuspected HAV infection (shedding virus), or those who are caring for an infected child, can increase the risk of contaminating fresh produce. Appropriate control measures include providing adequate sanitation and hand washing facilities for field workers (Codex 2012; Fiore 2004). Fruit can also be contaminated by the use of HAV-contaminated water for rinsing after harvesting. Potable water should be used for rinsing and for any ice used for packing fruit (Codex 2012; Fiore 2004). Although mechanical aril extraction systems are becoming more widely available, commercial production of pomegranate arils often still occurs by manual deseeding, with a concomitant risk of the introduction of HAV by contact with contaminated hands, equipment or water or by transfer of contamination from the surface of the fruit (Breuner et al. 2018). Post-processing handling of the product (before and after freezing) can also potentially introduce contamination. Possible control steps include prior surface decontamination of the fruit, use of potable water, reducing bare hand contact with the fruit during

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processing and providing workers with training in food hygiene and access to sanitation and hand washing facilities (Codex 2012; Fiore 2004; Tavoschi et al. 2015). There are currently no effective, realistic and validated risk management options to eliminate viral contamination of fresh produce prior to consumption without changing the normally desired characteristics of the food (Codex 2012). Although the drying process will reduce the HAV load in dried RTE pomegranate arils, drying does not appear to be an effective control measure for HAV due to the heat and desiccation resistance of the virus, as demonstrated in berry studies (Bai et al. 2020; Butot et al. 2009). Further processing of pomegranate arils, e.g. heat treatment, may result in inactivation of HAV. It is recommended to cook food to 85°C for 1 minute to inactivate HAV, recognising that the extent of virus inactivation is influenced by the food matrix. Product with higher sugar content require longer treatment times to achieve the same reduction in HAV, as demonstrated in berry studies (Bozkurt et al. 2020; Deboosere et al. 2004; FSANZ and NZ MPI 2015). Pomegranate arils destined to be dried and suspected of being contaminated with the virus should be immediately disposed of in a manner that prevents cross-contamination. Persons suspected of, or displaying signs of, infection should be excluded from food handing premises until fully recovered and no longer shedding the virus. Vaccination of food handlers can assist in reducing the risk of viral contamination of the food. Where feasible and appropriate, checking for HAV immune status of food handlers could be useful (Codex 2012). Widespread post-exposure vaccination has also been used as a control measure in outbreaks in the US and Canada (Collier et al. 2014; Swinkels et al. 2014). In Australia since 2006, targeted HAV vaccination programs have effectively reduced the number of notifications and hospitalisations in specific subpopulations at increased risk of infection. HAV is now uncommon in Australia. The relatively low overall hepatitis A seroprevalence in the population means a large proportion of the Australian population is susceptible to foodborne transmission of the disease (AIHW 2018; Thompson et al. 2017). Testing food for HAV is challenging, requiring matrix-dependent extraction and concentration techniques (Codex 2012). HAV contamination of food is difficult to detect through cell culture techniques (Grohmann and Lee 2003). Detection of HAV RNA can also be difficult, as the virus may not be homogenously spread through the food, there may be low levels of contamination, and the food may contain materials that inhibit the amplification process (used for viral detection). Detection of viral genetic material does not discriminate between infectious and non-infectious virus particles. A negative test result does not exclude the possibility of HAV contamination (Codex 2012; EFSA 2014; Enkirch et al. 2018; Tavoschi et al. 2015).
Surveillance information: Hepatitis A is a notifiable disease in all Australian states and territories, with a notification rate in 2020 of 0.3 cases per 100,000 population (85 cases). This was a substantial decrease from the previous five year mean of 1.0 case per 100,000 population per year (ranging from 0.6–1.7 cases per 100,000 population (NNDSS 2021). The reported notification rate includes both foodborne and non-foodborne transmission. Historically, the majority of HAV cases in Australia have been acquired overseas (OzFoodNet 2015, 2018). However due to the global pandemic in 2020 there was very limited overseas travel, which is anticipated to have led to the drop in reported Australian HAV cases. **Illness associated with consumption of dried RTE pomegranate arils contaminated with HAV** A search of the scientific literature via EBSCO, US CDC National Outbreak Reporting System and other publications from 2005 to 2020 did not identify any HAV outbreaks associated with consumption of dried RTE pomegranate arils. **Data on the prevalence of HAV in pomegranate arils** A search of the scientific literature via EBSCO and other publications from 2005 to 2020 identified that there is a lack of data on the prevalence of HAV contamination in pomegranate arils for sale in Australia or elsewhere.

Standards or guidelines
• Codex general principles of food hygiene (*CAC/RCP 1 – 1969)* highlights key hygiene controls at each stage of the food production and supply chain, from primary production through to final consumption (Codex 2020). • The Codex code of hygienic practice for fresh fruit and vegetables (*CXC 53-2003*) addresses Good Agricultural Practices and Good Hygienic Practices that help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to consumption (Codex 2017). • Annex 1 (Ready-to-eat fresh pre-cut fruits and vegetables) of the code of hygienic practice for fresh fruit and vegetables (*CXC 53-2003*) provides specific guidance to help control microbial, physical, and chemical hazards associated with the processing and distribution of ready-to-eat fresh fruit and vegetables that have been peeled, cut or otherwise physically altered from their original form but remain in the fresh state (Codex 2017).

Standards or guidelines
• 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 prevent or minimise the presence of human enteric viruses, especially norovirus and HAV, in foods (Codex 2012). • In Australia, the majority of horticultural produce is grown under recognised food safety schemes. The main schemes used are the Harmonised Australian Retailers Produce Scheme (HARPS), and schemes that are internationally benchmarked to the Global Food Safety Initiative (GFSI) (FSANZ 2020). Further, Chapter 3 (Food Safety Standards) of the *Australia New Zealand Food Standards Code* apply to food businesses that handle or sell horticultural produce. Some requirements in these standards can apply to transport and pack house activities (as long as they are not considered to be "primary food production"). Some elements of traceability are also provided through food receipt and recall provisions of Standard 3.2.2, along with labelling requirements under Standard 1.2.2.

Management approaches used by overseas countries
Regulation (EC) No 852/2004 (Annex 1 Part A: General hygiene provisions for primary production and associated operations) of the European Union outlines general provisions for the hygienic production of food, including fresh produce. This includes requirements on water use; health and hygiene of food handlers; cleaning and sanitising of facilities, equipment and vehicles; animal and pest exclusion; storage of waste; and the use of biocides (EU 2004). It recommends that food hazards present at the level of primary production should be identified and adequately controlled through the application of appropriate hygiene practices at farm level supplemented, where necessary, by specific hygiene rules for primary production. Fresh fruit or vegetables imported into Canada must meet Canadian requirements as set out in the *Safe Food for Canadian Regulations* as well as the *Food and Drug Regulations*. Under Section 8 of the *Safe Food for Canadian Regulations*, food that is imported, exported or inter-provincially traded must not be contaminated; must be edible; must not consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; and must have been manufactured, prepared, stored, packaged and labelled under sanitary conditions (CFIA 2019). In the US, the Produce Safety Rule of the *Food Safety Modernization Act* established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This includes requirements for water quality; biological soil amendments; sprouts; domesticated and wild animals; worker training and health and hygiene; and equipment, tools and buildings (FDA 2019b). The USDA has aligned the harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the requirements of the FDA Food Safety Modernization Act's Produce Safety Rule. While the requirements of both programs are not identical, the relevant technical components in the FDA Produce Safety Rule are covered in the USDA H-GAP Audit Program. However, the USDA audits are not regarded as a substitute for FDA or state regulatory inspections (FDA 2019a).

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