Imported food risk statement

Dried ready-to-eat berries and hepatitis A virus

Scope: Ready-to-eat (RTE) dried berries, including (but not limited to) cranberries, blackberries, blueberries, raspberries and strawberries. Retorted, fresh and frozen product is not covered by this risk statement.

Recommendation and rationale
Does hepatitis A virus (HAV) in imported dried RTE berries present a potential medium or high risk to public health:

☐ *High* ☑ *Medium* ☐ *No*

FSANZ concludes that hepatitis A virus (HAV) in imported dried RTE berries 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.
- There is some evidence of the presence of HAV in dried RTE berries; no outbreaks of foodborne illness have been reported.
- 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 berries.
- Although HAV cannot replicate in food, it can survive in dried RTE berries and still 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 virus:

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 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 symptomatic infected persons are generally unaware they present a hazard at the time most virus is shed in faeces (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 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

General description
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). 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 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 years and above reported consumption of dried RTE berries when eaten as is (i.e. excluding mixed dishes and processed foods). Ten percent of children (aged 2–16 years), 5% of adults (aged 17-69 years) and 3% of people aged 70 years and above reported consumption of dried RTE berries in mixed or processed foods or when eaten as is (ABS 2014). The reported percentages are based on a single day of consumption information from each nutrition survey and do not indicate the frequency of consumption of dried RTE berries. It is likely that consumption of berries has increased in the years since the 2011–2013 Australian Health Survey was conducted, driven by changing food consumption trends and evidenced by the increase in Australian berry production over recent years (Hort Innovation 2018) and importation of these products into Australia[1].
Risk factors and risk mitigation Berries 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 berries 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) throughout the supply chain up to the point of consumption (Codex 2017). During the primary production of berries, risk factors include the quality of water used for irrigation and the application of water-soluble fertilisers and agricultural chemicals, potential contact with human biosolids used as fertiliser and seepage of untreated or partially treated sewage into the soil. Risks can be managed by application of GAP, including the use of clean or potable water (free of human faecal contamination); proper management of fertiliser storage and treatment facilities; and minimising the contact of berries with irrigation water and soil-borne contaminants (Codex 2012, 2017; Fiore 2004). Harvesting of berries by hand is a key risk factor as it 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, 2017; Fiore 2004). Berries can also be contaminated by the use of HAV-contaminated water for rinsing after harvesting. Potable water should be used for rinsing berries and for ice used for packing (Codex 2012; Fiore 2004). Contamination of berries can occur during processing (e.g. during hand sorting of berries) and after processing (e.g. handling of product after freezing) by transfer from the hands of an infected food handler. Possible control steps include reducing bare hand contact with the fruit and providing workers with training in food hygiene and access to sanitation and hand washing facilities (Codex 2012; Fiore 2004; Tavoschi et al. 2015).

[1] Imported food data sourced from the Australian Department of Agriculture, Water and the Environment

General description
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 of berries, drying does not appear to be an effective control measure for HAV in berries due to the heat and desiccation resistance of the virus (Bai et al. 2020; Butot et al. 2009). Further processing of berries, 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. Products with higher sugar content require longer treatment times to achieve the same reduction in HAV (Bozkurt et al. 2020; Deboosere et al. 2004; FSANZ and NZ MPI 2015). Any berries destined to be dried and suspected of being contaminated with HAV 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 can also be used as a control measure in outbreaks (CDC 2016; Fiore 2004). 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 infection 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: HAV 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 berries 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 berries. **Data on the prevalence of HAV in dried RTE berries** A search of the scientific literature via EBSCO and other publications from 2005 to 2020 identified one survey of the prevalence of HAV in berries that included dried product. Three surveys were also identified of the prevalence of HAV in fresh berries collected from the farm. These surveys have also been included as the contamination of berries during the primary production stage is the same for both fresh and dried product, and the drying process will only reduce and not eliminate HAV contamination. It should be noted that due to the constraints of viral RNA extraction and the low levels of virus contamination, false negative test results are common. The purpose of these surveys was to collect surveillance data, and they were not associated with an outbreak. Information from these surveys is listed below: • International (2009–2016) – HAV was detected in 0.1% of strawberries (n=918) and 2.6% of red currants (n=39), but was not detected in raspberries (n=536), blueberries (n=126), mixed berries (n=122), blackberries (n=49), black currants (n=20) or cranberries (n=16). The berries sampled in this study were mainly frozen, although some were dried, in puree, syrup or part of a finished product (i.e. cake) (Li et al. 2018). • Czech Republic and other European countries – HAV was not detected in strawberries collected from the farm (n=156) (Dziedzinska et al. 2018). • South Korea (2016–2017) – HAV was detected on 0.8% of strawberries (n=120) collected from the farm (Shin et al. 2019). • Italy – HAV was not detected in berries (blackberries, blueberries, raspberries, red currants) collected from the farm (n=75) (Macori et al. 2018)

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 2020). • 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 V (Berries) of the code of hygienic practice for fresh fruit and vegetables *CXC 53-2003* provides specific guidance to minimise microbiological hazards during primary production until packing and distribution of fresh berries and consumer use, including fresh RTE berries and those processed without a microbiocidal step (Codex 2017). • 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 in foods, and more specifically norovirus and HAV in foods (Codex 2012). • In Australia, the majority of horticultural product 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 Standards (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 activities such as 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
The European Food Safety Authority (EFSA) recommends good hygiene, manufacturing and agricultural practices in berry producing countries. The *European Commission Regulation (EC) No 852/2004 – Annex 1 Part A: General hygiene provisions for primary production and associated operations* 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). 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*. Some products, such as Guatemalan raspberries, are associated with elevated food safety risks and have specific import requirements to minimize potential hazards (CFIA 2019a). 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 2019b). 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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