

Imported food risk statement
Ready-to-eat berries and hepatitis A virus

Commodity: Ready-to-eat (RTE) berries. Examples of this type of product include frozen and fresh berries (such as blackberries, blueberries, gooseberries, mulberries, raspberries and strawberries).

Virus: Hepatitis A virus (HAV)

Recommendation and rationale
<p>Is hepatitis A virus (HAV) in RTE berries produced and handled under Good Agriculture Practice/Good Hygienic Practice 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"/> <i>Uncertain, further scientific assessment required</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> • Effective control strategies minimise contamination at the primary production segment of the supply chain (i.e. through application of Good Agricultural Practices) and during food processing (i.e. through Good Hygienic Practices) • HAV is a virus which cannot reproduce (increase in numbers) in RTE berries • RTE berries are commonly consumed across all age groups in Australia • Outbreaks associated with HAV in RTE berries are infrequent internationally and rare in Australia • HAV infection causes incapacitating but not usually life threatening illness of moderate duration and sequelae is rare • There are very little data on the prevalence of HAV contamination in RTE berries, although the evidence that is available suggests a very low prevalence

General description
<p>Nature of the virus:</p> <p>HAV is a small (25 – 28 nm) non-enveloped virus that belongs to the <i>Picornaviridae</i> family of viruses. It has a single stranded RNA genome that is contained within an icosahedral shaped capsid. HAV cannot grow in the environment although it does persist and is considered to be extremely stable under a range of environmental conditions, including heating, drying and freezing. While HAV cannot grow in food and the contamination level cannot increase during processing or storage of food, HAV can survive from a contamination event through to the point of consumption (FDA 2012; FSANZ 2013; FERA 2014).</p> <p>Humans are considered to be the only source of HAV. Currently seven HAV genotypes are recognised (I – VII); four genotypes (I, II, III, VII) infect humans and 3 genotypes (IV, V, VI) infect monkeys. The majority of human HAV cases are caused by strains I and III (Wasley et al. 2010; FSANZ 2013).</p> <p>HAV is transmitted via the faecal-oral route by either person-to-person contact or consumption of contaminated food or water. Bloodborne transmission is considered to be rare as HAV is only present in the blood of infected individuals for approximately a two week period (FSANZ 2013).</p> <p>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</p>

to the onset of clinical symptoms (up to 10^9 infectious HAV particles per gram of faeces) (Wasley et al. 2010; Hollinger and Martin 2013). 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 (Millard et al. 1987; Butot et al. 2009; 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. HAV on berries is resistant to the freeze-drying processes (Butot et al. 2009). Frozen storage of berries (blueberries, raspberries and strawberries) for up to 90 days at -20°C had negligible effect on HAV infectivity (Butot et al. 2008).

Adverse health effects:

HAV is classified by the International Commission on Microbiological Specifications for Foods (ICMSF) as a serious hazard for the general population as it causes incapacitating but not usually life threatening illness of moderate duration and sequelae is rare (ICMSF 2002). Symptoms associated with HAV infection 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 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 or vaccination). 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 (Codex 2012; FSANZ 2013).

The number of HAV particles required to cause infection is not known, however, it is presumed to be 10 – 100 viral particles (FDA 2012).

Consumption patterns:

In the 2007 Australian National Children's Nutrition and Physical Activity Survey, 10% of children aged 2 – 3 years and 6% of children aged 4 – 8 years reported consumption of RTE berries (DOHA 2008a). In the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey), 14.2% of children aged 2 – 3 years, 11.5% of children aged 4 – 8 years and 7.8% of adults (aged 19 years and above) reported consumption of RTE berries (ABS 2014). These data included consumption of all types of fresh and frozen RTE berries (from domestic and imported product) but excluded berries consumed as part of mixed dishes such as smoothies and pies. 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 RTE berries.

Data sourced from the Australian Bureau of Statistics for January 2012 – June 2014, indicates Australia imports around 14,000 tonnes of frozen berries annually.

Key risk factors:

Water sources contaminated with human faecal material or water sources that are prone to flooding are important environmental risk factors in berry growing areas. In countries where HAV is endemic, the presence of children in and around growing areas may be an important risk factor in the spread of HAV during primary production. Children who are asymptomatic or have unsuspected HAV infection (shedding virus) and are working in the production field or being cared for by a food handler also increase the risk of contaminating fresh produce (Codex 2012).

Contamination may occur via handling of food by infected food handlers, especially if they do not practice good personal hand hygiene, or through contact with surfaces exposed to the virus.

HAV is resistant to several preservation methods used in the food industry, such as acidification, heating, drying and freezing (EFSA 2014).

Risk mitigation:

Effective control strategies focus on prevention of contamination at the primary production segment of the supply chain, i.e. through application of Good Agricultural Practices (GAP), and prevention of contamination and cross-contamination during food processing, i.e. through Good Hygienic Practices (GHP).

To prevent contamination, primary production of berries should take into consideration the location of the production site; wild and domestic animals and human activity; water use; manure use; personnel health, hygiene and sanitary facilities; cleaning and sanitising of equipment; and handling, storage and transport of the product (Codex 2003a; Codex 2012).

Control of HAV in food requires stringent application of GHP and personal health and hygiene practices throughout the supply chain. Any food suspected of being contaminated with the virus should be immediately disposed of in a manner that prevents cross-contamination with food contact surfaces, other foods or other persons. Persons suspected of, or displaying signs of, infection should be excluded from food handling premises until fully recovered and no longer shedding the virus. Vaccination of food handlers is an effective mitigation measure in areas where HAV is endemic or populations have low immunity to reduce 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).

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).

Testing for HAV in food is problematic. Due to the complex methods used (extraction of the virus from the food followed by molecular-based methods to detect virus RNA) test results are subject to variability depending on the type of food, the distribution of virus within the food matrix and the presence of material that can interfere with the test leading to false negative findings. Additionally, the level of virus in contaminated food can be extremely low, below the level that can be detected by available methods. However, testing for HAV may be a useful tool where there is suspicion of virus contamination such as during outbreak investigations or investigations of process failure.

HAV contamination of fresh produce occurs when there is a breakdown of GAP/GHP. Considering the challenges with detecting viruses in berries listed above, *E. coli* is often used as an indicator of overall process hygiene (ICMSF 2011). While the presence of *E. coli* is not a reliable indicator for the presence of HAV; it indicates a failure in one or more production processes to control hazards. Alternatively, satisfactory levels of indicator microorganisms does not confirm the absence of HAV contamination.

In Australia, the majority of horticultural product is grown under recognised food safety schemes, such as GlobalGap or Freshcare, which are a component of commercial supplier agreements (FSANZ 2011; FSANZ 2014). 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](#).

Compliance history:

No testing requirements currently apply to HAV in imported berries; therefore no compliance data are available from the Imported Food Inspection Scheme of the Australian Department of Agriculture. Berries are currently imported from multiple countries and are tested for pesticide compliance.

There were 14 notifications on the European Commission’s Rapid Alert System for Food and Feed (RASFF) for HAV in RTE berries between January 2007 – January 2015. Eleven of these (RASFF/2013 694, 756, 757, 880, 1087, 1091, 1229, 1334, 1350, 1403, 1602) were associated with a large multinational European berry-associated outbreak of HAV from berries grown and packed in Europe (EFSA 2014). One notification in 2014 was associated with European grown berries (RASFF/2014.0465). Two notifications were associated with berries grown outside of Europe, one consignment of strawberries from Morocco via Spain (RASFF/2014.0721) and one consignment of frozen strawberry cubes from China (RASFF/2012.1534).

In February 2015, a recall of an imported frozen mixed berries product occurred in Australia due to potential HAV contamination (the recall was later extended to include two related products). No other recalls due to HAV in either imported or domestic RTE berries have occurred in Australia in the period January 2007 – January 2015.

Surveillance information:

HAV is a notifiable disease in all Australian states and territories with a notification rate in 2014 of 1.0 cases per 100,000 population (227 cases). This was a decrease from the previous five year mean of 1.2 cases per 100,000 population per year (ranging from 0.6 – 2.6 cases per 100,000 population per year) (NNDSS 2015). In Australia during the period 2004 – 2010, 44% of HAV cases (median value) were locally acquired (OzFoodNet 2012).

HAV is included as part of the National Immunisation Program Schedule for Aboriginal and Torres Strait Islander children younger than five years of age living in Queensland, the Northern Territory, Western Australia and South Australia (DOHA 2011). HAV vaccination is also recommended for travellers to endemic areas and those at increased risk because of lifestyle or occupation (DOHA 2008b).

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 of 3,043 samples collected from 46 laboratories in 1998 found 41.1% of serum samples were seropositive for HAV (95% confidence interval (CI), 39.4%-42.9%) (Amin et al. 2001). A seroprevalence study over a 20 year period in Victoria found HAV seroprevalence had increased over time from 34.3% (95% CI, 31.7-36.9, n=753) in 1988, to 40.0% (95% CI, 37.1-42.8, n=1091) in 1998 and 55.1% (95% CI, 52.1-58.1, n=791) in 2008 (Heywood et al. 2012).

Illness associated with consumption of RTE berries contaminated with HAV

A search of the scientific literature via the EBSCO Discovery Service and the US CDC Foodborne Outbreak Online Database identified six HAV outbreaks associated with the consumption of RTE berries during the period 1995 – January 2015. Examples of these are listed below:

- Outbreak in Europe (multinational) in 2013 – 2014, >1400 cases of illness linked to consumption of frozen berries. HAV was isolated from multiple batches of frozen mixed berries that were grown and packed in Europe (EFSA 2014)
- Outbreak in four Nordic countries in 2012 – 2013, >100 cases of illness epidemiologically linked to consumption of frozen strawberries imported from Egypt and Morocco. Despite extensive food sampling and testing of frozen strawberries no HAV could be isolated (Gillesberg Lassen et al. 2013; Nordic outbreak investigation team 2013; Gossner and Severi 2014)
- Outbreak in New Zealand in 2002, 39 cases of illness linked to consumption of domestically grown raw blueberries. HAV was detected in faecal specimens from cases as well as a blueberry product from the orchard (Calder et al. 2003)

Data on the prevalence of HAV in RTE berries

There is no routine or regular monitoring of berry fruits for the presence of HAV globally and there is very limited prevalence data on the rates of contamination of berries (not involved in foodborne outbreaks) by HAV in the peer-reviewed literature. This is largely due to the constraints of viral RNA extraction and the low levels of virus in contaminated food and water.

- A survey across the Czech Republic, Finland, Poland and Serbia in 2009 – 2010 sampled fruit at retail as well as production and processing sites. HAV was not detected in fresh raspberries (n=60), frozen raspberries (n=39) or fresh strawberries (n=21) at retail. HAV was not detected in production areas in irrigation water (n=56), on the hands of food handlers (n=113), on toilets (n=9) or toilet door handles (n=10). In processing plants, HAV was not detected on conveyor belts (n=24) or on a food handlers hands (n=1) (Maunula et al. 2013)

Other relevant 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 2003b)
- Codex code of hygienic practice for fresh fruit and vegetables *CAC/RCP 53-2003* addresses Good Agricultural Practices and Good Manufacturing 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 packing (Codex 2003a)
- Annex V (Berries) of the Codex code of hygienic practice for fresh fruit and vegetables *CAC/RCP 53-2003* provides specific guidance to minimise microbiological hazards during primary production through packing and distribution of fresh berries, as well as fresh berries that are processed without a microbiocidal step (e.g. frozen berries eaten raw and RTE berries) and consumer use (Codex 2003a)
- 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 minimize the presence of human enteric viruses in foods, and more specifically norovirus and HAV in foods (Codex 2012)

Approach by overseas countries

Microbiological limits for HAV are not currently incorporated into international standards as an element of regulatory controls due to the limitations associated with test methodologies noted above (Codex 2012).

The European Food Safety Authority (EFSA) recommends good hygiene, manufacturing and agricultural practices in berry producing countries. 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.

In Canada, the Canadian Food Inspection Agency monitors and verifies that food products meet Canadian standards and regulation. This approach includes inspection of fresh fruit and vegetables, whether exported, imported or traded interprovincially. Section 65 of the *Processed Products Regulations* details import requirements for frozen berries – this includes that processed fruits and vegetables must be sound, wholesome, fit for human consumption, manufactured from sound raw materials, and prepared under sanitary conditions.

In the US under the *Food Safety Modernization Act* (FSMA), science-based minimum standards are being developed for the safe growing, harvesting, packing, and holding of produce on farms to minimise contamination that could cause serious adverse health consequences or death (FDA 2014). A [Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables](#) (the ‘GAPs Guide’) has also been developed to assist industry in the application of GAP/GHP throughout the supply chain (FDA 1998).

Other considerations

Quarantine restrictions apply to products under this commodity classification. Refer to the [ICON database](#) for the conditions and types of berries permitted to be imported into Australia.

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