Microbiological Surveillance Sampling: FY 19-20 Frozen Berries (Strawberries, Raspberries and Blackberries)

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Regulated Product(s)

- Food & Beverages
- Fruit/Fruit Product

Frozen Berries

Frozen berries are used as ingredients in smoothies, baked goods, ice cream, jams and syrups, among other foods, and may be eaten without having undergone a 'kill step,' such as cooking, to reduce or eliminate pathogens. Strawberries, raspberries, and blackberries are delicate and may become contaminated with bacteria or viruses if handled by an infected worker who does not use appropriate hand hygiene or if exposed to contaminated agricultural water or a contaminated surface, like a harvesting tote. Freezing preserves berries but generally does not kill pathogens, which can survive at low temperatures.

Frozen berries have been implicated as the likely vehicle in multiple outbreaks of hepatitis A virus (HAV) and norovirus infections in recent decades. The FDA reported three HAV outbreaks and one norovirus outbreak linked to frozen berries in the United States from 1997 to 2016. The HAV outbreaks resulted in 405 illnesses and 53 hospitalizations; the norovirus outbreak resulted in 136 illnesses. Worldwide, several other outbreaks of these viruses have been associated with frozen berries in recent years. For instance, a large HAV outbreak linked to mixed frozen berries occurred in Europe in 2013 and 2014, causing more than 1,500 illnesses.

Questions and Answers

When will the FDA collect samples?

The FDA plans to collect samples throughout the year, across all seasons.

Where will the samples be collected from?

The FDA will collect domestic samples of frozen berries from processors, distribution centers, warehouses and retail locations. The agency will collect import samples of frozen berries from ports of entry, importer warehouses, or other storage facilities where foreign goods are cleared for entry into the country.

Samples may be collected from the same establishment or importer on more than one occasion. To minimize impact on any one firm, the FDA will not exceed three collections every six months from the same establishment, as a general rule, assuming no violations are found.

What exactly do you plan to collect?

The agency will only collect frozen strawberries, frozen raspberries, and frozen blackberries in retail packaging.

What microbial hazards will the FDA test for?

The FDA is testing all samples for hepatitis A virus and norovirus.

Will the FDA provide pre-notification to facilities where it plans to conduct sampling?

Per standard FDA practice, the agency will not provide pre-notification to firms prior to collecting samples, to preserve the study's integrity. Sampling is a routine and critical activity that the agency is authorized to conduct to help ensure the safety of the food supply.

What happens when the FDA finds a positive sample?

If the FDA detects hepatitis A virus or norovirus, the agency will notify the firm of the findings and work with the firm to take appropriate action to protect the public health. The FDA also upon detecting a pathogen may take actions such as placing a firm on import alert, overseeing a recall, or issuing public warnings.

What should I expect when the FDA collects samples?

See detailed information on what to expect when the FDA collects samples.

Will the FDA publish the test results? If so, how often?

The FDA plans to publish the test results on a quarterly basis. Check here as they will be posted at the bottom of this page.

What is the FDA doing to minimize the impact of its sampling on industry and commerce?
The FDA is sensitive to the concerns of domestic firms and importers and strives to provide analytical results to industry as soon as they are available. The FDA will notify firms of all analytical results as soon as possible once sample analysis is complete.