July 24, 2019

Donna M. Garren, Ph.D.
Executive Vice President, Science and Policy
American Frozen Food Institute
2345 Crystal Drive, Suite 801
Arlington, VA 22202

Dear Dr. Garren:

Thank you for your recent correspondence, on behalf of the American Frozen Food Institute, regarding the U.S. Food and Drug Administration (FDA) microbiological sampling assignment for frozen berries. The FDA shares your concerns about the safety of the U.S. food supply and the importance of maintaining the public trust. The purpose of this letter is to address the issues raised in your letters dated June 13, and July 2, 2019, relating to the sampling assignment, regulatory actions, and the release and reporting of results. We are preparing a separate response that will speak to our test methods and the underlying science issues you raised in these letters and a letter dated July 10, 2019.

Consistent with the agency's mission, it is important for our frozen berries assignment to continue as part of the FDA's broader efforts to help ensure the safety of the U.S. food supply. While the primary focus of the assignment is to estimate the prevalence of hepatitis A virus (HAV) and norovirus (NoV) in frozen berries (raspberries, blackberries, and strawberries), we must take steps to protect consumers as appropriate based on our findings. As described in the surveillance sampling assignment, frozen berries have been implicated as the food vehicle in outbreaks of HAV and NoV infections in recent decades.

In August 2018, the FDA conducted outreach to industry and other stakeholders on the agency's planned surveillance sampling assignment for frozen berries. As part of the outreach, we detailed how we would carry out the assignment, including explanations of collection methods and sites, as well as sample analysis. We also at the time invited all stakeholders to provide feedback on the planned assignment as our purpose was to ensure that it would be carried out as effectively and efficiently as possible. Based on the feedback received, we made key changes to the assignment before issuing it. Those changes included limiting the sampling to individual types of frozen berries in finished retail packaging, removing mixed frozen berries from the scope of the assignment, and prioritizing early-in-the-supply-chain collection among the domestic samples.

After discussion of the issues outlined in your June 13 and July 2 letters, we have made additional modifications and clarifications to our frozen berries sampling assignment.

First, our sample collection strategy will be modified to collect samples at distribution centers rather than at retail. We realize many firms may choose to place products being sampled on a

test and hold status pending laboratory results given the long shelf-life of frozen berries. Therefore, removing retail collection from the sampling assignment will minimize the amount of product in commerce in the event a sample is determined to be positive, thereby further strengthening public health while minimizing market disruption.

Second, as the RT-qPCR method has undergone multi-lab validation by the FDA for the detection of HAV and NoV in soft fruit, this will remain the primary test under this assignment. However, going forward the agency will also implement Sanger sequencing as a routine component of this sampling assignment in order to characterize viruses present in any RT-qPCR positive samples. FDA will continue sharing the RT-qPCR results with the product owners or distributors as soon as results become available. Because an RT-qPCR positive suggests that product may have been in direct or indirect contact with insanitary conditions, firms with an RT-qPCR positive result may want to consider reviewing their Current Good Manufacturing Practices and supply-chain controls for employee hygiene, illness policies, and other possible sources of fecal contamination. For this sampling assignment, FDA will not request initiation of a voluntary recall unless further characterization (i.e., the Sanger sequencing) is achieved. For voluntary recalls that were previously initiated and completed, FDA will finish the recall classifications shortly and will send classification notification letters to the firms involved.

Moving forward, results from the RT-qPCR analysis should be available within five business days after the FDA servicing laboratory receives the sample. Sequencing results should be available within 10 business days after a positive RT-qPCR result. Per Field Management Directive 147, Communication of Sample Analysis Results for Food Products and Environmental Samples,[1] if the sample is found to be contaminated, the FDA collecting division will promptly relay the results of such analysis by phone to the owner, operator, or agent in charge. The FDA will follow up with a letter to provide the Sanger result(s) to the firm, whether or not the virus is able to be characterized. For those that are positive, FDA will share the sequencing information if requested by the firm.

If the FDA detects a positive using RT-qPCR and the Sanger sequencing further characterizes a virus, FDA plans to request a voluntary recall. The FDA has published final guidance regarding public notification of recalls, which shares the agency's current thinking on circumstances that would warrant such notification of the recall.[2] We will continue to monitor the assignment closely and may reevaluate the analytical and regulatory approach to the detection of positives if data obtained indicate such a change is appropriate.

We are committed to ongoing communications with stakeholders about the key findings arising from the frozen berries sampling assignment. As with the FDA's prior surveillance sampling assignments, the agency plans to share in-progress updates from the frozen berries assignment on the agency's website, including the number of samples collected, as well as positive and negative findings. The upcoming update for the frozen berries assignment will include sample collection and test results from November 18, 2018, to June 28, 2019, and will include information on the source (domestic or import) of the samples. Please note that the progress updates do not contain

[1] See *https://www.fda.gov/media/92539/download*.
[2] See *https://www.fda.gov/media/110457/download*.

conclusions. The agency will publish a final report on its findings and their significance on the FDA website once the assignment and report are complete.

In closing, we value our collaboration with AFFI and its members and share the commitment to using the best available tools and science to further strengthen the safety of the U.S. food supply.

Sincerely,

/s/

Frank Yiannas
Deputy Commissioner
Food Policy and Response