March 22, 2022

Alison Bodor, President & CEO
American Frozen Food Institute
2345 Crystal Drive, Suite 801
Arlington, VA 22202

Sent via email to: rachel.buff@hoganlovells.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug stay the sampling assignment until such time as FDA takes the following steps to ensure that the test methodology and interpretation of results as used in the study and that form the basis of the agency's decision to request voluntary product recalls when it detects Hepatitis A (HAV) or Norovirus (NoV) are grounded in an appropriate scientific basis:

1. FDA should perform a multi-laboratory validation of the FDA method for the detection of enteric viruses (HAV and Nov) in soft fruits, i.e., the reverse transcription quantitative polymerase chain reaction (RT-qPCR) detection assay, using independent laboratories outside the agency.

2. Once externally validated, the FDA method for the detection of enteric viruses in soft fruits, i.e., the RT-qPCR detection assay, should be published as a scientific manuscript in the peer-reviewed literature.

3. After steps 1 and 2 are complete, FDA should release protocols for the method in FDA's Bacteriological Analytical Manual (BAM) that are sufficiently detailed to enable the method to be evaluated and reliably reproduced by the relevant scientific community.

4. FDA should convene an international panel of experts (including members from within FDA such as MOD1, the Centers for Disease Control, USDA's Food Safety and Inspection Service, and academia) with expertise in virology and microbial risk assessments in foods, tasked with establishing transparent and risk-based interpretive criteria, including sample positivity and negativity criteria, for interpreting RT-qPCR test of enteric viruses in soft fruits, as well as interpretative criteria for results confirmed through sequencing. The panel's findings should be made publicly available, and the agency should provide an opportunity for public comment, before adopting the findings, as appropriate.

This petition was received and processed under CFR 10.35 for Petition for Stay of Action by this office on 03/18/2022 and it was assigned docket number FDA-2022-P-0392. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.24 22:55:12 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
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