September 28 , 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
Submitted electronically via www.regulations.gov

Re: Revocation of Methods of Analysis Regulation
Docket No. FDA-2020-N-1383

Dear Sir or Madam:

FMI - The Food Industry Association (FMI) appreciates the opportunity to provide comments on the proposed rule *"Revocation of Methods of Analysis Regulation."* As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org

We are very concerned about the proposed rule "Revocation of Methods of Analysis Regulation" that would remove the methods of analysis regulation (21 CFR 2.19). As a leading public health agency with a strong history of developing science-based policies and regulations, we are struggling to understand why the FDA thinks that this regulation is unnecessary when it provides the foundation for scientific analytical methods and validation of such methods.

FDA is not limited to use of AOAC methods of analysis when the method of analysis is prescribed in a regulation. Furthermore, the Methods of analysis regulation provides flexibility for the use of other methods of analysis for nonregulatory functions, outside of its enforcement activities. It is critical that the methods of analysis used for the purpose of the Agency's enforcement programs are credible and legally defensible.

We strongly advise FDA to maintain or revise 21 CFR 2.19 in order to permit the use of appropriate methods of analysis recognized by national and international standard organizations that have critically reviewed and approved by scientific committees to validate that the performance criteria of the method are fit for purpose.

FMI recommends the following criteria for laboratory methods used for verification activities and/or enforcement activities:

1. Methods are used for their intended purpose;
2. Methods are published in peer reviewed scientific journals for transparency;
3. Methods are validated by multiple independent laboratories;
4. Methods are recognized by a national or international standards organization; and
5. Methods used for enforcement should meet all of these requirements.

We are concerned that the revocation of section 2.19 would lead to a lack of scientific integrity in analytical methodology within the FDA and the industries regulated by the FDA. Additional reasons for FDA to maintain a regulatory reference for methods of analysis include the following points:

- The food industry aligns testing methods with the methods used by regulatory agencies. Verification of food safety programs often utilizes official analytical methods to assure that the known hazards are controlled.
- Recognized methods such as AOAC methods or other internationally accepted protocols ensure fair practices in food trade and companies rely on such methods for exports as well as imported products.
- International standards provide a global framework which ultimately benefits the consumer.
- AOAC methods are referenced by Codex Alimentarius in CXS 234-1999, *Recommended Methods for Analysis and Sampling*.
- Other regulatory bodies such as the EU also have regulations on official controls to ensure application of food and feed law. EU 2017/625 outlines the requirements for methods used for sampling and laboratory analysis during official controls.
- Removal of the regulation could allow for novel methods to be developed and used without any expectation of validation. We strongly encourage novel method development but expect that methods will be appropriately validated, a

verified for their intended purpose and published in peer reviewed scientific journals for use by the industry and regulatory officials.

Finally, for regulations specifying a method of analysis, we encourage the agency to provide for flexibility to use validated and published methods as technology advances. We expect FDA to uphold the strong scientific principles so integral to the agency's history and current role.

Thank you for the opportunity to comment on this proposed rule and would be pleased to engage with the agency on this important issue.

Sincerely,

Hilary S. Thesmar

Hilary S. Thesmar, PhD, RD, CFS
Chief Science Officer and Senior Vice President Food and Product Safety