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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Proposed Rule, Revocation of Methods of Analysis Regulation; Comment Request; Docket No. FDA-2020-N-1383 (July 15, 2022)

The undersigned organizations appreciate the opportunity to provide comments on the U.S. Food and Drug Administration (FDA or agency) proposed rule, *Revocation of Methods of Analysis Regulation*, revoking the methods of analysis regulation, § 2.19 (21 CFR 2.19), which describes an FDA policy to use certain methods of analysis to support FDA enforcement, as needed, and when the method of analysis is not prescribed in a regulation.

First and foremost, we recommend that FDA retain the methods of analysis regulation at 21 CFR 2.19 to assure robust transparency and certainty for relevant stakeholders, which include other regulatory agencies and bodies, standards-setting organizations, private and public laboratories, and industry. If that is not an option, we believe the proposed rule should not be finalized unless and until the agency adopts and publishes a written policy to replace 21 CFR 2.19, which for decades has served as a useful guidepost for both FDA and stakeholders. Under the current regulation, where a method of analysis is not prescribed in a regulation, FDA in its enforcement programs will utilize the methods of analysis published in the 13th Ed., 1980 of the AOAC INTERNATIONAL (AOAC) publication "Official Methods of Analysis of the Association of Official Analytical Chemists" and the "supplements thereto." Although the aforementioned 1980 edition of this compendia is outdated, the regulation, as written, is flexible to keep pace with advances in analytical instrumentation and technology and emerging issues, given there is an annual update with supplements to this official compendium and also as evidenced by the fact that FDA's enforcement actions include the use of AOAC methods from the modern era.

When the FDA utilizes an AOAC method, stakeholders understand that the method is validated, reproducible, fit for its intended use, and importantly, is an approved compendial method. This is because AOAC approved methods undergo rigorous and independent scientific scrutiny, including by FDA and other government officials that sit on AOAC expert panels tasked with reviewing methods prior to inclusion in the compendium. Additionally, AOAC methods are widely available to FDA and other stakeholders for purposes other than enforcement, such as routine testing to assure that hazards deemed reasonably likely to occur have been adequately addressed and that the finished food product is not adulterated and is safe. Use of AOAC methods by FDA and industry ensures that all parties are using the same method, which helps ensure results are comparable and of the same high quality.

The undersigned organizations are concerned that by revoking 21 CFR 2.19 without a clear policy to fill its void, in some cases, there will no longer be a rigorous standard for methods used

by FDA for enforcement purposes. As noted above, AOAC methods undergo rigorous and independent review and evaluation. Doubts about the validity and process used by FDA to establish and select a given method used during an enforcement action may lead to unintended consequences, including disputes between FDA and other stakeholders as defined above on the validity of the method deployed and/or its results, and confusion as to what methods companies should use for routine testing of the processing environment and the ingredients, other manufacturing inputs, and the food they produce to assure that safe food is produced each and every time.

Further, a key to industry's ability to comply with relevant regulations and assure that the food they produce is safe is access to the methods FDA uses. AOAC methods are known to accurately address a variety of hazards and are generally widely available. It is not clear whether methods identified in the FDA's Office of Regulatory Affairs Laboratory Procedures Manual would be widely available to all stakeholders and known prior to their use for enforcement purposes.

Indeed, we are particularly concerned by the lack of transparency that would result should FDA revoke 21 CFR 2.19. Although the regulation currently provides that "In the absence of an AOAC method the commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program," we are not confident FDA has been adhering to this language. The agency's website, for example, is hard to navigate and it is difficult to locate certain methods or information on how they were developed and validated. If the agency revokes 21 CFR 2.19, not only is there is no commitment on FDA's part to use a method that is validated, reproducible, and fit for purpose, but also there is no commitment to provide a copy of the method selected for enforcement purposes. This strikes us as particularly lacking due process. Moreover, this lack of transparency has the potential for disrupting food production if the methods for conforming to testing requirements are no longer clearly delineated.

While we understand that a regulation may be too rigid given the advances in food testing technologies and the need to develop methods rapidly in some cases to test for new and emerging contaminants, the undersigned organizations strongly request that, at the very least, FDA consider publishing a detailed guidance in the spirit of 21 CFR 2.19, that includes a method selection decision tree outlining the method criteria (that the method is a compendial method, accepted by recognized independent organizations, or validated by multiple independent laboratories, and the method is accessible to all stakeholders). There may be a scenario where a compendial method or otherwise is not available. FDA also should outline its approach to such a scenario, including how it will apply the same rigorous and independent scientific scrutiny given to compendial methods when developing and/or selecting the appropriate test method. Such guidance will provide transparency to stakeholders and allow for any disputes to be resolved swiftly, and outside of civil litigation, in the event of an enforcement action.

The undersigned appreciate FDA's important work and would like to thank the agency for the opportunity to comment. Our members have enjoyed the certainty, dependability, and authoritative nature that the AOAC compendia and its supplements have provided to companies as they verify hazard mitigation strategies are working as intended through routine testing. The food industry has always looked to those methods as the gold standard.

We look forward to partnering with FDA on science-based policies and frameworks that will ensure reliable methods of analysis are used to support enforcement action when needed.

Sincerely,

American Frozen Food Institute
American Herbal Products Association
American Spice Trade Association
Consumer Brands Association
Corn Refiners Association
Flavor & Extract Manufacturers Association
International Fresh Produce Association
National Confectioners Association
National Seasoning Manufacturers Association
Peanut and Tree Nut Processors Association
Refrigerated Foods Association
SNAC International