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## **IFT Comments to the FDA Regarding the Revocation of Methods of Analysis Regulation within 21 CFR 2.19**

September 21, 2022

Docket Number: FDA-2020-N-1383-0001

The Institute of Food Technologists (IFT) appreciates the opportunity to provide comments to the FDA regarding the proposed revocation on methods of analysis in 21 CFR 2.19. IFT recommends that instead of revocation, FDA update the methods of analysis portion of 21 CFR 2.19 to reflect the current state of affairs regarding continuous improvements being made to methods of analysis both domestically and internationally.

IFT is a global organization of approximately 12,000 individual members from 95 countries who are committed to advancing the science of food. Since 1939, IFT has engaged experts in food science, technology and related professions from academia, government and industry to help solve many of the world's greatest food related challenges. IFT provides scientific, technical and career development resources for advancing the science of food and its application across global food and agricultural systems. Our primary mission is to connect global food system technical communities to promote and advance the science of food and its applications. We believe that science is essential to ensuring a global food supply that is sustainable, safe, nutritious and accessible to all. Foundational to the application of science within food systems are the tools used to analyze food and agricultural products to determine many things, including meeting food safety requirements and fitness for consumption.

IFT disagrees with the premise that revocation is necessary due to newer methods being available, as stated in the description of the proposed rule, **“a general reference to the 1980 edition of the “Official Methods of Analysis of the Association of Analytical Chemists” is unnecessary because newer, updated methods of analysis may exist.”** The AOAC has updated and added new methods of analysis numerous times since 1980, and FDA is currently using many of them. While FDA's concern about referencing an outdated 1980 edition within a regulation is certainly valid, IFT believes that removing a general reference to a commonly used, globally recognized source of scientifically validated methods of analysis for use when FDA does not have a regulation that specifies a particular methodology, is inadvisable and may have unforeseen consequences. Rather, IFT believes FDA should amend 21 CFR 2.19 to incorporate language enabling the use of recognized updates to AOAC methods of analysis that they publish every three years. Language that could be used instead of the 1980 edition might be “the most current issued AOAC method available” for example, instead of using a specific date.



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The necessity of a common source of a generally recognized, scientifically validated, continuously updated set of methods of analysis, operating independently and objectively, for use with the science of food cannot be more profound. Many new developments in food science and technology occur long before FDA puts forth a written regulation in place with a specific method of analysis. Such new developments require an objective, globally accepted scientific basis in analysis that are frequently found as references within research papers from academic or other research institutions working on new technologies. Likewise, when no regulatory definition of a method of analysis is prescribed for use by FDA for conducting an analysis of a food product or food contact material, U.S. researchers in the food and agriculture industries will revert to the most appropriate, scientifically validated method, usually issued by AOAC. It is highly unlikely with the proposed revocation that researchers and industry would begin referencing the FDA's "Office of Regulatory Affairs Laboratory Procedures Manual and other resources" as stated in the proposal. While that may be useful for FDA internally, IFT believes it would not be useful broadly for academic researchers or industry. Most likely, the methods in the FDA Office of Regulatory Affairs Laboratory Procedures Manual were developed and validated under the auspices of AOAC. Other U.S. government agencies, as well as many globally, incorporate scheduled updates of regulations to keep up with advances in analytical methodologies, and IFT believes FDA could do likewise, as opposed to revoking an important general reference within CFR that is widely relied upon.

One of the consequences of revocation of this portion of 21 CFR 2.19 is the potential impact it would have on harmonization of global analysis methods. The Codex Alimentarius Commission (Codex) references AOAC and ISO as acceptable sources for methods of analysis related to global trade regulations on food and agriculture products, some of which do not fall under specific FDA stipulated regulations with defined methods included. AOAC and ISO work closely on revisions to methods of analysis to ensure consistency across global trade related analyses related to Codex, and IFT believes FDA's revocation would likely be harmful regarding global regulatory harmonization efforts at Codex, and could potentially create inadvertent trade barriers for the USA with other countries and inhibit economic activity. IFT notes that this issue was not considered by the FDA in its proposal under Section VI. Economic Analysis of Impacts, and has the potential to become a significant economic issue. Another potential concern that IFT would highlight to FDA related to the proposed revocation is under Section IX. Federalism. All 50 states and some US territories have various state laboratories that leverage and reference AOAC methods as their source for conducting important analyses. FDA moving to its own internal "Office of Regulatory Affairs Laboratory Procedures Manual" could create, among other things, legal issues if FDA and various state analytical laboratories disagreed over methodologies to use. Likewise, disagreements over analyses on food and agricultural products being imported to the USA or exported from the USA with other countries could potentially become problematic. Therefore, IFT believes that maintaining the AOAC reference with modified language to take into account the



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regular updating of analytical methodologies as science advances would be the most appropriate pathway to take for FDA.

IFT appreciates the FDA's consideration of IFT's comments. If there are any questions regarding our input, please do not hesitate to contact Bryan Hitchcock (VP Science, Policy and Learning) at [bhitchcock@ift.org](mailto:bhitchcock@ift.org) or me at [jruff@ift.org](mailto:jruff@ift.org).

Sincerely,

John Ruff MA, CANTAB, CFS

Chief Science and Technology Officer

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