



## FDA Proposes Rule Impacting Methods of Analysis

### The Issue

The Food and Drug Administration (FDA) proposed a rule on July 15, 2022, to revoke its methods of analysis regulation. It is current FDA policy to use the AOAC methods of analysis for FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA now suggests the regulation is “unnecessary” as the agency’s preferred methods of analysis may be identified in other FDA compliance and laboratory procedures resources.

***Your help is needed to tell the FDA about the importance of methods of analysis regulation.***

### What’s at Stake

By revoking the regulation, assurances given to consumers and industry that proper methods of analysis are required and used in laboratories will be removed.

By revoking the regulation, potential tools for traceability may be removed from commerce and import delays of perishable commodities will increase due to lack of confidence and quality of testing data.

By revoking the regulation, the standing of thousands of methods of analysis used by industry and government worldwide may be undermined.

### What to Do

FDA needs to hear from you now! Please file an official comment at <https://www.regulations.gov/commenton/FDA-2020-N-1383-0001> by completing the form. You may add your thoughts in the comment box provided in the link or attach a letter, if you prefer. The comment period closes on September 28, 2022.

### What to Say

1. Introduce yourself. Explain how you use methods of analysis and why they are important to you and your work.
2. Ask the FDA not to revoke the methods of analysis regulation. Ask the FDA to continue to utilize, and incorporate by reference, the AOAC methods of analysis and its supplements in its enforcement programs.

### Questions?

Contact AOAC at [CommentsHelp@aoac.org](mailto:CommentsHelp@aoac.org).

**Thank you for your prompt response to this urgent matter!**