Laboratory Accreditation for Analysis of Foods Proposed Rule

Food Lab Conference

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FDA, Office of Regulatory Affairs, Office of Regulatory Science

High-level Overview

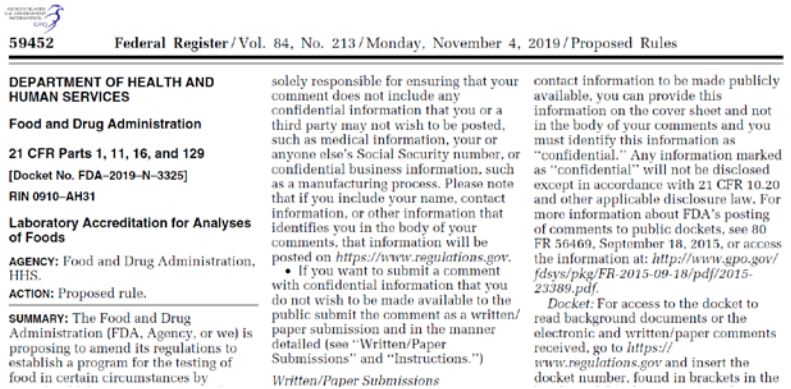
- Would create a program for the accreditation of laboratories, the use of which would be required in certain food testing circumstances

- Program required by FDA Food Safety Modernization Act (FSMA)

Important Dates

- January 4, 2011
- November 4, 2019
- July 6, 2020
- Early 2022

FDA FOOD SAFETY MODERNIZATION ACT



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, and 129

[Docket No. FDA–2019–N–3325]

RIN 0910–AH31

Laboratory Accreditation for Analyses of Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend its regulations to establish a program for the testing of food in certain circumstances by

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

Written/Paper Submissions

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the

Proposed Rule Link

https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-laboratory-accreditation

Discussion Limitations

- Since we are still in the comment period we are limited in what we can discuss.

FDA Food Safety Modernization Act

- FSMA requires:
  - FDA to establish a program for testing of food by accredited laboratories
  - FDA to establish an online registry of FDA-recognized accreditation bodies (ABs) and AB-accredited laboratories
  - Use of a laboratory from the registry required in certain circumstances (e.g., for certain tests of food under Import Alert)
  - Results shall be sent by laboratory directly to FDA

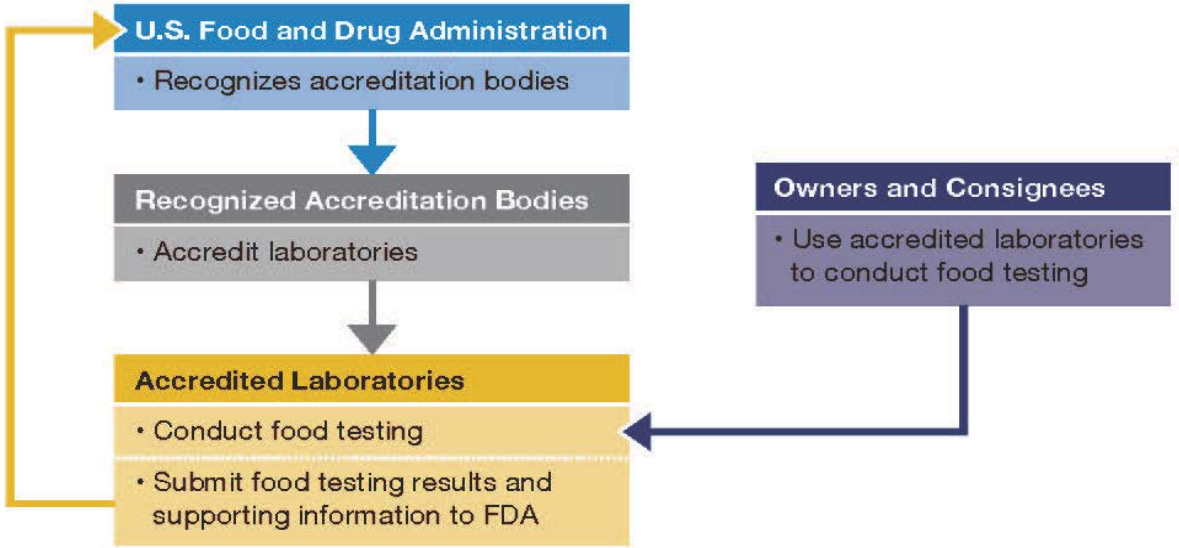
Key Point:

- Only labs that voluntarily participate in this program will be able to conduct the tests covered by the rule.

Testing under the Rule

- Certain corrective action testing required by existing FDA regulations (bottled water, shell eggs, sprouts);
- To support removal from import alert through successful consecutive testing;
- To support the release of a detained import;
- Food Testing Order (FTO) (new tool);
- Certain corrective action testing conducted in response to certain enforcement circumstances (uncommon).

Structure of the Program for the Accreditation of Laboratories to Conduct Food Testing



Accreditation Bodies

Accreditation Body (AB): a third party organization that assesses another entity (e.g., testing laboratory) to determine whether the entity satisfies a set of standards and is competent to perform a certain function

- There is an ISO/IEC standard for ABs (17011)
- Handful of ABs in the U.S.; most countries have one
- ILAC is the international organization for the ABs that accredit laboratories

Test Records

- Test results sent directly to FDA
  - Required by statute
- Submit analytical report to FDA
  - Increased clarity around documentation
  - Pathway whereby labs with positive track record may submit significantly abridged reports

Incorporation by Reference (IBR)

- NPRM would IBR two widely-accepted international voluntary consensus standards
  - ISO/IEC 17011: ABs
  - ISO/IEC 17025: Labs
- National Technology Transfer and Advancement Act & OMB Circular A-119

Requirements for Recognized ABs

- Meet ISO/IEC 17011:2017 and be an ILAC signatory
  - Similar to other government laboratory accreditation programs
- Meet impartiality and conflict of interest requirements
- Evaluate laboratories for accreditation; oversee accredited laboratories
- Provide substantive scientific review of certain laboratory documents to support accreditation

Requirements for Accredited Laboratories

- Meet ISO/IEC 17025:2017
- Demonstrate competence for each method to which seeks accreditation
- Meet impartiality and conflict of interest requirements
- Meet quality assurance requirements
- Develop or obtain certain sampling records, e.g., written sampling plans

More on Methods:

- Would require methods used be included within the accredited laboratory's scope of accreditation.
- Not proposing a defined inventory of possible scopes; rather, under this program laboratories would be able to become accredited for a variety of food analytical methods.

More on Sampling:

- Not proposing requirements for accreditation of sampling but invite comments.
- Proposing FDA oversight of sampling via records developed (if lab collected sample) or obtained (if sample collected by non-lab) by lab:
  - Sampler's qualifications
  - Sampling plans
  - Sample collection report

Comment Submission

- Go to https://www.regulations.gov
- Reference Docket No. FDA-2019-N-3325 for Laboratory Accreditation for Analysis of Foods
- Submit by: 6 July 2020
- Important to provide FDA with information, comments, industry perspective, etc. so that the program works well and is effective (improves public health)

FDA Office of Regulatory Affairs
Office of Regulatory Science

Thank you!