FSMA PROPOSED RULE ON LABORATORY ACCREDITATION: WHAT IT SAYS AND WHAT IT SHOULD SAY

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Caricature courtesy of ASM artist

THE TIMELINE

- Food Safety Modernization Act, P.L. 111-353 passed into law on January 4, 2011
- Section 202, Laboratory Accreditation for Analyses of Foods
- FDA issued proposed rule on Laboratory Accreditation for Analyses of Foods on November 4, 2019.
- Public comments on the proposed rule originally due within120 days.
- Two extensions offered; new deadline: July 6, 2020
- By consent decree, FDA must issue final rule by February 4, 2022.

A LOOK AT

THE LAW, THE REGULATION, THE COMMENTS

- The Law: what it says
- The Proposed Rule: what is proposed
  - "Would" not "shall"
- Interpretations and Recommendations: comments on the proposed rule

Four areas will be examined:
Applicability, Reporting, Quality Standards, Accreditation

FOOD LABORATORY ALLIANCE

APPLICABILITY:
WHAT THE LAW SAYS (IN PART)

- Food testing shall be conducted by a federal or non-federal laboratory that has been accredited for the purpose of testing:
  - in support of admission of an article of food under section 801(a)*; and
  - under an Import Alert that requires successful consecutive tests.

* 21 USC §381(a) Allows for prohibiting interstate commerce of foods that may violate the Federal Food, Drug, and Cosmetic Act (adulterated or misbranded)

APPLICABILITY:
WHAT THE REGULATION SAYS

- Food testing must be conducted by an accredited laboratory if at least one of the following conditions are met:
  - Explicit testing requirements to address identified or suspected food safety problem
  - As required by FDA in a food testing order
  - Address an identified or suspected food safety problem & presented to FDA as hearing evidence prior to recall or as part of corrective action plan
  - Support admission of an article of food related to import rules
  - Support removal from an import alert through consecutive testing

APPLICABILITY:
WHAT THE LAW SAYS (MORE)

- Food testing shall be conducted by a federal or non-federal laboratory that has been accredited for the purpose of testing:
  - in response to a specific testing requirement under this Act or implementing regulations, when applied to address an identified or suspected food safety problem; and
  - As required by the HHS Secretary, as the Secretary deems necessary, to address an identified or suspected food safety problem

GOALS:
WHAT THE LAW SAYS

- Increase the number of qualified laboratories eligible to perform testing, beyond the number qualified on the date of FSMA enactment

- "Accessible, timely, accurate and consistent food laboratory services"

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APPLICABILITY: COMMENTS

- Law permits a broader scope of applicability
- Proposed rule narrows the scope
  - Defining "identified or suspected"
  - Testing as evidence
  - Specific follow-up testing
  - Food testing orders
- Expand number of laboratories that must be accredited
  - Existing FSMA rules for verification testing, at a minimum
  - Pathway for accreditation for all food testing laboratories

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REPORTING:
WHAT THE LAW SAYS

- Recognized accreditation bodies & accredited laboratories report to the HHS Secretary any changes that would affect recognition

- Model standards shall include methods to ensure that reports of analyses are certified as true and accurate

- Results of any such testing shall be sent directly to FDA, except HHS Secretary may by regulation exempt test results from such submission requirement if the Secretary determines that such results do not contribute to the protection of public health. Required test results may be submitted to FDA electronically

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REPORTING:
WHAT THE REGULATION SAYS

- Accredited laboratories required to submit test results, sampling reports, analytical reports, validation and verification studies, and more to FDA about food testing conducted under this program. If non-standard method is used, documentation of method required.
- Documentation must be certified as true and accurate by mgmt.
- Among the items full analytical reports must contain:
  - Documentation, in full and step-by-step analysis conducted by accredited laboratory
  - Raw data, identify and describe negative and positive quality controls
  - All calculations
  - Identification of the analyst who conducted each step
  - Identification of the source and purity of reference standards used

REPORTING:
WHAT THE REGULATION SAYS

- Among the items full analytical reports must contain (continued):
  - Certified reference materials
  - Certified reference cultures traceable to a nationally or internationally recognized type culture collection
  - Proficiency testing, including qualifications of the analyst, c.v.
  - Individual PT worksheets
- If all information is not submitted to the FDA, related testing may be considered "invalid"
- All document submitted to FDA would display an unique identifier for each test results, report, notification or study. Test results would be cross referenced to it.

- FDA tentatively concludes that all submissions from accredited laboratories to FDA under this program must include detailed identifiers.
- Protection for trade secrets and confidential commercial information would be offered

REPORTING:
COMMENTS

- To become a recognized FDA accreditation body, an accreditation body must be a full member of the ILAC and signatory to ILAC MRA that has demonstrated competence to ISO/IEC 17011:2017
- Part of the purpose for requiring accreditation bodies to be ILAC MRA signatories is that there is an acceptance of data and results from laboratories accredited under this mark
- "Accredited once, accepted everywhere"
- Acceptance of results need not be duplicated

REPORTING:
COMMENTS

- As such, the following documentation should not be required with each test result submission to the FDA:
  - All sampling plans related to food testing conducted
  - Written documentation of sampler's qualifications
  - Certification from accredited laboratory's management
  - Documentation of reference for the method(s) of analysis used
  - Calculations
  - Identification and signature of the analyst(s) for each testing step
  - CVs
  - More

REPORTING:
COMMENTS

- Much of the requested information on references standards is currently available on the certificate/statement of analysis.
- Recollecting of some of this data is redundant, time-consuming and unnecessary
- Opportunity for accredited laboratories in good standing to submit an abridged analytical report to the FDA related to specific food testing disciplines. Unclear definitions on when this is permitted.

QUALITY STANDARDS:
WHAT THE LAW SAYS

- HHS Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body
- Model standards shall include methods to ensure:
  - Appropriate sampling, analytical procedures (including rapid) and commercially available techniques are followed and reports of analyses are true & accurate
  - Internal quality systems established and maintained
  - Procedures to evaluate/respond promptly to complaints
  - Individuals who conduct sampling and analyses are qualified by training and experience
  - Other criteria, as appropriate

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QUALITY STANDARDS:
WHAT THE REGULATION SAYS

- Accredited laboratories must participate in proficiency testing program(s)
  - At least once/year for each method within accreditation scope
- Ensure procedures for monitoring validity of test results includes use of reference materials or quality control samples with each batch of samples it tests
- Maintain conformance with ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
- Incorporates provisions of AOAC 17025 Guidelines

QUALITY STANDARDS:
COMMENTS

- Use of reference materials, quality control samples, proficiency testing – all critical components of ensuring accurate and reliable test results. Require in addition to ISO/IEC 17025:2017
- More frequent proficiency testing permits trending of results
- Proficiency testing providers should be accredited to ISO/IEC 17043, where available
- AOAC 17025 Guidelines related to reference materials and quality control samples is encouraged

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BENEFITS TO GOVERNMENT AGENCIES WITH 3RD PARTY ACCREDITATION BODIES

- Conducting the assessment process
- Accreditation decisions
- Instructing and qualifying the assessors
- Initiating adverse actions to accreditation

GOVERNMENT BENEFITS (CONT.)

- Accreditation bodies can tailor programs to regulator needs by:
  - Establishing program requirements more stringent than or in addition to ISO/IEC 17025
  - Require more frequent proficiency testing
  - Confirming the laboratories are competent to perform specific tests
  - Requiring specific personnel qualifications
  - Enables varying degrees of government oversight of the ABs

EXAMPLES OF FEDERAL GOVERNMENT RELIANCE ON PRIVATE SECTOR ABS

- Consumer Product Safety Commission
- DoD Environmental Laboratory Accreditation Program

CONSUMER PRODUCT SAFETY COMMISSION

- Relies on ILAC MRA Signatory Accreditation Bodies
- All labs assessed to ISO/IEC 17025:2017 and ILAC Policies
- Requires no additional oversight / obligations of the ABs
- CPSC observes ILAC Accreditation Body Evaluation

DOD ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP)

- All labs assessed to ISO/IEC 17025 and ILAC Policies
- Additional DoD Environmental Program Requirements
- DoD EDQW receives all assessment reports
- ABs also provide monthly status reports to DoD
- DoD EDQW can observe on-site assessments
- Annual face-to-face meetings between DoD and ABs
- Observe ILAC Accreditation Body Evaluation
- Participates in annual AB Assessor Training

DOD ROLE

- Perform accreditation body oversight functions
- Provides project management support at DoD sites
- Accreditation program maintenance / update criteria

BENEFITS TO AGENCIES

- Shifts expense from government to private sector
- Timely assessments and deliverables
- ILAC ABs have full time staff that support timely review of reports, CARs, and other accreditation services
- Use of technical experts that are trained to conduct thorough, efficient and effective on-site assessments

FSMA PROPOSED RULE AND ACCREDITATION

- Closer to the DoD ELAP model rather than the CPSC
- Relies on ILAC Recognized ABs
- Criteria is ISO/IEC 17025 and ILAC policies
- Includes more stringent requirements

REDUNDANCIES IN REPORTING

- Requires that lab:
  - Submit full analytical report packages to FDA including:
    - Sampling plans and sampling collection reports
    - Sampler qualification records
    - Lab management certifying results
    - All original compilations of raw data secured in the course of analysis
    - Calculations
    - Etc.

ASSESSMENT/ACCREDITATION

- On-site assessment includes review of :
  - Records from sample receipt to reporting results such as:
    - Sampling plan and report
    - Test reports
    - Raw data
    - Validation/verification studies

REDUNDANCIES IN ACCREDITATION DECISIONS

- The rule calls for the Administration to make Accreditation Decisions
  - Suspension
  - Enforced withdraw

This may cause confusion between Accreditation Body decisions and status and that of the Administration's decisions.

RECOMMENDATIONS

- Adopt model where FDA *recognizes* Accreditation Bodies and relies on the ABs for:
  - Accreditation decisions
  - Assessment processes including lab report review
  - On-going evaluation such as PT monitoring
- FDA provides oversight
  - Program
  - Criteria
  - Enforcement

QUESTIONS?

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