

ISO/IEC 17025 Accreditation – a Key Building Block of the Nation’s Integrated Food/Feed Safety System

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Outline

- Background
 - Why accreditation?
- How is laboratory accreditation aligned to FSMA and the Integrated Food/Feed Safety System (IFSS)?
- FDA's collaborative efforts to promote ISO/IEC 17025:2005 accreditation for the nation's food/feed testing laboratories
- Outcomes and vision for the future

Driving Forces of Laboratory Accreditation



- Integrated Food/Feed Safety System
- Partnership for Food Protection



- **Manufactured Food Regulatory Program Standards**
- **Animal Feed Regulatory Program Standards**



- Food Safety Modernization Act

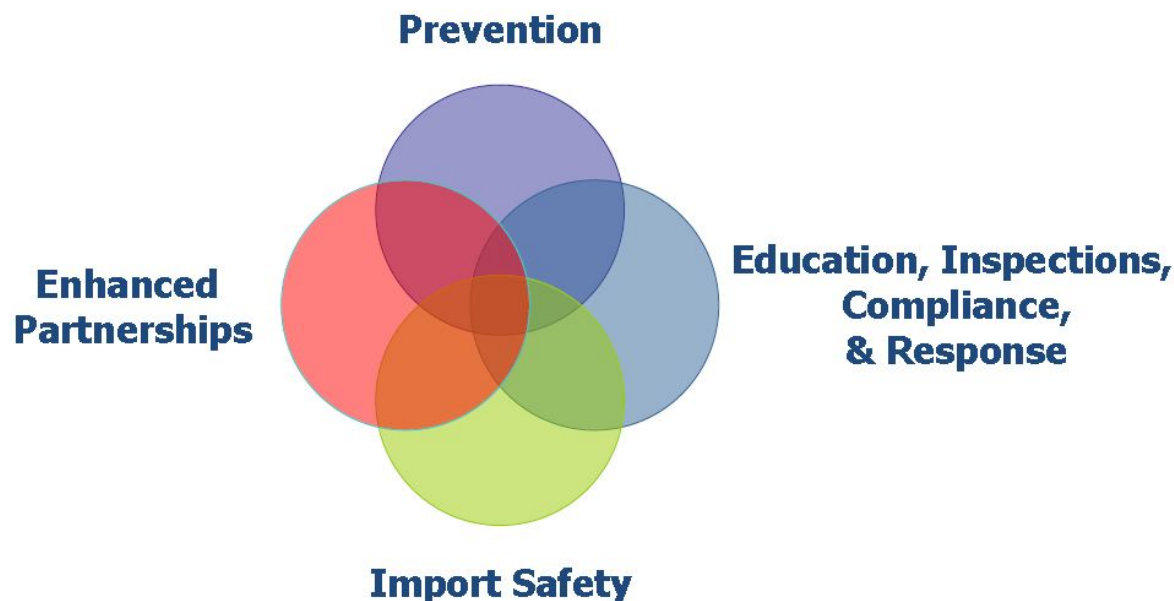
Section 202 of FSMA

Laboratory Accreditation for Analyses of Foods

Key Deliverables

- Establish lab accreditation program
 - Develop a process and criteria for recognition and accreditation
 - Develop a process and criteria for periodic review
 - **Develop model standards for testing labs**
 - Develop internal database to support program
- Establish public registry of recognized ABs and accredited labs
- **Accredited labs to conduct food testing**
 - Develop process for electronic submission of data
- **Develop process for reviewing State/local labs results for purposes of recall, CE activities**

Implementing FSMA through an Integrated Food System



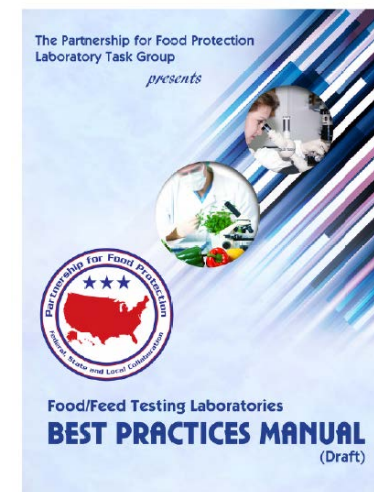
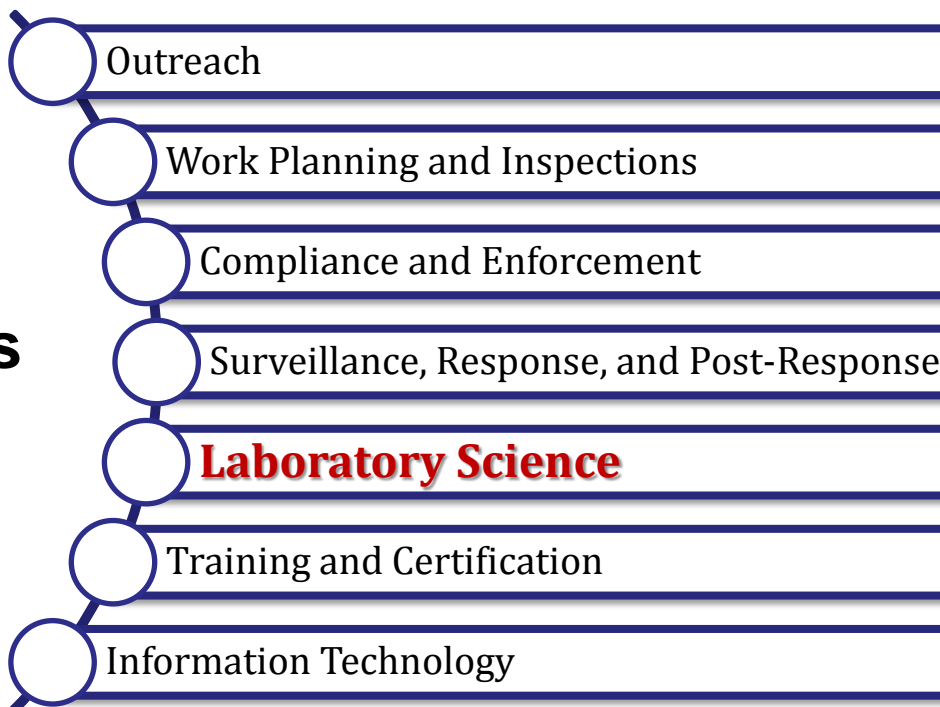
Partnerships:

- Federal, state, tribal, territorial and local regulatory and public health partners
- Academia
- Industry
- Other private sector
- Consumers

The Partnership for Food Protection “Mutual Reliance for a Safer Food Supply”

- a major vehicle to achieve the goals and outcomes for an IFSS set forth in FSMA

Goal Areas



Support ISO/IEC 17025
Laboratory Accreditation

Laboratory Accreditation is one of the Key Building Blocks of the Nation's Integrated Food/Feed Safety System

- Laboratory Accreditation supports the production of reliable, consistent and defensible data
- Using accredited laboratories can help establish and assure confidence for decision making to take regulatory action
- Laboratory accreditation supports the effort to establish and implement the national standards throughout the country
 - Uniform inspectional coverage and sample collection and analysis
 - Greater use of each other's analysis and observations in protecting public health

Manufactured Food Regulatory Program Standards (MFRPS) and Animal Feed Regulatory Program Standards (AFRPS)

- **MFRPS and AFRPS are set of National Standards to establish and to improve the Manufactured Food and Animal Feed Regulatory Programs**
- **Standard 10 require State program utilizes regulatory laboratories that meet the managerial and technical requirements of ISO/IEC 17025:2005, or are accredited by recognized accreditation body**
- **MFRPS :**
 - **2011 – MFRPS one year contract –(20+ laboratories)**
 - **2012 – 5 year ISO CAP grant – 31 awardees**
- **AFRPS:**
 - **2015 – 5 year ISO CAP grant to national feed laboratories**



Timeline of the Laboratory Accreditation Efforts

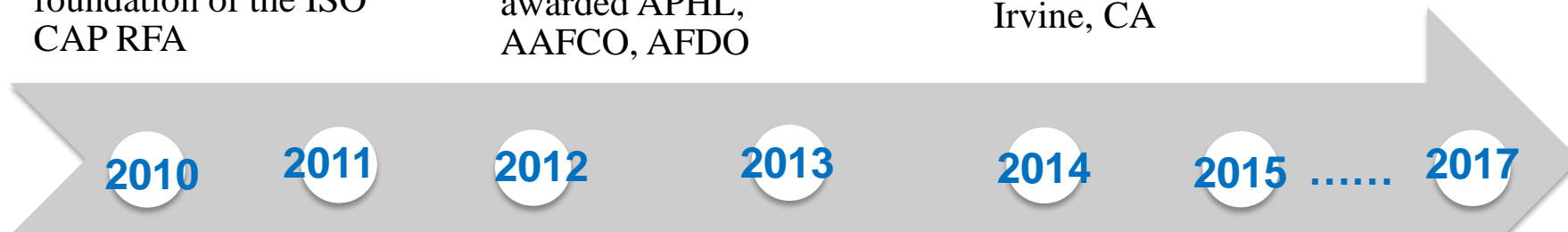
St. Louis Meeting

(APHL, AFDO, AAFCO, USDA/FSIS, and FDA) – initiation of the FDA/State laboratory accreditation plan – foundation of the ISO CAP RFA

ISO CAP –5-yrs grant, awarded 31 state laboratories

Association CAP – awarded APHL, AAFCO, AFDO

ISO CAP 2nd Annual meeting in Irvine, CA



2010

2011

2012

2013

2014

2015

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2017

IFSS & PFP

MFRPS-

Standard 10 contract

FSMA (section 202)

ISO CAP 1st Annual meeting at Raleigh, NC

FSMA Accreditation Rule is in the making
•Model laboratory Standard

ISO CAP 3rd extended Annual meeting in San Diego, CA

AFRPS grant
PFP Best Practices regroup
Data Acceptance working group

FDA Collaborative Efforts in Promoting ISO 17025 Laboratory Accreditation

Laboratory Accreditation Program:

ISO CAP under MFRPS:

- Awards to 30 MFRPS laboratories for 5 years
- OP, OAGS and ORS work together to provide management oversight and technical support

Association CoAg Accreditation Assistance:

- Co-Ag steering committee (APHL, AFDO, AAFCO and FDA) provide oversight on the laboratory accreditation efforts

Ad Hoc FERN lab assistance

ISO CAP under AFRPS (*new*)

ISO CAP Program Guidance



Expectation by the year of 2017

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Accreditation successfully achieved and expanded!!



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2011

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2017

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Examples of collaborative efforts with the associations on supporting ISO accreditation

- FDA funded three associations: APHL, AFDO, AAFCO
- Co-Ag steering committee (APHL, AFDO, AAFCO and FDA)
- Collaborative training efforts (FDA, APHL)
- Web based repository resource center and discussion board (APHL)
- Ad Hoc Labs assistance (APHL, FDA)
- Data Acceptance working group (APHL, AFDO, AAFCO, FDA)
- Sampling working group – GOODSample document (AAFCO)
- Check Sample Program (AAFCO)
- QA/QC guidelines (AAFCO)
- Development of a competency based career spanning training curriculum framework (AFDO)

Program Outcomes

- Increased number of accredited food and feed testing laboratories
- Increased testing capacity by accredited laboratories
- Harmonized laboratory standards throughout the country
- Increased data sharing and data acceptance for regulatory action
- Enhanced the Collaborative Relationship in building the nation's Integrated Food/Feed Safety System
 - **Increased public health protection**

Vision for the Future

- Continue to promote laboratory accreditation and prepare a sustainability plan
- Continue to implement and improve the PFP best practices
- Continue to implement MFRPS and AFRPS
- Develop and implement FSMA model laboratory standards
- State laboratories participate in National Surveillance Program
- Greater use of state data for regulatory action
- Coordinated, faster and more effective response to food safety events



Thank You!

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