



U.S. Food and Drug Administration  
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# U.S. Food and Drug Administration Office of Regulatory Affairs

## Manufactured Food Regulatory Program Standards (MFRPS-ISO Sampling Agreements) December 18, 2013 2:00-3:00 PM ET

Conference Call Number: 1-888-455-4952

Participant Code: STANDARDS

<http://foodshield.connectsolutions.com/coles>



# **Agenda**

## **MFRPS-ISO Sampling Agreements**

- **Welcome and Introductions**
- **Rationale for Sampling Agreements**
- **What Types of Samples are covered in this initiative**
- **APHL Insight**
- **Proposed Federal Sampling Assignments**
- **Example of a State Sampling Plan (NY AG and Markets) and Example of a Sampling Agreement**
- **Sampling Resources**
- **MFRPS Meeting in Texas (2014)**
- **Q & A**
- **Conclusion**

# Speakers

- **Tim Weigner - FDA-ORA-OP-SIS Director**
- **Guy F. Delius - ORA-OP-SIS-CSO**
- **Shari Shea – Director of Food Safety, APHL**
- **Wendy Campbell –FDA-ORA-C&G**
- **Tim McGrath - FDA-ORA-ORS, Deputy Director**
- **John M. Luker– Asst. Director NY AG and Markets**
- **Dan Rice - Director Food and Laboratory Division  
NY AG and Markets**
- **Karen Stephani – NY AG and Markets**

# Objectives

- **Provide awareness of MFRPS-ISO grant deliverables regarding developing a sampling agreement**
- **Provide awareness of what may be considered suitable samples within the context of this initiative**
- **Provide awareness of the potential Federal sampling assignments.**
- **Provide awareness of a State sampling agreement-plan example.**
- **Share examples of sampling resources.**
- **Provide answers to questions from participants on the topic/call.**

# ISO/MFRPS and Sampling

- **Both ISO-MFRPS and Sampling Agreements propel state food laboratory programs forward by supporting public health missions and response frameworks, harmonizing the direction of an integrated food safety system.**
- **Sampling Agreements requires and enhances communications among state (Food and Laboratory) agencies for improved State and Federal routine and emergency food safety response and actions.**



# **ISO (Sampling) Impact on MFRPS**

- **ISO standards (Sampling in particular) relate to several MFRPS Standards - Specifically**
- **Standard 3 (Inspection program)**
- **Standard 4 (Inspection audit program)**
- **Standard 5 (FBI and outbreak response)**
- **Standard 8 (State Resources)**
- **Standard 10 (Laboratory Support)**

## **Coordination Needed**

- **Successful programs will exhibit integrated planning and enhanced/routine communications between the Laboratory and Food program regarding sampling.**
- **A robust ISO-sampling program is needed to advance the MFRPS. As is a strong MFRPS program is needed to advance ISO and sampling.**

# **Importance of Sampling Agreement**

- **Supports laboratory in obtaining or expanding scope of ISO 17025 accreditation**
- **Supports manufactured food program in achieving conformance with MFRPS**
- **Meets the goals of the RFA**
  - **Lab commitment to analyze surveillance and emergency samples**
  - **Sharing lab results through eLEXNET**
  - **Increase national lab capacity and enhance efforts to protect the food supply**

# **Date Extension for Sampling Agreements**

- **Deadline extended to April 1, 2014**
- **New timeframe allows for**
  - **Additional time for collaboration**
  - **Insight into FDA national surveillance plan option**
  - **Attend MFRPA meeting, including laboratory workshop**
  - **Provide time for review of sampling agreements and revisions, if needed**
  - **Laboratory and manufactured food program to finalize implementation strategy by 9/1/14**

# **ISO-MFRPS Sampling Protocols**

- **These ISO-MFRPS sampling protocols will help outline the parameters (types of samples) to be collected under this initiative.**

# Association of Public Health Laboratories (APHL)

- **Shari Shea – Director of Food Safety for the Association of Public Health Laboratories**
  - **Communication**
  - **Collaboration**
  - **Planning**
  - **Positive Outcomes for Food Safety and Laboratory Programs.**



# **FDA's Proposed Sampling Assignments**

- **Still in development**
- **Not a substitute for developing a sampling plan**
- **Assignments to be developed in spring '14**
- **Sampling/analysis to begin FY'15**

# **FDA's Proposed Sampling Assignments**

- **Envisioned assignments to be developed in consultation with other FDA Centers**
- **Suggested proposals currently include**
  - **Large-scale surveillance assignments**
    - **Similar to the Surveillance Sampling Program - Avocados**
  - **Large-Scale Produce Testing**
    - **Similar to USDA Microbiological Data Program (MDP)**
    - **Pre-arranged scheduling**
  - **National Events Surveillance Testing**
    - **Political conventions, etc**

# **State Sampling Agreement Example: New York Agriculture and Markets**

- **John M. Luker: Asst. Director New York State Department of Agriculture and Markets**
- **Dan Rice: Laboratory Director with New York State Department of Agriculture and Markets**
- **Karen Stephani: New York State Department of Agriculture and Markets**



## **In 2012 the NY State Food Laboratory**

- **Tested 306 manufactured foods from manufacturers and distributors**
- **> 1000 additional manufactured food samples from retail sources**
- **All samples submitted by agency food safety inspectors**



## **NY State intends to meet the FDA sampling agreement by:**

- **Preparing a formal sampling agreement between the laboratory and the food safety and inspection division**
- **Manufactured foods testing will be tracked by sample type and analytes tested for**

# Sampling Agreement Example

- This Example may provide useful in State programs developing their own *“Sampling Agreements”*.

# **Sampling Resources**

- **List of some available resources for Sampling**
- **Links to helpful sites related to Food Product Sampling**

# **MFRPS National Meeting**

- **March 10-13, 2014.**
- **Fort Worth Texas**
- **Specialized Sampling workshop on March 10**
- **MFRPS enrollees, State Liaisons and ISO lab grantees are encouraged to attend. MFRPS and ISO grant funding may be used appropriate for this meeting. Refer to your NGA for criteria.**

# Question and Answers

- **Questions and Answers**
  - **Tim McGrath**
  - **Tim Weigner**
  - **Wendy Campbell**
  - **Shari Shea**
  - **Guy Delius**
  - **Dan Rice**
  - **John M. Luker**
  - **Karen Stephani**

# Contact

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