The Partnership for Food Protection
Laboratory Task Group

*presents*

Partnership for Food Protection
Federal, State and Local Collaboration

## Food/Feed Testing Laboratories

# BEST PRACTICES MANUAL

(Draft)

## Table of Contents



Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish notice in the Federal Register soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collection of information in a future issue of the Federal Register.

# INTRODUCTION

# INTRODUCTION

## Background of the PFP Laboratory Task Group

The Partnership for Food Protection (PFP) is a group of dedicated officials from federal, state, local, and tribal governments that have been brought together to build the foundation of an integrated food/feed safety system in the United States. In August 2008, the Food and Drug Administration (FDA) hosted a national meeting, Gateway to Food Protection, which reenergized efforts to work toward an integrated approach to address the challenges of the growing global food supply. Following this meeting, the PFP initiative was established to provide guidance on implementing the necessary infrastructure and food safety strategies essential to building an integrated food/feed safety system. The PFP is divided into several focused workgroups charged with advancing federal, state, and local partnerships in a coordinated and efficient manner. One of the workgroups established to assist in accomplishing these goals was the Laboratory Task Group (LTG). The LTG is co-led by FDA and state partners and has been meeting via teleconference since January 2011.

The PFP LTG is comprised of seven subcommittees: Accreditation, Regulatory Annex, Proficiency Testing, Sampling, Methods, Analytical Worksheet Packages, and Reporting (See Figure 1). These subcommittees are led by FDA and state laboratory professionals and are comprised of members from multiple federal, state and local agencies. Supporting reference documentation identified by each subcommittee is embedded within this draft best practices manual and consolidated in Appendix 2.

## Purpose of the Food/Feed Testing Laboratories Best Practices Manual (Draft)

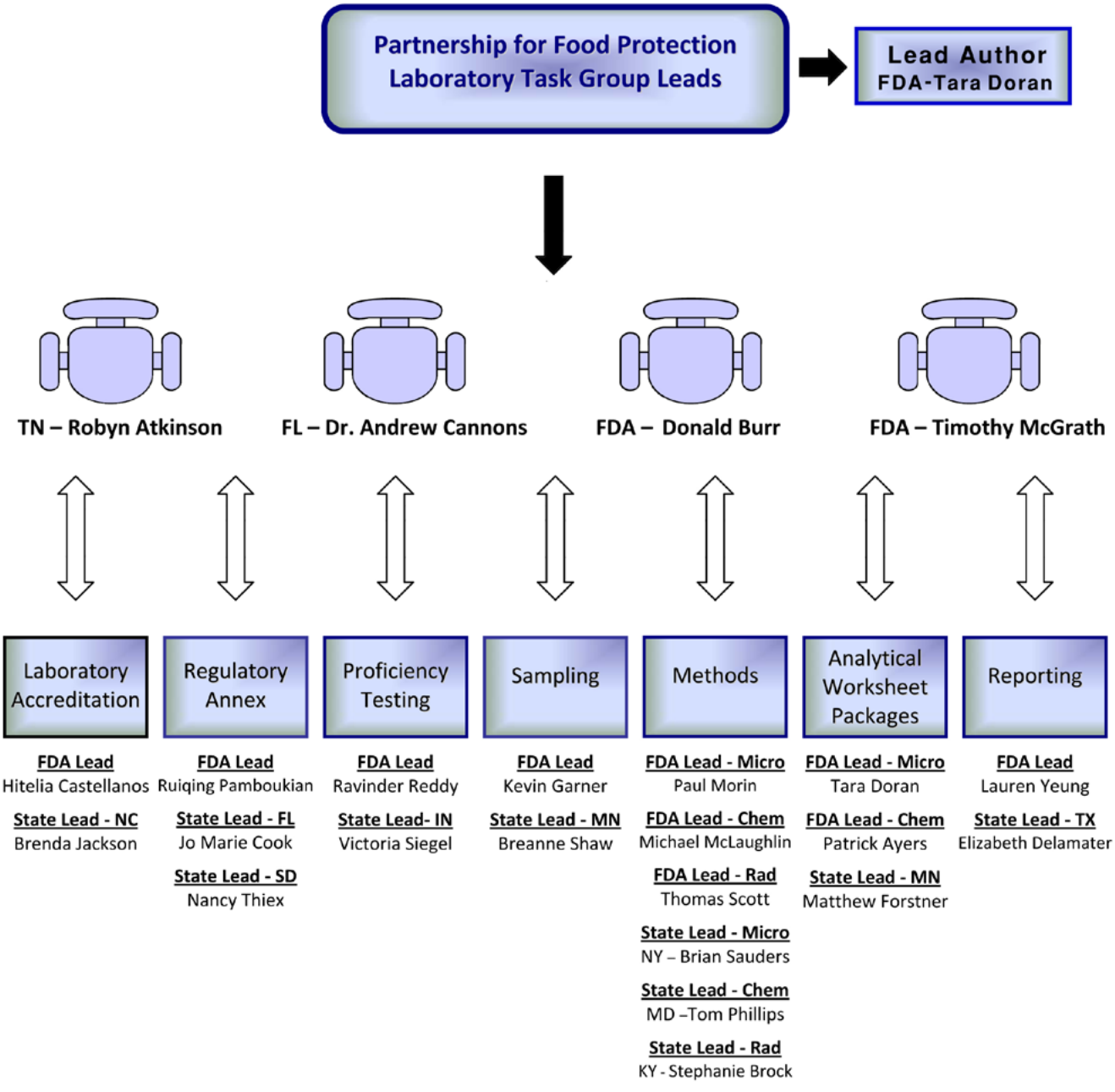
The PFP LTG was charged to document best practices and procedures for food/feed laboratories to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies. The Food/Feed Testing Laboratories Best Practices Manual (Draft) provides a set of tools, definitions, and references that laboratories can use to improve their operations. This draft best practices manual is a summary-level compilation of the work of the LTG subcommittees. It primarily reflects the experiences and perspectives of FDA and state and local food regulatory agencies who participated in the PFP LTG. As such, state, local, and tribal regulatory laboratories and FDA laboratories will be most able to directly apply the manual's best practices to improve their operations. The manual may be particularly useful for governmental laboratories that submit analytical data to regulatory agencies in support of government food safety initiatives and routine enforcement. Laboratories may be able to integrate these best practices into relevant initiatives and frameworks (e.g., Manufactured Food Regulatory Program Standards (MFRPS)).

The manual does not implement the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) or other statutes, nor is it a substitute for laboratory requirements that may be proposed as part of FSMA rulemakings.

The draft best practices manual generally may be useful to laboratories working towards the goal of establishing a food or feed testing program that may become a functional and productive part of a national integrated food/feed safety system.

As governmental food safety partners move towards more preventive based approaches to food safety, including widespread surveillance efforts, the demand for laboratories that meet recognized best practices of analytical competency, and thus can contribute to a wide range of food safety initiatives run by any number of agencies (federal or state), will rise dramatically. Utilizing these best practices may enable regulatory agencies to more expeditiously utilize laboratory data to identify, prevent and remove unsafe food products from the marketplace. Considering the rapid globalization of the U.S. food market, and the growing pressure to ensure that imported food is safe for consumption, it has never been more important to leverage the resources of the nation's food laboratories and join forces to take a prevention-based approach to food safety.

Figure 1



# LABORATORY ACCREDITATION

Chapter 1

# LABORATORY ACCREDITATION

Chapter 1

## Background and Objectives

Accreditation can be defined as a rigorous assessment, conducted by an independent science-based organization, to assure the overall capability and competency of a laboratory and its quality management systems. This assessment results in formal recognition of the technical competence of a laboratory to perform specified methodologies. Achieving laboratory accreditation can be an expensive and time-consuming endeavor. Given this, there must be value added to a lab in order for it to undergo the accreditation process. The continued increase in the number of laboratories–federal, state, local, private, and foreign–undergoing this process, is testimony to that value. Investment in laboratory accreditation for the nation's food testing laboratories will provide added value for the mission of protecting the public health by providing greater laboratory capacity of quality data submitted to regulatory food agencies.

One of the main accreditation standards utilized by testing laboratories throughout the world is International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2005(E). The PFP LTG Accreditation Subcommittee was charged with defining the process for food/feed testing laboratories to become accredited to ISO/IEC 17025. The subcommittee accomplished this goal by dividing its work into two tasks:

- Task 1: Developed an action plan for creating and implementing a management system that meets the management and technical requirements of ISO/IEC 17025 (Deliverable: Steps to ISO/IEC 17025 Accreditation).
- Task 2: Performed an evaluation to compare and contrast four other quality standards or programs in order to determine their correlation with the management and technical requirements of the ISO/IEC 17025:2005 standard. The subcommittee compared the quality standards of the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the Association of American Feed Control Officials (AAFCO), the NELAC Institute (TNI), and Clinical Laboratory Improvement Amendments (CLIA) requirements, to ISO/IEC 17025:2005. The analysis was performed to assist laboratories meet the requirements of ISO/IEC 17025:2005 if they are already accredited or certified to these other quality standards or programs.

## Definitions

**Accreditation Body:** An independent entity that operates in conformity with the standard ISO/IEC 17011 and that is technically competent to accredit testing laboratories using the standard ISO/IEC 17025:2005.

**Recognition:** The action or process of recognizing or being recognized. The acknowledgement of the existence, validity, or legality of something, such as a standard or a particular technical competence.

## Task 1 - Steps to ISO/IEC 17025 Accreditation:

The tables below were created to provide a guideline for the process a laboratory would follow to achieve ISO/IEC 17025 accreditation. This information was gathered from state and federal laboratories based on their experiences. The columns are constructed as follows:

- **Execution** provides a list of suggested tasks required to complete each step.
- **Training/Resources/Assistance** includes potentially useful aids for the laboratory at each step.
- **Why is this step important to successful accreditation?** Provides supporting discussion points to emphasize and clarify the value each step brings to the accreditation process.

When reviewing the tables, the reader must bear in mind that each laboratory will be starting from a different baseline. Therefore, an individual laboratory may find it has already achieved some of these steps, and the information provided will be of different value to each laboratory.

*Note: These tables were constructed with the goal of helping laboratories achieve accreditation to ISO/IEC 17025. Other specific requirements imposed or recommended by state or federal agencies, laws, regulations, professional associations, or individual accrediting bodies have not been addressed. However, a laboratory should be able to use this information as part of its project management process to implement ISO/IEC 17025 and any other quality requirements.*

## Step 1: 'Buy-In' at all levels: Upper management, middle management and laboratory staff

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Information sessions for management [Commissioners, Directors, Managers, Supervisors, Human Resources (HR)] to learn why accreditation is needed, benefits of accreditation, and get management's commitment to the process<br>• The above information session should include a mini course [i.e., 1 day] on the ISO/IEC 17025:2005(E) standard, with emphasis on clauses 4.1, 4.2, and 5.2.<br>• Information sessions for laboratory staff by someone knowledgeable in both laboratory and management system to explain the value of accreditation | How?<br>• Webinars and/or onsite meetings by FDA and state representatives<br>• National Association of State Department of Agriculture (NASDA) meetings<br>• Association of Food and Drug Officials (AFDO) meetings<br>• Association of Public Health Laboratories (APHL)<br><br>What?<br>• Content may vary [i.e. level of management, laboratory staff and Human Resources]<br><br>Who?<br>• Need someone who can relate to the laboratory roles and explain why the laboratory should "climb this mountain" | • Support for having your laboratory accredited to ISO/IEC 17025 must start at the top of the organization to be successful.<br>• Everyone in the organization must know why ISO/IEC 17025 accreditation is important and that it can only be done with management support<br>• Implementation is time-consuming and management must understand and allow for the time commitment<br>• HR needs to be informed of the pending changes in the laboratory to handle employee issues [i.e., changes in work plans, goals, objectives, performance reviews, accountability, and to address complaints, grievances]<br>• Upper management will need to decide if implementation of the management system applies laboratory-wide or just in laboratories with in-scope tests |

## Step 2: Establish Organization

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Hire/assign a dedicated quality manager position [i.e., Quality System Manager (QSM)]<br>• Hire/assign other quality positions depending on size of laboratory | • Job descriptions from other state laboratories<br>• Conference calls with accredited laboratories to discuss successful organizations | • It is essential to have a dedicated QSM position to be the subject matter expert (SME) on the ISO/IEC 17025 standard for the laboratory and approve all policies and procedures |

## Step 2: Establish Organization (continued)

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Define roles and responsibilities for the quality management staff (who does what), write job descriptions.<br>• Define the organization and management structure (organization chart helps)<br>• Seek a person with laboratory experience [laboratory work], auditing experience, and good skills in the following areas: organization, presentation, and writing | • Advertise nationally for the Quality System Manager (QSM) position | • In addition one staff member needs to be dedicated to be the liaison with regulatory agencies, other customer(s) (internal inspections/regulatory group), and the accrediting body. (This could be part of the QSM's role)<br>• It is also beneficial to have one staff member, preferably the QSM, or small quality group to take the lead in training, organization, scheduling, coordinating, task mastering, etc.<br>• Upper management must decide where in the organization the QSM position should report to be most effective. See ISO/IEC 17025:2005(E), clause 4.1.5(i). Laboratories should be familiar with this ISO requirement prior to making organization chart decision.<br>• Past roles and responsibilities for QSM may need to change in order to meet ISO/IEC17025 requirements |

## Step 3: Training at Multiple Levels

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Obtain a copy of ISO/IEC17025 standard (must be purchased). www.iso.org<br>• Training for all; number of days may vary depending on laboratory role<br>• Quality Manager should attend comprehensive ISO/IEC 17025 training<br>• In-house trainer may be needed at this point to be able to answer questions<br>• Quality supervisors 3-4 day; Bench analysts 1-2 day introduction; Support staff – ½ day introduction<br>• Visit accredited laboratories<br>• Decide who will conduct internal audits (IA)s and start the training process | • Managing Change classes for supervisors and laboratory staff [1]<br>***Training sources:***<br>• Private consultants<br>• Accrediting bodies<br>• FDA staff Online courses<br>• Other accredited laboratories<br>• Accreditation bodies, public or in-house accreditation training programs<br>• Conference calls or webinars scheduled throughout the process addressing ISO/IEC 17025 clause-by-clause | • ISO/IEC 17025 implementation may bring significant changes to some laboratory processes. Helping laboratory staff learn how to accept and adapt to change may facilitate the process<br>• Basic training at the beginning of the accreditation process, for all levels of laboratory staff, is essential to educate everyone on the ISO/IEC 17025 requirements, answer their questions, dispel fears, explain how the process can be incrementally approached and what each person's role is in the process, etc.<br>• Introductory training might be duplicated in tiers, such as large group training for entire laboratories then small group training for individual laboratories to focus on laboratory specific issues |

## Step 3: Training at Multiple Levels (continued)

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Internal auditors audit work, procedures, records, and documents. Auditors need to be qualified, trained, and independent, whenever the resources permit | | • Early internal audit training benefits the entire implementation process |

[1] Whoever is assigned the responsibility for ISO/IEC 17025 implementation [e.g., the Quality Manager] will take on a role of educator/instructor [this may be large group, small group or one-on-one].

## Step 4: Choose the Accreditation Body that will assess the laboratory management system

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • If additional criteria beyond ISO/IEC 17025 are deemed necessary (e.g., accreditation including the Analytical Laboratory Accreditation Criteria Committee (ALACC) criteria), identify an accrediting body capable of providing accreditation including the additional criteria<br>• Examine potential candidates credentials such as full membership of International Laboratory Accreditation Cooperation (ILAC)<br>• Determine how potential accrediting bodies select assessors (qualifications, experience, etc.). Establish a timeline for accreditation | • ILAC Website: www.ilac.org<br>• Accredited laboratories may provide some references based on experience | • Establish relationship with the accreditation body early in the process<br>• The accreditation body may help the laboratory to understand the accreditation process<br>• Be aware that some accreditation bodies may have additional program specific requirements or policies |

## Step 5: Gap Analysis

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| ***Laboratory conducts:***<br>• Internal gap analysis, first to identify what is already in place and facilitate deeper understanding of existing processes<br>• Accreditation body may conduct the initial gap analysis. This may add additional costs<br>• External gap analysis – FDA may provide technical assistance | • Share list of accredited laboratories<br>• Private consultant<br>• Utilize accreditation body checklist for gap analysis<br>• Utilize others accreditation bodies' check lists for gap analysis<br>• Obtain proficiency tests check list from accreditation bodies | • All laboratory personnel and upper management must identify clearly where the laboratory is with respect to the ISO/IEC 17025 standard requirements, to understand the time and resources necessary to achieve accreditation |

## Step 6: Identify Accreditation Requirements

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| ***Identify:***<br>• Laboratory fields (chemistry, microbiology, radiochemistry, etc.)<br>• Test methods or technology to be accredited<br>• Equipment lists, equipment calibration/maintenance program<br>• Proficiency testing (PT) sample plans, PT results (related to the proposed scope)<br>• Quality Manual, e.g. management system addresses and conforms to all elements of ISO/IEC 17025 | • Accreditation body checklists<br>• Discuss proposed scope with upper management and technical personnel to gain their ownership<br>• Check with other laboratories for suggestions on equipment inventories, PT sample programs, etc.<br>• Write a draft Quality Manual; build into it as you develop standard operating procedures (SOPs) | • Early identification will guide how methods need to be written |

## Step 7: Write Quality Management system (QMS) Procedures

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Write Quality Manual to define policies [often written by quality staff]<br>• Documents in the quality manual should be easy to follow: management system quality procedures SOPs/ work instructions records<br>• Write Document Control procedures e.g. Documents should be: authorized, available, uniquely identified, reviewed/revised, removed, and archived when out of date. A software program may be an option. | • List of policies and processes that must be documented in Quality Manual<br>• Online frequently asked questions (FAQs)<br>• List of QMS procedures that will meet ISO/IEC 17025 requirements | • Since the Quality Manual states policies it will need review and approval by upper management<br>• To facilitate ownership of the procedures and processes, procedures could be developed by teams with representatives from management, quality manager, quality laboratory staff<br>• An external review of the QMS procedures prior to issuance and training will prevent errors, gaps, misunderstandings, etc. This will be another good educational step for the quality manager and laboratory before they proceed with implementation. |

## Step 8: Implement QMS

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Assign a competent trainer from your staff or hire a professional instructor<br>• Issue procedures<br>• Train, train, train<br>• Read<br>• Large group overview<br>• Smaller group, laboratory specific<br>• In laboratory hands-on<br>• Examples: Use different media to train personnel<br>• PowerPoint presentations<br>• Questionnaires<br>• Surveys | • Train<br>• FDA, PFP, other labs, etc. for support, Q&A | • Even though laboratory personnel may have a good understanding of what the ISO/IEC 17025 standard requires, this training focuses on how to meet those requirements in their specific laboratory |

## Step 9: Write Technical SOPs and Implement Changes

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Write test methods, work instructions, equipment instructions, select or create appropriate forms, etc. for the in-scope test methods / technologies | ***Reference Sources:***<br>• Accreditation consultant suggestions on documents and records needed | • This is a critical step in the implementation process to evaluate laboratory processes |

## Step 10: Build Records

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Records to support actions in every document [QMS, SOPs, work instructions, etc.]<br>• Software is recommended for document control | • Guidelines from accreditation body on ISO/IEC 17025 and other quality requirements.<br>• Have technically competent staff to review the methods for accuracy, change them if needed, and ensure timely training on updated SOPs. | • Records are the 'eyes' into the laboratories to prove data is accurate, traceable, reproducible, and defensible. They give the laboratory and management confidence in the laboratory's work |

## Step 11: Conduct Internal Audits (IA) and Management Review

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Conduct internal audit (IA) | • FDA may provide technical assistance. | • Required by ISO/IEC 17025 standard |

## Step 11: Conduct Internal Audits (IA) and Management Review (continued)

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Use competent staff at different areas to perform audits<br>• Document nonconformities<br>• Execute corrections, corrective actions, and monitoring<br>• Identify opportunities for improvement<br>• Ensure management system suitability | • Final Gap Analysis before applying for accreditation<br>• Training on Writing Corrective Action Reports (available through accreditation bodies, online courses, etc.) | • More 'eyes' on the process<br>• Internal Audits are opportunities for continuous improvement and increased efficiency |

## Step 12: Initial Assessment by Accreditation Body

| Execution | Training/Resources/Assistance | Why is this step important to successful accreditation? |
|---|---|---|
| • Complete application for accreditation with accreditation body of choice<br>• Submit required supporting documents<br>• Schedule Assessment | • Accreditation Body Guidance | • Obtain Accreditation |

## Task 2 - Assessment Overview of other Quality Programs:

In addition to the action plan described above to assist laboratories on the road to ISO/IEC 17025 accreditation, the Accreditation subcommittee also reviewed quality programs associated with other certifications or accreditations. Programs evaluated include AAVLD Requirements of an Accredited Veterinary Medical Diagnostic Laboratory; AAFCO Quality Assurance/Quality Control Guidelines for State Feed Laboratories; TNI 2009 Standard; and the CLIA regulations at 42 CFR Part 493.

**AAVLD Requirements**

Overall, the AAVLD requirements are a more general version of the ISO/IEC 17025 standard. For example, AAVLD contains no requirements on estimating measurement uncertainty. In order to comply with ISO/IEC 17025 standard a laboratory will need to elaborate on each general requirement of AAVLD and conform to the requirements of ISO/IEC 17025. More information on AAVLD accreditation can be found at www.aavld.org.

**AAFCO Recommendations**

The AAFCO QA/QC Guidelines are supplements to ISO/IEC 17025 providing recommended actions to implement the ISO/IEC 17025 requirements. More information on AAFCO QA/QC guidelines can be found at www.aafco.org.

**TNI Recommendations**

Laboratories accredited to the 2009 TNI standard are competent to test environmental samples and conform to the requirements of ISO/IEC 17025. The type of tests, materials, and proficiency testing programs that these laboratories utilize are not necessarily related to food and feed testing. TNI accredited laboratories would need to extend their scope of accreditation to perform testing on food and/or feed samples. More information on the TNI standard can be found at www.nelac-institute.org.

**CLIA Requirements**

The scope of CLIA covers human specimen testing. Food and feed testing are not under CLIA's scope. ISO/IEC 17025 is more comprehensive and applies to all testing laboratories, whereas CLIA contains clinical-specific standards.

CLIA and ISO have very different structures. CLIA's managerial and technical requirements do not follow the ISO/IEC 17025 standard structure. CLIA is based on a management system approach that follows the route of a specimen through the laboratory, and in some respects is more prescriptive than ISO/IEC 17025, but does not require a quality management system. Several ISO/IEC 17025 elements not explicitly specified or required by CLIA are document control, management reviews, internal audits, and a quality manual. More information on CLIA can be found at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

***Some potential issues to be considered by CLIA certified laboratories involved in food testing:***
Food testing involves very different procedures from clinical human specimen testing, including sample handling, sample preparation, methods, most instrumentation, data analysis, and reporting. Clinical laboratories performing food testing should have policies and procedures for handling and testing of food samples to ensure sample accountability, integrity, and that the data produced are accurate and reliable. For example, are the methods readily available in the laboratory? Are analysts properly trained and authorized for food testing? Have proficiency tests for such tests been done successfully? Has quality control been implemented for food testing? Are internal audits being performed? Could test conditions be replicated based on existing records?

***Options for CLIA certified laboratories involved in food testing:***
(1) Seek full ISO/IEC 17025 accreditation for the food testing section of your laboratory.
(2) CLIA laboratories occasionally performing food testing could apply their current requirements (CLIA) to their food safety section and fill in the gaps found in this comparison.
(3) Consider deferring food testing to another agency within your state public health system or to another state or local laboratory accredited to ISO/IEC 17025.

## Conclusion:

The ISO/IEC 17025 international standard (General requirements for the competence of testing and calibration laboratories) focuses on laboratory operations and management, with the goals of ensuring that testing laboratories operate a quality management system, are technically competent, and generate technically valid results. This standard allows laboratories to demonstrate that they produce reliable, high quality, well-documented data.

Other laboratory quality programs exist, and of those evaluated it was concluded that all of these quality programs vary in the degree to which they meet or align with the requirements of ISO/IEC 17025. Although the criteria of other quality programs may contain requirements that extend beyond those of ISO/IEC 17025 in certain areas, laboratories meeting the requirements of any of these other quality programs should still anticipate that some additional work will be necessary to comply with all of the requirements of ISO/IEC 17025. Overall, the recently issued TNI standard for environmental laboratories aligns well with ISO/IEC 17025, incorporating most of the ISO/IEC 17025 standard by direct reference. It will most likely require some time for TNI-accredited laboratories to fully comply with (and to be evaluated for compliance with) ISO/IEC 17025 for food/feed testing. In contrast, CLIA requirements are client-sample focused and do not require a management system. This alone represents a major departure from ISO/IEC 17025 requirements. However, some public health laboratories, which conform to CLIA requirements, may be in the process of becoming, or may have already become, accredited to ISO 15189 Medical laboratories – Particular requirements for quality and competence, a standard that may provide better alignment to the ISO/IEC 17025 standard and should be evaluated. The laboratory quality guidelines of AAVLD and AAFCO are designed to assist veterinary and feed testing laboratories respectively. Both AAVLD and AAFCO support and recommend that feed/food testing laboratories pursue accreditation to the ISO/IEC 17025 standard using each organization's respective guidelines for implementation of ISO/IEC 17025 requirements.

The pursuit of accreditation is not obtained free of charge. Some of the costs may include consultant services, assessor fees to audit your management system before accreditation can be granted, initial registration fees, periodic surveillance visits fees to make sure your system still meets the standard, and participation in proficiency testing programs. All laboratory employees, including upper management and support staff, must get involved in the accreditation process to guarantee the success of the management system.

# REGULATORY ANNEX

Chapter 2

# REGULATORY ANNEX

Chapter 2

## Background and Objectives

Food/feed laboratories may submit analytical data to regulatory agencies in support of government food safety initiatives and routine enforcement. The Regulatory Annex Subcommittee engaged state and federal stakeholders to develop best practices for food/feed laboratories that engage in such testing. These best practices have been designed to support confidence in the integrity and scientific validity of data, and to facilitate acceptance of data by food safety regulatory agencies. These best practices are not intended to substitute for or interpret the specific legal requirements and policies of food safety regulatory agencies. Rather, these best practices reflect the experiences of PFP LTG members that engage in such testing. They supplement the best practice of ISO/IEC 17025 accreditation for food/feed laboratories engaged in testing to be submitted to food safety regulatory agencies.

## Definitions

***These terms are used in the following best practices:***

**Regulatory Food/Feed Laboratory:** A regulatory laboratory conducts measurements and tests, which result in qualitative and/or quantitative analysis findings that may be used to interpret and enforce and/or be used as evidence to determine whether there has been a violation of a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.

**Regulatory Action:** A regulatory action occurs when a governmental agency acts to enforce compliance with a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law. A violation occurs when it is established through competent and substantial evidence that an action, including the manufacture or distribution of a product, or a failure to act does not meet the requirements of a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.

**Sample:** A portion of material selected from a larger quantity of food or feed material.

***Laboratory Sample:*** The sample or subsample(s) sent to or received by the laboratory.

***Sub-sample:*** May be: (a) a portion of the sample obtained by selection or division; or (b) an individual unit of the lot taken as part of the sample; or (c) the final unit of multistage sampling.

**Sampling:** The process of collecting sample(s).

**Sample Accountability:** Physical accountability ensures that the laboratory samples, test samples, test potions, test solutions, etc., are traceable. The life of the laboratory sample should be documented until final disposal, including all test samples and test portions. Such documentation may be needed to support regulatory action. Regulatory guidance on disposal may vary with agencies.

**Sample Security:** Physical security of samples prevents intentional adulteration or substitution of the laboratory sample. This ensures that the material collected remains representative of the product, and that it is usable as evidence in court.

**Sample Integrity:** Sample integrity ensures nothing the laboratory does has the effect of making the material non-representative. Some aspects of sample integrity include sample storage, handling and transport in the laboratory, maintenance of proper storage temperature, and opening sample containers in the appropriate level of controlled environment. Laboratory waste disposal, workflow layout, cross-contamination, etc. also can affect sample integrity. Records supporting maintenance of sample integrity may include, for example: sample storage refrigerator temperatures, microbiology laboratory environmental monitoring, etc.

**Data integrity:** Is the assurance that results reported by the laboratory are accurate, complete, and true representations of the laboratory sample and analysis.

**Chain of Custody:** The order of places where, and the persons with whom, physical evidence was located from the time it was collected to its submission at trial. Laboratory samples are physical evidence. Chain of custody includes policy and procedure for handling and transfer of laboratory samples, as well as the full documentation of compliance with this policy and procedure for each laboratory sample. Documentation of chain of custody, including all test portions and test solutions, provides evidence that sample accountability, integrity, and security have been maintained.

**Standard methods:** Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and FDA published methods. The laboratory's procedures are traceable to a recognized, validated method, if one is available.

**Non-standard method:** This refers to a method that is not taken from authoritative and validated sources. This includes methods from scientific journals and unpublished laboratory-developed methods.

## Best Practices

**Key Element A. Sample Accountability, Security, Integrity and Chain of Custody**

***The regulatory laboratory:***

- Establishes, implements and maintains a management system that assures sample accountability, integrity, security, and chain of custody requirements for regulatory action are met.
- Establishes, implements and maintains a management system that assures the integrity and legal defensibility of analytical data produced by the laboratory.
- Documents its policies, systems, programs, procedures and instructions for communicating regulatory requirements, making regulatory decisions and taking regulatory action, within the scope of the laboratory's responsibilities.

**Key Element B. Record Retention**

The regulatory laboratory has policies and procedures to assure that records are retained and protected in a manner that assures actions are legally defensible.

**Key Element C. Test Methods**

***The regulatory laboratory:***

- Uses fit-for-purpose methods or methods otherwise identified as suitable by a regulatory/enforcement agency. The laboratory uses standard methods whenever possible. If a standard method is not found the laboratory may use either a non-standard method or modify a method for use with the concurrence of a regulatory agency.
- Have procedures and records for method validation that, at a minimum, meet the requirements of a responsible regulatory agency.
- Uses statistical procedures and data presentation as required by a regulatory agency.

The methods best practices produced by the PFP LTG Methods Subcommittee in Chapter 5 may be a useful reference.

**Key Element D. Sampling (including Sub-sampling)**
Regulatory sample collection is conducted in accordance with regulatory agency requirements. The regulatory laboratory has policies, procedures, and records for sample integrity, security, accountability, and chain of custody to meet such requirements.

The sampling best practices produced by the PFP LTG Sampling Subcommittee in Chapter 4 may be a useful reference.

*Note: If the laboratory is not the sampler, then the laboratory includes appropriate regulatory sampling documentation as part of the sample receipt review.*

**Key Element E. Data Reporting**

- Regulatory laboratory reports may identify relevant regulations and any interpretations or compliance decisions.
- Regulatory samples include legally defensible identification of the responsible firm or owner and any related information required by a regulatory agency.

**Key Element F. Proficiency Testing**
The proficiency testing best practices produced by the PFP LTG Proficiency Testing Subcommittee in Chapter 3 may be a useful reference.

**Key Element G. Technical Records**
Requirements for documentation of sample chain of custody, security, accountability, and integrity are completed and maintained to meet the needs of a regulatory agency.

**Key Element H. Conflict of Interest**
***The regulatory laboratory:***

- Identifies potential conflicts of interest or bias for key personnel.
- Implements policies and procedures to prevent potential, actual or apparent conflicts of interest, whether from an internal or external source.
- Establishes and maintains data integrity policy and procedures that are legally defensible.
- Have policies and procedures to assure that scientific misconduct including fabrication, falsification, and/or plagiarism does not occur or are reported and investigated.
- Provides planning, training and method implementation in a manner that assures data integrity.
- Have policies to assure confidentiality if required by a regulatory agency.
- Specifies the responsibility, authority and inter-relationships of all personnel who make or affect regulatory actions.

**Key Element I. Subcontracting**
Subcontracted regulatory work complies with the best practices for regulatory work.

*Note: Any subcontracted regulatory work appropriately implements any sample integrity, accountability, security, and chain of custody requirements of the regulatory agency. Subcontracting of work may impact regulatory use of the resulting data and should be undertaken with consultation of a regulatory/enforcement agency.*

# PROFICIENCY TESTING

Chapter 3

# PROFICIENCY TESTING

Chapter 3

## Background and Objectives

The PFP LTG Proficiency Testing Subcommittee assessed the current state of food/feed proficiency testing programs and systems and compiled best practices for laboratory proficiency testing. A proficiency test is defined as the evaluation of laboratory testing performance by means of inter-laboratory comparisons. Proficiency test samples are to be treated in the same manner as routine client samples. Proficiency test samples should include all sample types as appropriate. Proficiency testing is a requirement of accreditation and any group applying for accreditation can benefit from the selection of appropriate proficiency tests. Laboratories that are already accredited may use the information to extend their scope of accreditation or to find suitable resources for short-term projects in a related field for which they are not currently accredited.

The Proficiency Testing subcommittee was tasked with developing best practices for laboratories with respect to proficiency testing requirements and this was done by assessing the current state of food/feed proficiency testing relevant to the PFP (food/feed analytical data, food safety/defense) and developing best practices for proficiency testing. This subcommittee focused on currently available proficiency test series/programs (including federal, state and private assets), leveraging existing proficiency testing series/programs and identifying potential enhancements.

## Best Practices

The PFP LTG Proficiency Testing Subcommittee identified proficiency testing best practices for use by laboratories. To accomplish this, the subcommittee turned to established standards and requirements for laboratory proficiency testing (standards were identified after consulting with the PFP Accreditation Subcommittee), and specifically mined out any language that would apply to laboratory proficiency testing.

***Proficiency testing best practices identified by the PFP LTG Proficiency Testing Subcommittee are:***

- Laboratories participate in a check sample or proficiency testing program for all tests/methods/technologies/techniques covered under their accreditation as a means of demonstrating laboratory competency.
- If laboratories are not fully accredited but are working to meet the best practices outlined by the PFP, these laboratories participate in a check sample or proficiency testing program for all tests/methods/technologies/techniques used to test food/feed samples as a means of demonstrating laboratory competency.
- Where possible, laboratories participate in a check sample or proficiency testing program provided by a proficiency test provider adhering to, or accredited to, ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing.
- Laboratories participate in check sample or proficiency testing programs relevant to their accreditation scope(s) or regulatory testing on a regular basis. Suggested frequency is at least once per year for each test/method/technology/technique covered under the laboratory's accreditation or used for performing testing to support regulatory action, with the entire accreditation scope being covered over a 4 year period.
- Laboratories share the results of their proficiency testing participation and testing with their accrediting body and take corrective actions, when needed, to ensure that any problems are rectified and the laboratory is then able to demonstrate competency for the test/method/technology/technique at hand.

- In the absence of a proficiency test program series that addresses a particular test/method/technology/technique required for compliance with these best practices, the laboratory relies on documented internal quality control checks and measures.

## Conclusion

The Proficiency Testing subcommittee has identified best practices for proficiency testing by food/feed testing laboratories. These best practices may or may not be included in existing accreditation standards. The Proficiency Testing subcommittee will continue to work on developing additional tools and resources for use by laboratories seeking to follow the proficiency testing best practices of the PFP.

# SAMPLING

Chapter 4

# SAMPLING

Chapter 4

## Background and Objectives

The Sampling subcommittee was tasked with assessing the current state of food/feed sampling relevant to the PFP and developing uniform sample collection best practices. Uniformity in sample collection is essential to achieve consistent laboratory analytical results between multiple federal, state and local food/feed safety agencies. While many regulatory laboratories collect samples themselves, some regulatory laboratories may subcontract with an independent third party to collect samples.

This deliverable aims to identify elements to consider for sampling best practices. To accomplish this, the Sampling subcommittee developed general sampling guidelines and began compiling references to specific food/feed sampling procedures.

### Definitions for Food and Feed Sampling

- *Official Sample:* Sample taken in a manner so that it can serve as the basis for enforcement and/or legal action and handled in a manner that preserves integrity as evidence including identity, ownership, traceability and a clear record of chain of custody.
- *Investigation Sample:* Taken during a food safety inspection to document inspector observations, support regulatory actions or provide other information.
- *Surveillance Sample:* Taken as part of routine inspections or surveys to identify any lack of compliance with state, federal or other laws and regulations.
- *Documentary Samples:* Evidence of sample is collected such as labeling, photos, drawings, invoices, transportation records, inventory which may be used in investigations or connection to previously collected samples.
- *Emergency Response/Food borne Outbreak Samples:* Taken during an investigation for food borne illness or in response to a food-related emergency.
- *Food borne outbreak:* An incident in which two or more persons experience a similar illness resulting from ingestion of a common food.
- *Convenience Sample/Grab Samples:* A sample chosen on the basis of accessibility, expediency, cost or efficiency but may not be representative of the whole lot of food or feed. These may sometimes be surveillance samples but may also be samples taken in response to a consumer complaint or incident.
- *Import/Domestic Import:* Foreign products which have not yet cleared customs are "imports" and foreign products which have cleared customs are "domestic imports." A foreign product which is manipulated in a major manner, which changes the product or composition, is no longer considered an import under U.S. law.
- *Monitoring Sample:* Used to collect information such as incidence, number and species of foodborne pathogens in food or the incidence, amount and frequency of chemical ingredients, additives, residues or contaminants but not intended to support regulatory action.
- *Violation:* A sample found to be non-compliant with established food laws/codes/regulations.
- *Compliance (Follow-up) Sample:* Taken to determine compliance with specific food law/code often as a follow-up to a violative finding in a surveillance sample.
- *Law Enforcement Sample:* Taken during a specific investigation by law enforcement to support possible legal action for non-compliance with federal, state or local regulations.
- *Laboratory Sample:* The sample or subsample(s) sent to or received by the laboratory.

- *Custody Seals:* An official closure, adhesive seal or locking device that is affixed to the sample container after collection. The seal is affixed such that the sample material cannot be reached without breaking the seal or rupturing the container and is dated and signed by the collecting individual. Each time the seal is broken, a custody record should be kept. A new official seal may be affixed, dated and signed as the regulatory agency requires. If possible, broken seals should become part of the official documentation.

## Best Practices

Sampling often begins with routine collections for surveillance purposes, food safety inspections, monitoring studies or as a response to a complaint. Samples collected may include investigative, documentary, emergency response, law enforcement, research or convenience samples. If there is any possibility of future regulatory action, official samples should be collected in a manner that will assure legal defensibility. The best practices in this chapter address such sample collection. The essential characteristics of a valid, official sample include ensuring that the sample contains a representative portion of the lot, sampled in a manner that assures it is not changed in its physical, chemical or biological nature from the whole. In addition, the sample should be collected, preserved and handled in a manner consistent with the intended testing. Also, any required sample reserve portions should be collected and the sample should be accompanied by accurate records that legally establish its identity, responsible individuals and chain of custody. If needed, information should be attainable on sample movement in commerce including trace-forward and trace-back. Evidence of import or interstate movement may be needed to establish federal jurisdiction, if applicable. While often needed for sample collection at the federal level, a formal notice of inspection, receipt of samples, payment for samples and report of analyses may not be necessary for sample collection at the state and local level. However there are advantages in defending a legal case if sampling activities are formally witnessed with these types of documents.

Whether samples are collected by the laboratory itself or by an independent third party, coordination of sampling with the receiving laboratory is essential to assure that a sample is representative of the lot sampled, received with sample integrity preserved, and that analyses are conducted in an accurate and timely manner. The capabilities of the laboratory and staff must be considered. To assist in determining that the appropriate sample is being collected, the sampling subcommittee identified the following Critical Elements applicable to sampling:

**Critical Element 1.** The sampler has policies, procedures, and records to assure sample integrity, security, accountability, and chain of custody
**Critical Element 2.** The sampler has a statistically appropriate sampling plan
**Critical Element 3.** The sampler has a training program
**Critical Element 4.** The sampler is prepared to develop "incident specific" sampling plans prior to beginning collection

**Critical Element 1.** ***The sampler has policies, procedures, and records to assure sample integrity, security, accountability, and chain of custody***

A sampler has policies and procedures in place to ensure that work is carried out in a manner consistent with quality management directives. Procedures include record keeping including record retention; procedures to ensure the integrity of the sample; procedures to protect the security and confidentiality associated with samples collected for regulatory action; procedures for sample accountability including a procedure for customer feedback; and procedures to ensure samples have sufficient, unbroken, chain of custody documentation from collection through delivery to the testing organization.

**Critical Element 2.** ***A sampling plan for samples taken to support regulatory action***

In agreement with the laboratory, a sampling plan is created to include the number and type of samples to be collected; requirements specific to the testing to be performed; sampling procedures, packaging, preservation, transportation; and the timing of sample receipt

*(Note: More specific performance characteristics of a sampling plan may need to be adopted, especially for microbiological testing. Please consult the references provided below).*

## The sampling plan addresses the following items:

**Sample Collection:**

- *Specific Procedures* - Where possible, use established federal or international reference procedures. The procedure takes into account the biological, chemical and/or physical characteristics of the item sampled and the analytes of interest. While sampling a specific commodity for a specific analytical purpose may vary, sampling procedures include measures taken to assure the sample is representative of the lot, the size and/or number of individual items forming the sample and the method by which the sample is taken, handled and transported. (While sample size and number of subs may range from 12 – 20 subs of 5 lbs. each for FDA sampling shiploads of product in import status, surveillance sampling at the state level may be limited to 1-5 lb. samples taken from a single truckload or a single item at the retail level.) Procedures may also need to include the statistical criteria to be used for acceptance or rejection of a lot and procedure to be adopted in cases of dispute. Sampling procedures are documented in writing.
  - *Collection Technique* - Sampling operations are carried out using techniques that ensure the sample is representative of the lot, that the sample of the product is in the same condition as it was before sampling, and that the collection technique does not compromise the compliance status of the lot. It is not possible to specify the exact manner of collection of all samples; however, if non-routine, the manner of collection is clearly described.
  - *Representative* - Sampling procedures are designed so that the sample represents the composition of the entire lot being sampled. For example, equal sized subsamples may be taken from multiple sections of the entire lot and combined to form a single sample, such as the four corners and middle of a warehouse bin or randomly selecting several boxes from a large shipment. There are very specific procedures for the sampling of some types of foods/feeds in manufacturing and import settings. In the case of convenience and other small sample sizes, care is taken to assure there is no reason to suspect that the sample selected is any different from others of the same type in the same lot.
  - *Aseptic Sampling (for microbial analysis)* - Aseptic sampling is a technique used to prevent contamination by the sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Samples are collected and submitted in a manner which will prevent multiplication or undue reduction of the bacterial population. Contamination from atmospheric conditions or handling is prevented. Controls of the sterile containers, gloves and other sampling equipment are submitted with samples to verify the sterility of the technique and the environmental conditions during the timeframe of sampling. Samples collected using aseptic technique permit testimony that the bacteriological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the time of the original shipment.

- *Sample Integrity* – Samples are collected and packaged in a manner that preserves the sample and the analytes of interest and assures that no significant change in composition occurs from the moment of sampling until the analysis is complete. Procedures assure that sample or analyte contamination or degradation does not occur. Suitable containers and storage temperatures are chosen to assure sample integrity. (For example, plastic packaging or permanent markers may interfere with pesticide or hydrocarbon analysis while foil packaging may interfere with metals analysis. Vitamins may degrade in sunlight. Some samples are frozen. Some samples require the use of a preservative to retain the analytes of interest.)
- *Transportation* - A large amount of time and effort is wasted if the sample arrives in a state which is unfit for the analysis requirements. Samples are transported in a manner that prevents deterioration of the sample matrix or contamination of the sample and preserves the analytes of interest. All samples are handled, packaged, temperature controlled and shipped to prevent compromising the identity or integrity of the sample. Samples are packed with shock absorbing materials to protect against breakage of containers or damage to seals. Frozen samples remain frozen; perishable products may be frozen, if freezing does not interfere with the planned analysis; products requiring refrigeration (e.g., fresh crabmeat for bacteriological analysis) are shipped with ice packs. Samples are individually wrapped to avoid cross contamination during transport. Samples for microbiological examination remain aseptic. Even if the food/feed arrives in good condition, transportation conditions are controlled to assure the analyte of interest does not deteriorate in transit.

**Sample Custody:**
Samples are identified and handled in a manner that maintains sample integrity and a proper chain-of-custody by being in the sampler's possession, within sight, sealed with a tamper proof seal, or locked up. The sample is collected, identified, and sealed, before taking another sample. More than one sample is never placed in the same officially sealed package. Sample custody records are maintained from the time of collection until a sample is reported and discarded by the laboratory. Custody records document the movement and transfer of a sample by recording each action taken, the date/time, the location and responsible person at each transfer.

**Records/Documentation:**
At the time of collection, records are obtained that fully describe every sample. Official samples are documented completely, accurately and legibly to be able to withstand legal scrutiny.

- *Sample Identification:* Identify each sample with a unique sample identification number, initial and date the custody seal. Include the purpose of the sampling, date and time of collection, place of collection and the name of the collector.
- *Jurisdiction (if applicable):* Records documenting interstate shipment may be needed to establish federal jurisdiction and authority to initiate formal legal action.
- *Responsible person(s):* Record enough information to clearly establish responsibility. The person who owns/holds/sells the product is usually the responsible party. In some cases, a product may be held by a facility, such as in cold storage or shipping carrier, but owned by another. During investigation of violations, it may be important to document additional information. There may be several additional responsible parties such as the exporter, importer, grower, packer, manufacturer, distributor, etc.
- *In-Transit:* A bill of lading documents the ownership of product collected from trucks, ships, loading/receiving docks or holding facilities.
- *Adulterated while held for sale:* For foods that became adulterated or misbranded after initial shipment, document the act of adulteration, when and how it occurred and the person(s) responsible for causing the violation. Laboratory testing may be necessary to document the adulteration.

- *Imports:* If possible, document the port of entry, the importer of record and the import entry number. Otherwise, establish a paper trail of records going back as far as possible in the distribution chain.
- *Identity:* Describe and document the commodity or species in enough detail that additional product could be collected in the future and that regulatory action can be taken based on the description. For example, pesticide regulations may establish tolerances for sweet corn and field corn at different levels. When collecting samples from individuals, ask the individual to initial and date the label, wrappings, promotional literature, etc., for later identification in court.
- *Photos:* of the product and any identifying packaging are very helpful and are becoming mandatory for many samplers. Assure that a unique code is included in the picture to identify the specific sample such as an inspector sample number. Most photos also have a date stamp. Assure that the date stamp is accurate.
- *Lot:* A discrete unit of food or feed which has been grown, harvested or manufactured at the same time and in the same manner and is identified as having the same characteristics/ qualities. A lot clearly distinguishes the product as different from others of the same commodity and is traceable through invoices and shipping / receipt records. A lot may consist of several cases of processed food shipped on the same day from the same manufacturer or a tanker of juice, or a field of tomatoes planted at the same time. The owner of the product identifies lots of product in a manner that will allow a recall of adulterated product. Document the lot identity and size. In some cases, the monetary value of the lot is also documented. It may be advisable to affix some kind of label with sampler initials and date on the sampled container to distinguish it from others.
- *Condition:* Record the temperature, packaging (paper, plastic, open case), processing (fresh, frozen, canned) and any other physical attributes of the sample at the time of sampling.
- *Manner of collection:* The sampling procedure is documented in writing, either by reference to standard procedures and/or by detailed descriptions made by the collector at the time of collection.
- *Observations:* At the time of collection, record anything else that distinguishes the sample from others such as sanitary conditions at the facility, unusual appearance or anything that is not already recorded such as an unusual manner of collection. Any information given by the firm/owner/dealer is recorded.
- *Records backup and retrieval:* Records stored only on electronic media are supported by hardware and software necessary for retrieval. Records sorted or generated by computers have hard copy or secure backup copies. Access to archived information is documented with an access log. Records are protected against fire, theft, loss or deterioration and are retained for a specified period, if required a regulatory authority.

**Critical Element 3.** ***Samplers have a training program***

Samplers establish and maintain data integrity procedures. The term "data" used in this element refers to field measurement data and all other recordkeeping. The data integrity that documents field sampling and measurement activities provides assurance that a highly ethical approach to field sampling and measurement is a key component of all planning, training and method implementation. Persons conducting sampling have documented education, training, technical knowledge and experience for their assigned functions including:

- Knowledge of biological, chemical and physical properties of the samples and analytes of interest and the significance of these properties in the proper conduct of their sampling.
- Hands-on, practical performance of sampling techniques and procedures.

- Hands-on calibration, use and maintenance of sampling apparatus and equipment.
- Hands-on packaging, preservation, temperature control and shipping of samples to assure sample and analyte or microorganism integrity.
- Awareness of prevailing statutes, regulations and ordinances and relevant Hazards Analysis and Critical Control Points (HACCP).
- Food safety and public health principles.
- Communication skills.
- Awareness of safety hazards and prevention of injury. Samplers are provided with information and personal protective equipment specific to their collection assignments and sufficient to conduct sampling safely. Samplers are made aware of any possible hazards associated with the samples themselves. Samplers comply with all safety procedures of those entities they visit.
- Data integrity procedures and documentation that assures sampling is conducted according to established protocols.
- Written acknowledgement of understanding applicable policies and procedures.

Sampler training is reviewed and updated and sampling performance observed and documented at periodic intervals, such as annually.

**Critical Element 4.** ***Samplers and analyzing laboratories may need to establish "incident specific" sampling plans to ensure that collections are being done in the most appropriate fashion***
Samplers and analyzing laboratories work together to develop incident specific sampling plans. It is difficult to predict all situations associated with food collections; therefore an established procedure for creating a statistically appropriate sampling plan is implemented. To assist entities with drafting generic and incident specific sampling plans, a list of references has been provided. While not all inclusive, this list may help guide this process.

## References:

In addition to the best practices listed above, the Sampling subcommittee assessed the existing available standards that may be applicable in a regulatory sampling scenario. Some additional resources are listed below.


- *FDA Investigations Operations Manual* - Chapter 4: FDA guidance for sampling items under FDA jurisdiction and Chapter 8: FDA guidance for sampling items related to complaints, outbreaks and emergency response activities. http://www.fda.gov/
- *FDA Office of Regulatory Affairs Laboratory Manual Vol. 3* – Section 2 Chain of Custody – Sample Handling, http://www.fda.gov/
- *FDA Manual of Compliance Policy Guides* – http://www.fda.gov/
- *FDA* Bacteriological Analytical Manual, Edition 8, Revision A, 1998. Chapter 1. http://www.fda.gov/
- *FDA* Compliance Programs. www.fda.gov/ora/cpgm.
- *USDA Pesticide Data Program Procedures* - http://www.ams.usda.gov/AMSv1.0/pdp
- *USDA Microbiological Data Program Procedures* - http://www.ams.usda.gov/AMSv1.0/mdp
- *AAFCO Requirements for Sampling* - Feed Inspector's Manual, 2nd Edition, May 1, 2000, http://www.aafco.org/
- *AAFCO Quality Assurance/quality Control Guidelines for state Feed Laboratories, 2007*
- *ISO/IEC 17025:2005(E)* - General requirements for the competence of testing and calibration laboratories, http://www.iso.org/
- *Food and Agriculture Organization of the United Nations, Sampling* - http://www.fao.org/

- *NELAC Requirements for Sampling* - Field Sampling and Measurement Organization Sector Volume 1 and General Requirements for Field Sampling and Measurement Organizations, May 1. 2007, http://www.nelac-institute.org/
- *AOAC Official Methods of Analysis*, 18th Edition, Rev. 4, 2011, https://my.aoac.org
- *ALACC Criteria:* AOAC International - Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals, March 2010, https://my.aoac.org
- *Compendium of Methods for the Microbiological Examination of Foods* [(American Public Health Association (APHA)] - Chapter 2 of the 4th edition contains guidelines for sampling foods for microbiological analysis. It also contains guidelines for developing sampling plans. www.apha.org
- *CODEX* – General Guidelines on Sampling – CAC/GL 50-20004 (FAO/WHO, 2004), http://www.codexalimentarius.org/
- *ISO* – ISO 2859, 3951 and 7218, http://www.iso.org/iso/home.htm
- *Manufactured Food Regulatory Program Standards, September 2010* – www.fda.gov/
- *Canadian Food Inspection Agency* – www.inspection.gc.ca
- *International Commission on Microbiological Specifications for Foods (ICMFS)* - Book 7 (Microorganisms in Foods 7: Microbiological Testing in Food Safety Management; 2002) and Book 8 (Use of Data for Assessing Process Control and Product Acceptance (Intl Commission on Microbiological Specifications for Foods; 2011)
- *Sample collection Procedures for Radiochemical Analytes in Environmental Matrices*, Office of Research and Development, National Homeland Security Research Center, U.S. EPA, December 2006, EPA/600/S-07/001, www.epa.gov
- *A Performance-Based Approach to the Use of Swipe Samples in Response to a Radiological or Nuclear Incident*, EPA 600/R-11/122, October 2011, www.epa.gov

*Disclaimer: The Sampling subcommittee was not able to collect an exhaustive list of references or sampling procedures. Definitions may vary and there is a need to harmonize the best practices with U.S. federal and state agencies, professional organizations such as AAFCO and international standards such as AOAC, ISO and Codex. In time a National Sampling Operations Manual may be developed but it will never be able to include all the variations in samples and methodology encompassed in food safety. Sampling procedures must change as science advances and methods change. It will have to be a flexible and living document, frequently updated. By the same token, it cannot be so general as not to be useful. It should provide specific guidelines where these are generally known as acceptable practice.*

## Conclusion

The Sampling subcommittee has identified best practices for food/feed sampling intended for laboratory testing. There is a need for a wider group of sampling experts to identify and compile best sampling practices that can be published as a National Sampling Operations Manual for use by organizations seeking to follow the PFP best practices. Samplers may refer to the FDA Investigations Operations Manual (IOM) and compliance program guides or equivalent State or internationally recognized procedures such as AOAC, ISO or CODEX to standardize sample size and collection methods. In addition to developing best practices for sampling, the Sampling subcommittee will continue to work on compiling references to specific sampling procedures.


# METHODS

## Chapter 5

# METHODS

Chapter 5

## Background and Objectives

The development and/or selection of methods for food/feed regulatory laboratory analysis is a complex process that involves a number of practical as well as technical issues. Many considerations must be taken into account including, but not limited to, method source, accuracy, validation, through-put, robustness, precision and practicality. The PFP was established to provide best practices for food/feed testing laboratories to ensure the safety of the nation's food/feed supply. Key factors that impact method selection often are dependent on a combination of cost, assay sensitivity/specificity, and availability. In addition, public health regulatory laboratories conduct routine surveillance testing based on established regulatory standards as well as outbreak and emergency testing on known, evolving, or unknown hazards. Methods used for routine testing are often well validated and consistent with the ISO/IEC 17025 standard. However, testing used for outbreaks and emergency investigations may benefit from situational method development. The charge of this subcommittee was to provide best practices to the food/feed laboratory community when addressing the challenges of method development and method selection.

## Best Practices for Selection of Methodology

**Determine if Method is Fit for Purpose** - It is important to define the purpose and application of the chosen or desired analytical method. Basic application of knowledge, training and experience in the selection/development process is critical and may involve the following list of considerations:

1. Define the analytical requirement- First and foremost, what information is needed and what are the particular specifications (e.g. analyte(s), matrices, limit of detection (LOD), limit of quantitation (LOQ), etc.)
2. Determine if a method already exists which can fulfill the requirements by conducting a thorough search of available methods compendia and/or literature.
3. If a method is available, has it been validated? - A validated method (particularly those which have gone through a multi-laboratory validation) helps ensure a degree of reliability, repeatability, and robustness for the analytical process including integrity of the observed data. A laboratory also looks at the validation organization and ensures that its specifications will produce a method that meets the analytical requirements (see #1 above). Regardless, the method is verified in the laboratory in question to ensure it can be performed properly.
4. If a validated method is available, is it appropriate and practical for the analysis? Does it have the necessary high capacity, high throughput capabilities needed? Older validated methods, while reliable, might be difficult to use or require equipment no longer in use.
5. If a practical, validated method is not available, is a non-validated, appropriate method available from the peer-reviewed literature? – A method from a peer-reviewed journal has had some level of review but must be verified to work in the laboratory.
6. If no method is available, then one may need to be developed and validated within a laboratory (a critical skill for all regulatory laboratories as this is a principal source for new methods).
7. Does the laboratory have the necessary resources (personnel, equipment, budget, literature access and training) to develop or adapt a method if one is not available from a reliable source? – In the situation where methods are not available, the laboratory itself is able to accurately assess its capabilities to develop/adapt a method and produce a method that would meet the analytical requirements.

8. Does the laboratory have the proper quality control and quality assurance procedures in place? Proper QA/QC will help ensure that methods conducted and/or developed in a laboratory will perform as needed. This can include an independent assessment of the laboratories technical performance.
9. Does the laboratory have the proper safety guidelines in place? Proper safety guidelines will help ensure that method evaluation and/or development is conducted without undue risks. In some cases, very strict guidelines are required to work with some compounds/ organisms such as those on the Centers for Disease Control and Prevention (CDC) Select Agent List.

*Disclaimer: The list above is by no means exhaustive or comprehensive. Every situation a laboratory will face in responding to its analytical needs/situations will have unique characteristics. However, a basic approach format such as this one will help ensure that the results generated meet the defined analytical requirements.*

**Determine if Validation Level is Sufficient** - One can define method validation as being "the process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with what the application requires." The method's performance capabilities and suitability are evaluated in the process as are the method's performance parameters. The FDA has recently produced two documents that provide the necessary validation guidelines for the food regulatory laboratory community. These are:

- Guidelines for the Validation of Chemical Methods for the FDA Foods Program http://www.fda.gov/scienceresearch/fieldscience/ucm273423.htm.
- Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM273418.pdf

These guidelines draw from pre-existing validation protocols such as those from the Association of Official Analytical Chemists International (AOACI) www.aoac.org, the International Union of Pure and Applied Chemistry (IUPAC) www.iupac.org, and the Food Emergency Response Network (FERN) www.fernlab.org

**Determine if a Method is Available** - There are a number of methods compendia that are generally available to food/feed testing laboratories. Some of these require subscriptions or have restricted access. The PFP LTG Methods Subcommittee has identified a list of various method sources and has categorized them according to disciplines.

**Multidisciplinary Compendia**

- Association of Official Analytical Chemists International (AOACI) Official Methods of Analysis (18 Ed, ver. 4) http://www.eoma.aoac.org/
- American Association of Cereal Chemists (AACC) Approved Methods of Analysis http://methods.aaccnet.org/
- Standard Methods for the Examination of Water and Wastewater (APHA) http://www.apha.org/
- Standard Methods for the Examination of Dairy Products (APHA) http://www.apha.org/
- FERN MCC Approved Methods www.elexnet.com
- CDC method manuals (several available such as the NIOSH Manual of Analytical Methods) http://www.cdc.gov/niosh/docs/2003-154/method-a.html
- EPA Standardized Analytical Methods Manual (SAM 2010) http://www.epa.gov/nhsrc/sam.html
- Recommended Procedures for the Examination of Seawater and Shellfish. 4th ed. (APHA) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1530666/
- Standard Methods for the Examination of Seawater and Shellfish (FDA) http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm

- FDA Compliance Program Guidance Manual
  http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograMManual/default.htm
  - Methods and Guidance for the Analysis of Water (Official EPA Versions)
    http://www.ntis.gov/products/epa-water-methods.aspx
  - Methods of Analysis for Infant Formulas (FDA)
    http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm114665.htm
  - Compendium of Microbiological Procedures and Chemical Tests (FDA) www.elexnet.com

**Microbiological Methods Compendia**

- FDA Bacteriological Analytical Manual (BAM)
  http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm
- USDA Microbiology Laboratory Guidebook http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook
- Compendium of Methods for the Microbiological Examination of Foods, 4th Edition (APHA)
  http://www.apha.org/advocacy/priorities/issues/rebuilding/advocacyedition.htm
- FDA Microbiological Methods
  http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm
- Health Canada Official Methods for the Microbiological Analysis of Foods
  http://hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php
- International Commission on Microbial Specifications for Foods (ICMSF)
  http://www.icmsf.org/
- USDA MDP - SOPs for Laboratory Activities http://www.ams.usda.gov/AMSv1.0/mdp
- Manual for the Surveillance of Vaccine-Preventable Diseases (CDC)
  http://www.cdc.gov/vaccines/pubs/surv-manual/index.html

**Chemical Methods Compendia**

- Official Methods and Recommended Practices of the AOCS, 6th Edition
  http://www.aocs.org/Methods/?navItemNumber=584
- USDA Chemistry Laboratory Guidebook
  http://www.fsis.usda.gov/Science/Chemistry_Lab_Guidebook/index.asp
- FDA Pesticide Analytical Manual (PAM)
  http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006955.htm
- FDA Elemental Analytical Manual (EAM)
  http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006954.htm
- Food Chemicals Codex
  http://www.usp.org/store/products-services/food-chemicals-codex-fcc
- ICUMSA Methods Book 2009 http://www.icumsa.org/index.php?id=134
- Health Canada Chemical Methods - Compendium of Methods for Chemical Analysis of Foods
  http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/chem/index-eng.php
- National Forage Testing Association Reference Methods
  http://foragetesting.org/index.php?page=reference
- United States Pharmacopeia/ National Formulary (USP/NF) http://www.usp.org/usp-nf
- Homeopathic Pharmacopeia http://www.hpus.com/
- Japanese Pharmacopeia http://www.pmda.go.jp/english/pharmacopoeia/online.html
- Pharmacopeia of the Peoples Republic of China
  http://www.usp.org/store/products-services/chinese-pharmacopoeia
- British Pharmacopeia http://www.pharmacopoeia.co.uk/
- Indian Pharmacopeia http://ipc.nic.in/

**Radiological Methods Compendia**

- HASL-300 (Volume I, 28th Edition February, 1997) http://www.orau.org/ptp/PTP%20Library/library/DOE/eml/hasl300/HASL300TOC.htm
- DOE Methods Compendium http://www.eichrom.com/radiochem/methods/compendial/doe_rp550.aspx
- ORISE Laboratory Procedures Manual http://orise.orau.gov
- Compendium of EPA-Approved Analytical Methods for Measuring Radionuclides in Drinking Water, DOE 1998 http://www.orau.org/ptp/PTP%20Library/library/DOE/Misc/radmeth3.pdf

**Macro Methods Compendia**

- Macroanalytical Procedure Manual (MPM) (FDA) www.fda.gov/food/foodscienceresearch/laboratorymethods/macroanalyticalproceduresmanualmpm/default.htm

*Disclaimer: This list is not considered comprehensive but should provide a reasonable number of options for laboratories searching for appropriate analytical methods.*

## Conclusion

The Methods subcommittee has developed an initial set of best practices for method selection, suggested validation protocols and a list of method source compendia for the regulatory food/feed laboratory community. Adherence to these best practices should reinforce confidence in laboratory competency and may facilitate the acceptance of laboratory analytical data by regulatory agencies.

# ANALYTICAL WORKSHEET PACKAGES

Chapter 6

# ANALYTICAL WORKSHEET PACKAGES

Chapter 6

## Background and Objectives

Currently, food/feed testing laboratories across the nation have unique ways of recording raw data. For the purposes of data review and regulatory action, it is imperative that laboratories document the required information on their worksheets, especially with respect to analytical trace-back and quality control.

The Standardized Worksheet Subcommittee (SWS) was tasked with providing best practices for recording raw analytical food/feed testing data. These best practices will provide laboratorians with a list of critical information in their raw data worksheets to properly document the analytical processes. Consideration should be given to translating the best practices to electronic format for collection of data by a Laboratory Information Management System (LIMS), since some laboratories are working towards paperless systems.

## Best Practices

The SWS devised a list of elements that should be contained in raw data worksheets. The raw data worksheets may be hard copies filled out by an analyst by hand, electronically, or data entered into a LIMS. These elements are detailed below.

**Detailed Sample Description**

- Detailed visual description of the sample including color, shape, texture or other general appearance
- Any identification numbers on the sample – unique sample identifier
- Detailed description of the containers used to transport the specimen down to the container in contact with the product
- The number of all sub-samples submitted with the samples
- The gross weight of the sample/subsamples (if applicable)
- The collectors, controls, standards or any other items contained in the shipment
- The physical condition of the sample upon receipt including temperature statement. Include any apparent abnormalities if observed
- Detailed description of container in contact with the sample including material and dimensions
- Product codes and lots as applicable
- Description of the label on commercial sample containers

**Sample Chain of Custody**

- Receipt date
- Received from/by
- Secured storage information (from receipt through testing)
- Seals present on the sample
- Storage conditions
- Reserve sample storage information
- Disposition of samples; i.e. shipment to another laboratory, long term storage, destruction

**Analytical Information**

- Name of the laboratory
- Unique sample identification on all pages of the worksheet
- Product name on all pages of the worksheet
- Method reference
- Summary of results
- Analyst and reviewer signature

**Quality Control**

- Equipment identification information
- Lot numbers on sterile supplies used
- Lot numbers on media used
- Lot number for reagents used
- QC standard information
- QC organism information

**Raw Data**

- Detailed sample preparation information
- All calculations including formulas used
- All standard preparations
- Any dilution schemes
- Calibrations
- Test conditions
- Deviations, additions or exclusions
- Any raw data associated with analysis including observations

**Attachments**

- Instrument Printouts, computer generated charts and data sheets, photographs, photocopies etc.
- Must have a unique attachment number/letter (Example Attachment A)
- Each page of the attachment must have the attachment number/letter at the top
- Each page of the attachment must have the product name at the top
- Each page of the attachment must have the unique sample ID number at the top
- Each page of the attachment must have the initials or signature of the primary analyst
- Each page of the attachment must be sequentially numbered (example 1 of 4, 2 of 4)
- If the attachment is of awkward size it can be mounted to mounting paper

**Labels** *(Note: not considered an attachment)*

- Commercial labeling – original labels, photograph of labels or photocopies of labels. The label may be mounted to mounting paper if necessary.
- Labels should have sample identification, the date the sample analysis began and the analyst initials recorded on the label, photograph or photocopy.

**General Good Record Keeping Practices**

- Document/version control as required by ISO/IEC 17025
- Clear annotation of entries
- Logical sequence of recordings
- Consecutive page numbers (example 1 of 12, 2 of 12…12 of 12)
- All unused areas are lined out and dated/initialed. Can use a diagonal line to cross out multiple areas at once

- All entry errors are corrected by putting one line through the error, clearly rewriting the entry, dating and initialing the error and an explanation of the error if it is not obvious
- No correction fluid or correction tape on worksheets
- No blacking out entry errors
- All data packages are recorded using blue or black ink

## Conclusion

The SWS has identified uniform best practices for recording raw analytical food/feed testing data. The overall goal of the SWS is to provide a means for laboratories to follow best practices without duplicating efforts by designing their own worksheets.

# REPORTING

Chapter 7

# REPORTING

Chapter 7

## Background and Objectives

As part of the PFP Laboratory Task Group, the Reporting subcommittee was tasked with developing best practices for reporting of analytical data as well as recommendations with respect to electronic data capture and future national IT development. Historically, while several laboratories have a working laboratory information management system (LIMS), there is no universal, mandatory national Information Technology (IT) system for food testing laboratories, and few laboratories are truly 'paperless.'

The reporting subcommittee identified reporting best practices, assessed the current state of food/feed electronic data sharing and reporting relevant to the PFP (food/feed analytical data, food safety/defense) and provided recommendations to IT subcommittees and working groups within PFP on how current or future systems could be utilized to meet reporting needs.

## Best Practices

The reporting subcommittee devised a list of "best practice" elements for a test report. The PFP reporting subcommittee found the test reporting requirements contained within ISO/IEC 17025:2005 to be a robust foundation that supports confidence in laboratory competency and facilitates the acceptance of laboratory data. Specifically, the subcommittee regards the requirements in ISO/IEC 17025:2005(E), clauses 5.10.1, 5.10.2, 5.10.3.1, 5.10.3.2, 5.10.5, 5.10.6, 5.10.7, 5.10.8, 5.10.9, to be best practices for reporting analytical data.
The subcommittee also identified the following additional best practices:

- Test reporting requirements may vary greatly depending on the specific regulatory policy and/or program at hand. The establishment of exact criteria for data reporting (electronic or otherwise) will require input from the entities making regulatory (compliance & enforcement) decisions for the acceptance of this data and any subsequent action that may be taken by an agency with regulatory authority.
- Procedures are established to prevent the production of unauthorized reports or other documents. These steps would include the restriction of access to word processing packages and company letterhead to authorized people. Electronic records, electronic signatures, and handwritten signatures executed to electronic records are equivalent to paper records and handwritten signatures executed to paper.
- Food/feed testing laboratories accredited by an independent third-party entity may have to fulfill additional requirements (as detailed by their accrediting body) to support confidence in laboratory competency and to facilitate the acceptance of the laboratory test result reports.

Regarding use of the accreditation symbol or other reference to the laboratory's accreditation:

- The accreditation symbol is only used in a test report when the identified test method is under the scope of accreditation. If the test report contains results from both non-accredited and accredited tests, the report acknowledges that work falling outside of the laboratory's accreditation scope is included.
- Test reports containing opinions and interpretations outside of the laboratory's accreditation scope does not contain or display the accreditation symbol or other reference to the laboratory's accreditation status.

Further, the subcommittee proposed recommendations with respect to electronic data capture and future IT development. The recommendations are listed below and have been shared with relevant PFP IT subcommittees. The structure of any data report should have a set of "minimum data elements" that meets the test reporting best practices outlined in this document.

- The system should maintain flexibility to allow for the accommodation of additional reporting requirements as determined by the specific regulatory policy and/or program at hand.
- The system should allow for communication between the data submitter and the agency receiving the data and taking the potential regulatory action.
- The system should allow for security parameters to meet data storage security needs based on user roles/permissions.
- Should resources permit, it would be extremely advantageous to develop capabilities for housing raw analytical data in such a system (essentially a national LIMS). If this were to be pursued, the system should not only encompass all of the test reporting best practices outlined in this document, but also encompass all of the best practices for analytical worksheet packages as identified by the PFP Standardized Worksheet Subcommittee in Chapter 6.

## Conclusion

The Reporting subcommittee developed best practices for data included on reports generated by food/feed testing laboratories. Adherence to these best practices support confidence in laboratory competency and facilitate the acceptance of laboratory data by agencies. It is important to note that because the data included on reports must always meet the needs of the data customer, the data elements in a report may vary on a case by case basis. The Reporting subcommittee also considered the current state of electronic data reporting for federal and state laboratories and generated recommendations on how such systems could be used or enhanced to meet the electronic data reporting needs of food/feed testing laboratories. These recommendations were shared with relevant PFP IT subcommittee.

# ACKNOWLEDGEMENTS

# LINKS TO SUPPORTING DOCUMENT

# ABBREVIATIONS, ACRONYMS AND DEFINITION OF TERMS

Appendix 1, 2, 3

# ACKNOWLEDGEMENTS

## Appendix 1


### Laboratory Task Group – Co-Chairs

**Timothy McGrath**
Timothy.McGrath@fda.hhs.gov
301-796-6591
FDA, Office of Regulatory Affairs
LTG Co-Chair

**Andrew Cannons, Ph.D.**
andrew_cannons@doh.state.fl.us
813-974-4002
FL Department of Health, Tampa Lab
LTG Co-Chair; Methods; PT

**Donald H. Burr**
Donald.Burr@fda.hhs.gov
240-402-3846
FDA, Office of Regulatory Affairs
LTG Co-Chair; PT

**Robyn Atkinson, Ph.D.**
rmatkinson@utah.gov
801-965-2424
Utah Department of Health
LTG Co-Chair; Accreditation; PT

### Laboratory Task Group – Subcommittee Leads

**Patrick Ayres**
Patrick.ayres@fda.hhs.gov
303-236-3066
FDA, Office of Regulatory Affairs
Lead: Standardized Worksheets - chem

**Stephanie C. Brock**
StephanieC.Brock@ky.gov
502-564-8390
Kentucky Department for Public Health
Lead: Methods - Rad

**Hitelia Castellanos**
Hitelia.Castellanos@fda.hhs.gov
301-796-8172
FDA, Office of Regulatory Affairs
Lead: Accreditation
Member: PT, Regulatory Annex

**Jo Marie Cook**
JoMarie.Cook@freshfromflorida.com
850-617-7505
Florida Department of Agriculture &
Consumer Services
Lead: Regulatory Annex
Member: Sampling, Methods

**Liz Delamater, Ph.D.**
Elizabeth.Delamater@dshs.state.tx.us
512-776-7592
Texas Department of State Health Services
Lead: Reporting
Member: Regulatory Annex

**Tara Doran**
Tara.Doran@fda.hhs.gov
301-796-6619
FDA, Office of Regulatory Affairs
Lead: Standardized Worksheets
Member: Reporting

**Matthew Forstner**
Matthew.Forstner@state.mn.us
651-201-6568
Minnesota Department of Agriculture
Lead: Standardized Worksheets
Member: Methods

**Kevin Garner**
Kevin.Garner@fda.hhs.gov
301-796-6616
FDA, Office of Regulatory Affairs
Lead: Sampling

**Brenda Jackson**
Brenda.L.Jackson@ncagr.gov
919-733-7366
N. Carolina Dept.of Agriculture & Consumer Services
Lead: Accreditation
Member: Methods

**Mike McLaughlin**
Michael.McLaughlin@fda.hhs.gov
301-796-8158
FDA, Office of Regulatory Affairs
Lead: Methods

## Laboratory Task Group – Subcommittee Leads

**Jennifer Letts**
Jennifer.Letts@fda.hhs.gov
301-796-6318
FDA, Office of Regulatory Affairs
Regulatory Annex

**Paul Morin**
Paul.Morin@fda.hhs.gov
718-340-7181
FDA, Office of Regulatory Affairs
Lead: Methods Member: Standardized Worksheets

**Ruiqing Pamboukian, Ph.D.**
Ruiqing.Pamboukian@fda.hhs.gov
301-796-8157
FDA, Office of Regulatory Affairs
Lead: Regulatory Annex
Member: Accreditation

**Tom Phillips**
tom.phillips@maryland.gov
410-841-2721
Maryland Department of Agriculture
Lead: Methods

**Ravinder Reddy**
Ravinder.Reddy@fda.hhs.gov
708-728-4112
FDA, Center for Food Safety and Applied Nutrition
Lead: National PT
Member: Methods

**Brian D. Sauders, Ph.D.**
brian.sauders@agriculture.ny.gov
518-485-8774
New York State Department of Agriculture & Markets
Lead: Methods
Member: Accreditation; Reporting

**Thomas A. Scott**
Thomas.scott@fda.hhs.gov
781-756-9749
FDA, Office of Regulatory Affairs
Lead: Methods - Rad

**Bryanne Shaw**
Bryanne.Shaw@state.mn.us
651-201-6571
Minnesota Department of Agriculture
Lead: Sampling

**Victoria S. Siegel, Ph.D.**
vsiegel@purdue.edu
765-494-1565
Office of Indiana State Chemist, Purdue University
Lead: National PT
Member: Methods

**Nancy Thiex**
nancy.thiex@sdstate.edu
605-695-3098
South Dakota State University
Lead: Regulatory Annex
Member: Accreditation; Methods

**Lauren Yeung**
Lauren.Yeung@fda.hhs.gov
301-796-6623 FDA,
Office of Regulatory Affairs
Lead: Reporting
Member: Standardized Worksheets, PT

## Laboratory Task Group – Subcommittee Members

## Laboratory Task Group – Subcommittee Members

**Jeffrey Archer**
Jeffrey.archer@fda.hhs.gov
870-543-4076
FDA, Office of Regulatory Affairs
Standardized Worksheets

**Kevin L. Armbrust**
armbrust@mscl.msstate.edu
662-325-3324
State Chemical Lab of Mississippi

**Linda Aston**
laston@ucdavis.edu
California Animal Health and Food Safety
Standardized Worksheets

**Frankie Beacorn**
Frankie.Beacorn@fsis.usda.gov
706-546-3578
USDA, Food Safety and Inspection Service
Methods

**Tom Beacorn**
Thomas.Beacorn@fsis.usda.gov
706-546-3426
USDA, Food Safety and Inspection Service

**Linda Benjamin, Ph.D.**
Linda.Benjamin@fda.hhs.gov
240-276-9204
FDA, Center for Veterinary Medicine
Regulatory Annex; Sampling; Methods

**Amy Brown**
Amy.brown@freshfromflorida.com
850-617-7510
Florida Department of Agriculture & Consumer Services
Reporting

**Bill Burkhardt**
William.Burkhardt@fda.hhs.gov
251-690-3361
FDA, Center for Food Safety and Applied Nutrition
PT; Methods

**Cathy Burns**
Cathy.Burns@fda.hhs.gov
303-236-3021
FDA, Office of Regulatory Affairs
Standardized Worksheets

**Bev Byrum**
byrum@agri.ohio.gov
614-728-6220
Ohio Department of Agriculture

**Andrew Capps**
Andrew.Capps@ncagr.gov
919-733-7366 x272
N. Carolina Dept. of Agriculture and Consumer Services
PT

**Pak Chu**
Pak.Chu@fda.hhs.gov
301-210-4583
FDA, Center for Veterinary Medicine
Methods

**Jo Marie Cook**
JoMarie.Cook@freshfromflorida.com
850-617-7505
Florida Dept. of Agriculture & Consumer Services
Sampling; Regulatory Annex

**Tim Croley**
Timothy.Croley@fda.hhs.gov
240-402-2038
FDA, Center for Food Safety and Applied Nutrition

**Tom Cronau**
tcronau@isdh.in.gov
317-921-5850
Indiana State Department of Health Laboratories
Accreditation; PT

**Ashley Demander**
Ashley.demander@state.co.us
303-692-3288
Colorado Dept. of Public Health and Environment
Standardized Worksheets

**Jessica Dyer**
Jessica.Dyer@ncagr.gov
919-733-7366 x262
N. Carolina Dept. of Agriculture and Consumer Services
Standardized Worksheets; Accreditation

**Hesham A. Elgaali**
helgaali@isdh.in.gov
317-921-5813
Indiana State Department of Health Laboratories
Accreditation; PT

## Laboratory Task Group – Subcommittee Members

**Jayne Finnigan**
jfinnigan@dhhs.state.nh.us
603-271-1782
New Hampshire Dept. of Public Health Services
Standardized Worksheets

**Mark French**
Mark.French@freshfromflorida.com
850-617-7556
Florida Department of Agriculture & Consumer Services
Regulatory Annex; PT

**Karim George**
Karim.George@ky.gov
502-564-4446
Kentucky Department for Public Health
PT

**Gale Hayden Hagood**
ghagood@mscl.msstate.edu
662-325-2955
State Chemical Lab of Mississippi
Accreditation

**Walter Hammack**
Walter.hammack@freshfromflorida.com
850-617-7514
Florida Dept. of Agriculture & Consumer Services
Methods

**Darcy Hanes, Ph.D.**
Darcy.Hanes@fda.hhs.gov
301-210-5372
FDA, Center for Food Safety and Applied Nutrition

**Ken Hill**
khill@isdh.in.gov
317-921-5510
Indiana State Department of Health Laboratories
Accreditation; PT

**Susan Humphries**
Susan.Humphries@freshfromflorida.com
850-617-7560
Florida Dept. of Agriculture & Consumer Services
Accreditation

**Maria Lucia Ishida, Ph.D.**
Maria.Ishida@freshfromflorida.com
850-617-7559
Florida Dept. of Agriculture & Consumer Services
Methods; PT

**Sun Kim**
Sun.Kim@freshfromflorida.com
850-617-7562
Florida Dept. of Agriculture & Consumer Services
Methods

**Keith Lampel**
Keith.Lampel@fda.hhs.gov
240-402-2007
FDA, Center for Food Safety and Applied Nutrition

**Chris Lane**
Chris.lane@fda.hhs.gov
949-608-4434
FDA, Office of Regulatory Affairs
Standardized Worksheets

**Chad S. Linton**
clinton@ag.state.wv.us
304-558-2227 x4045
West Virginia Department of Agriculture
Sampling

**Mark Madson**
Mark.Madson@fda.hhs.gov
303-236-3060
FDA, Office of Regulatory Affairs

**Chris Malota**
Chris.malota@dshs.state.tx.us
512-458-7111 x6464
Texas Department of State Health Services
Standardized Worksheets

**Cynthia Mangione**
Cynthia.mangione@agriculture.ny.gov
518-457-0906
New York State Dept. of Agriculture & Markets
Standardized Worksheets; Accreditation

**Terri McConnell**
Terri.McConnell@fda.hhs.gov
404-253-1217
FDA, Office of Regulatory Affairs
Standardized Worksheets

**Patryce D. McKinney**
Patryce.McKinney@alaska.gov
907-375-8206
ADEC Environmental Health Lab
Accreditation

## Laboratory Task Group – Subcommittee Members

**Zachary Miller**
Zachary.Miller@fda.hhs.gov
303-236-9694
FDA, Office of Regulatory Affairs
Standardized Worksheets

**Lucinda Mitchell**
Lucinda.mitchell@ky.gov
502-564-4446
Kentucky Department of Public Health
Accreditation

**Edette Newby**
Edette.Newby@fda.hhs.gov
301-436-2068
FDA, Center for Food Safety and Applied Nutrition

**Ritu Nalubola**
Ritu.Nalubola@fda.hhs.gov
301-796-3252
FDA, Center for Food Safety and Applied Nutrition

**Gene Niles**
Gene.Niles@Illinois.gov
618-532-6701
Illinois Department of Agriculture

**Debbie Oglesby**
debra.oglesby@agriculture.ny.gov
518-485-5012
New York State Dept. of Agriculture and Markets
Regulatory Annex

**Palmer Orlandi**
Palmer.orlandi@fda.hhs.gov
301-796-6592
FDA, Office of Regulatory Affairs
Methods

**Gail Parker**
Gail.Parker@freshfromflorida.com
850-617-7513
Florida Dept. of Agriculture & Consumer Services
PT

**Pradip Patel**
ppatel@isdh.in.gov
317-921-5530
Indiana State Department of Health Laboratories
Accreditation; PT

**Cathy Pentz**
Cathy.Pentz@fsis.usda.gov
706-546-3570
USDA, Food Safety and Inspection Service
Accreditation

**Audrey Pilkington**
audrey.pilkington@ncagr.gov
919-733-7366
N. Carolina Dept. of Agriculture and Consumer Services
Accreditation

**Charlie Pixley**
Charles.Pixley@fsis.usda.gov
706-546-3559
USDA, Food Safety and Inspection Service
Methods

**Mark Rasmussen**
Mark.Rasmussen@fda.hhs.gov
301-210-4255
FDA, Center for Veterinary Medicine
Sampling

**Dan Rice**
daniel.rice@agriculture.ny.gov
518-457-4478
New York State Dept. of Agriculture and Markets
Sampling

**Andrea Saldana**
Andrea.saldana@dshs.state.tx.us
512-458-7111 x6464
Texas Department of State Health Services
Standardized Worksheets

**Yvonne Salfinger**
Yvonne.Salfinger@freshfromflorida.com
850-617-7555
Florida Dept. of Agriculture & Consumer Services
Accreditation; Methods; Reporting

**Bob Sheridan**
Robert.sheridan@agriculture.ny.gov
518-457-8885
New York Department of Agriculture and Markets
Methods

**Brenda Snodgrass**
brenda.snodgrass@ag.ok.gov
405-522-5440
Oklahoma Dept of Agriculture, Food & Forestry
Accreditation; Reporting

**Karen Stephani**
Karen.Stephani@agriculture.ny.gov
518-457-0906
New York Department of Agriculture and Markets

## Laboratory Task Group – Subcommittee Members

**Jasmine Thompson**
Jasmine.thompson@fda.hhs.gov
949-608-3520
FDA, Office of Regulatory Affairs Standardized Worksheets

**Aneddail Torres-Ayala**
Annedail.torres-ayala@azdhs.gov
602-364-1656
Arizona Department of Health
Standardized Worksheets

**Socrates Trujillo**
Socrates.Trujillo@fda.hhs.gov
240-402-2037
FDA, Center for Food Safety and Applied Nutrition

**Buffie Vaught**
bmink@purdue.edu
765-494-0244
Purdue University

**Robert D. Waltz**
rwaltz@purdue.edu
765-494-1492
Office of Indiana State Chemist, Purdue University

**Luann Wetzler**
Luann.wetzler@nebraska.gov
Nebraska Department of Agriculture
Sampling

**Kathleen Wickman**
kwickman@oda.state.or.us
503-872-6633
Oregon Department of Agriculture
Accreditation

**Ron Willett**
Ronald.Willett@ncagr.gov
919-733-7366
N. Carolina Dept. of Agriculture and Consumer Services
Sampling; Regulatory Annex

**Christina Wilson**
wilsonc@purdue.edu
765-494-7440
Purdue University
Methods

**Regina Wixon**
Regina.Wixon@sdstate.edu
South Dakota State University
Methods

**Ching-Ching Wu**
wuc@purdue.edu
765-494-7459
Office of Indiana State Chemist, Purdue University

**Kang Xia**
kx6@msstate.edu
662-325-5896
Mississippi State University

**Sarah Yachetti**
sarah.yachetti@fda.hhs.gov
301-210-4681
FDA, Center for Veterinary Medicine

**Philip Zillinger**
pzilling@isdh.in.gov
317-921-5571
Indiana State Department of Health Laboratories
Accreditation

# LINKS TO SUPPORTING DOCUMENTS

Appendix 2

| Supporting Documents and Links |
|---|
| **American Association of Cereal Chemists (AACC) Approved Methods of Analysis** http://methods.aaccnet.org/ |
| **America n Association of Veterinary Laboratory Diagnosticians (AAVLD)** www.aavld.org/ |
| **American Public Health Association (APHA)** www.apha.org |
| **APHA Compendium of Methods for the Microbiological Examination of Foods, 4th Edition** http://www.apha.org/advocacy/priorities/issues/rebuilding/advocacyedition.htm |
| **APHA Recommended Procedures for the Examination of Seawater and Shellfish 4th ed.** http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1530666/ |
| **APHA Standard Methods for the Examination of Dairy Products** https://secure.apha.org/scriptcontent/BeWeb/Orders/ |
| **APHA Standard Methods for the Examination of Water and Wastewater** https://secure.apha.org/scriptcontent/BeWeb/Orders/ |
| **Association of American Feed Control Officials (AAFCO)** www.aafco.org/ |
| **Association of Official Analytical Communities (AOAC)** https://my.aoac.org/ |
| **Association of Official Analytical Chemists International (AOACI)** www.aoac.org/ |
| **Association of Official Analytical Chemists International (AOACI) Official Methods of Analysis** http://www.eoma.aoac.org/ |
| **CDC - U.S. Centers for Disease Control and Prevention** www.cdc.gov |
| **CDC Manual for the Surveillance of Vaccine-Preventable Diseases** http://www.cdc.gov/vaccines/pubs/surv-manual/index.html |
| **CDC NIOSH Manual of Analytical Manuals** http://www.cdc.gov/niosh/docs/2003-154/method-a.html |
| **Clinical Laboratory Improvement Amendments (CLIA)** www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/ |
| **CODEX Alimentarius International Food Standards** http://www.codexalimentarius.org/ |
| **DOE - Department of Energy** http://energy.gov/ |

| Supporting Documents and Links |
| --- |
| **DOE – Oak Ridge Institute for Science and Education (ORISE)**<br>http://orise.orau.gov/ |
| **DOE Compendium of EPA-Approved Analytical Methods for Measuring Radionuclides in Drinking Water**<br>http://www.orau.org/ptp/PTP%20Library/library/DOE/Misc/radmeth3.pdf |
| **EPA - Environmental Protection Agency**<br>www.epa.gov |
| **EPA Methods and Guidance for the Analysis of Water**<br>http://www.ntis.gov/products/epa-water-methods.aspx |
| **EPA Standardized Analytical Methods Manual (SAM 2010)**<br>http://www.epa.gov/sam/ |
| **FDA - Food and Drug Administration**<br>www.fda.gov |
| **FDA Bacteriological Analytical Manual (BAM)**<br>http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm |
| **FDA Compendium of Microbiological Procedures and Chemical Tests (FDA)**<br>www.elexnet.com |
| **FDA Compliance Program Guidance Manual**<br>www.fda.gov/ora/cpgm |
| **FDA Elemental Analytical Manual (EAM)**<br>http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006954.htm |
| **FDA Guidelines for Method Validation**<br>http://www.fda.gov/ScienceResearch/FieldScience/ucm273423.htm |
| **FDA Investigations Operations Manual (IOM)**<br>http://www.fda.gov/ICECI/Inspections/IOM/ |
| **FDA Macroanalytical Procedure Manual (MPM)**<br>http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006953.htm |
| **FDA Manufactured Food Regulatory Program Standards (MFRPS)**<br>http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/ |
| **FDA Methods of Analysis for Infant Formulas**<br>http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm114665.htm |
| **FDA Microbiological Methods**<br>http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm |
| **FDA ORA Lab Manual**<br>http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/default.htm |
| **FDA Pesticide Analytical Manual (PAM)**<br>http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006955.htm |

| Supporting Documents and Links |
|---|
| **FDA Standard Methods for the Examination of Seawater and Shellfish**<br>http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm |
| **Food and Agriculture Organization of the United Nations**<br>http://www.fao.org/ |
| **Food Chemicals Codex**<br>http://www.usp.org/store/products-services/food-chemicals-codex-fcc |
| **Food Emergency Response Network (FERN)**<br>www.fernlab.org |
| **Food Emergency Response Network Approved Methods**<br>www.elexnet.com |
| **Food Safety and Modernization Act (FSMA), PUBLIC LAW 111–353—JAN. 4, 2011, 21 USC 301**<br>http://www.gpo.gov |
| **Foodshield website**<br>www.foodshield.org |
| **HASL-300 (Volume I, 28th Edition February, 1997)**<br>http://www.orau.org/ptp/PTP%20Library/library/DOE/eml/hasl300/HASL300TOC.htm |
| **Health Canada Canadian Food Inspection Agency (CFIA)**<br>www.inspection.gc.ca |
| **Health Canada Chemical Methods - Compendium of Methods for Chemical Analysis of Foods**<br>http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/chem/index-eng.php |
| **Health Canada Official Methods for the Microbiological Analysis of Foods**<br>http://hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/index-eng.php |
| **International Commission for Uniform Methods of Sugar Analysis (ICUMSA) Methods Book 2009**<br>http://www.icumsa.org/index.php?id=134 |
| **International Commission on Microbial Specifications for Foods (ICMSF)**<br>www.icmsf.org |
| **International Laboratory Accreditation Cooperation (ILAC) website**<br>www.ilac.org |
| **International Organization for Standardization (ISO)**<br>www.iso.org |
| **International Organization for Standardization (ISO) standard ISO/IEC 17025**<br>http://webstore.ansi.org/default.aspx |
| **International Union of Pure and Applied Chemistry (IUPAC)**<br>www.iupac.org |
| **National Environmental Laboratory Accreditation Conference (NELAC)**<br>www.nelac-institute.org |

| Supporting Documents and Links |
| --- |
| **National Forage Testing Association Reference Methods**<br>http://foragetesting.org/index.php?page=reference |
| **Official Methods and Recommended Practices of the AOCS, 6th Edition**<br>http://www.aocs.org/Methods/?navItemNumber=584 |
| **Pharmacopeia of the Peoples Republic of China**<br>http://www.usp.org/store/products-services/chinese-pharmacopoeia |
| **Pharmacopeia, British**<br>http://www.pharmacopoeia.co.uk/ |
| **Pharmacopeia, Homeopathic**<br>http://www.hpus.com/ |
| **Pharmacopeia, Indian**<br>http://ipc.nic.in/ |
| **Pharmacopeia, Japanese**<br>http://www.pmda.go.jp/english/pharmacopoeia/online.html |
| **Pharmacopeia/ National Formulary, United States (USP/NF)**<br>http://www.usp.org/usp-nf/ |
| **USDA - United States Department of Agriculture**<br>www.usda.gov |
| **USDA Agricultural Marketing Service (AMS)**<br>www.ams.usda.gov |
| **USDA AMS Microbiological Data Program (MDP)**<br>http://www.ams.usda.gov/AMSv1.0/mdp |
| **USDA AMS Pesticide Data Program (PDP)**<br>http://www.ams.usda.gov/AMSv1.0/pdp |
| **USDA Microbiology Laboratory Guidebook (MLG)**<br>http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook |

# ABBREVIATIONS, ACRONYMS & DEFINITION OF TERMS

## Appendix 3

**AACC** American Association of Cereal Chemists
**AAFCO** Association of American Feed Control Official
**AAVLD** American Association of Veterinary Laboratory Diagnosticians
**AFDO** Association of Food and Drug Officials
**ALACC** Analytical laboratory Accreditation Criteria Committee
**AMS** Agricultural Marketing Service (USDA)
**AOAC** Association of Analytical Communities
**AOACI** Association of Official Analytical Chemists International
**AOCS** American Oil Chemists' Society
**APHA** American Public Health Association
**APHL** Association of Public Health Laboratories
**BAM** Bacteriological Analytical Manual (FDA)
**CDC** U.S. Centers for Disease Control and Prevention
**CFIA** Canadian Food Inspection Agency
**CFR** Code of Federal Regulations
**CLIA** Clinical Laboratory Improvement Amendments
**CODEX** Codex Alimentarius Commission
**COMPACT** Compendium of Microbiological Procedures and Chemical Tests
**CPGM** Compliance Program Guidance Manual (FDA)
**DOE** U.S. Department of Energy
**EAM** Elemental Analysis Manual (FDA)
**EML** Environmental Measurements Laboratory (DOE)
**EN** European Standards
**EPA** U.S. Environmental Protection Agency
**FAO** Food and Agriculture Organization
**FAQ** Frequently Asked Question
**FD&C** Act Food Drug and Cosmetic Act (FDA)
**FDA** U.S. Food and Drug Administration
**FERN** Food Emergency Response Network
**FR** Federal Register
**FSIS** Food Safety and Inspection Service (USDA)
**FSMA** Food Safety Modernization Act
**FY** Fiscal year
**HACCP** Hazard Analysis Critical Control Point
**HASL** Health and Safety Laboratory
**HR** Human Resources
**IA** Internal Audit
**ICMSF** International Commission on Microbiological Specifications for Foods
**ICUMSA** International Commission for Uniform Methods of Sugar Analysis
**ID** Identification
**IFSS** Integrated Food/Feed Safety System
**ILAC** International Laboratory Accreditation Cooperation
**IOM** Investigations Operations Manual (FDA)
**ISO/IEC** International Organization for Standardization/International Electrotechnical Commission
**IT** Information Technology
**IUPAC** International Union of Pure and Applied Chemistry
**LIMS** Laboratory Information Management System
**LOD** Limit of Detection
**LOQ** Limit of Quantitation
**LTG** Laboratory Task Group
**MCC** Methods Coordination Committee (FERN)
**MDP** Microbiological Data Program (USDA AMS)
**MFRPS** Manufactured Food Regulatory Program Standards (FDA)
**MLG** Microbiology Laboratory Guidebook (USDA)
**MPM** Macroanalytical Procedures Manual (FDA)
**NELAC** National Environmental Laboratory Accreditation Conference
**NPO** National Program Office (FERN)
**ORA** Office of Regulatory Affairs (FDA)
**ORISE** Oak Ridge Institute for Science and Education (DOE)
**PAM** Pesticide Analytical Manual (FDA)
**PDP** Pesticide Data Program (USDA AMS)
**PFP** Partnership for Food Protection
**POC** Point of Contact
**PT** Proficiency Test
**Q&A** Question and Answer
**QA/QC** Quality Assurance/Quality Control
**QMS** Quality Management System
**QSM** Quality System Manager
**RAC** Regulatory Annex Subcommittee
**SAM** Standardized Analytical Methods Manual (EPA)
**SOP** Standard Operating Procedure
**SWS** Standardized Worksheet Subcommittee
**TNI** The NELAC Institute
**USDA** U.S. Department of Agriculture
**USP/NF** United States Pharmacopeia and The National Formulary

**Accreditation:** A rigorous assessment, conducted by an independent science-based organization, to assure the overall capability and competency of a laboratory and its quality management systems.

**Accreditation Body:** An independent entity that operates in conformity with the standard ISO/IEC 17011 and that is technically competent to accredit testing laboratories using the recognized standard ISO/IEC 17025:2005

**Chain of Custody:** The order of places where, and the persons with whom, physical evidence was located from the time it was collected to its submission at trial. Laboratory samples are physical evidence. Chain of custody includes policy and procedure for handling and transfer of laboratory samples, as well as the full documentation of compliance with this policy and procedure for each laboratory sample. Documentation of chain of custody, including all test portions and test solutions, provides evidence that sample accountability, integrity, and security have been maintained.

**Custody Seals:** An official closure, adhesive seal or locking device that is affixed to the sample container after collection. The seal is affixed such that the sample material cannot be reached without breaking the seal or rupturing the container and is dated and signed by the collecting individual. Each time the seal is broken, a custody record should be kept. A new official seal may be affixed, dated and signed as the regulatory agency requires. If possible, broken seals should become part of the official documentation.

**Data integrity:** The assurance that results reported by the laboratory are accurate, complete, and true representations of the laboratory sample and analysis.

**Field:** Any location outside the controlled environment of a laboratory

**Food borne outbreak:** An incident in which two or more persons experience a similar illness resulting from ingestion of a common food.

**Import/Domestic Import:** Foreign products which have not yet cleared customs are "imports" and foreign products which have cleared customs are "domestic imports". A foreign product which is manipulated in a major manner, which changes the product or composition, is no longer considered an import under U.S. law.

**Method, Non-standard:** This refers to a method that is not taken from authoritative and validated sources. This includes methods from scientific journals and unpublished laboratory-developed methods.

**Method, Standard:** Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and FDA published methods. The laboratory's procedures should be traceable to a recognized, validated method, if one is available.

**Recognition:** The action or process of recognizing or being recognized. The acknowledgement of the existence, validity, or legality of something, such as a standard or a particular technical competence.

**Regulatory Action:** A regulatory action occurs when a governmental agency acts to enforce compliance with a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law. A violation occurs when it is established through competent and substantial evidence that an action, including the manufacture or distribution of a product, or a failure to act does not meet the requirements of a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.

**Regulatory Food/ Feed Laboratory:** A regulatory laboratory conducts measurements and tests, which result in qualitative and/or quantitative analysis findings that may be used to interpret and enforce and/ or be used as evidence to determine whether there has been a violation of a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.

**Sample Accountability:** Physical accountability ensures that the laboratory samples, test samples, test potions, test solutions, etc., are traceable. The life of the laboratory sample should be documented until final disposal, including all test samples and test portions. Such documentation may be needed to support regulatory action. Regulatory guidance on disposal may vary with agencies.

**Sample Integrity:** Sample integrity ensures nothing the laboratory does has the effect of making the material non-representative. Some aspects of sample integrity include sample storage, handling, and transport in lab, maintenance of proper storage temperature, and opening sample containers in the appropriate level of controlled environment. Laboratory waste disposal, workflow layout, cross-contamination, etc also can affect sample integrity. Records supporting maintenance of sample integrity may include, for example: sample storage refrigerator temperatures, microbiology laboratory environmental monitoring, etc.

**Sample Security:** Physical security of samples prevents intentional adulteration or substitution of the laboratory sample. This ensures that the material collected remains representative of the product, and that it is usable as evidence in court.

**Sample, Compliance (Follow-up):** Taken to determine compliance with specific food law/code often as a follow-up to a violative finding in a surveillance sample.

**Sample, Convenience Sample/Grab:** A sample chosen on the basis of accessibility, expediency, cost or efficiency but may not be representative of the whole lot of food or feed. These may sometimes be surveillance samples but may also be samples taken in response to a consumer complaint or incident.

**Sample, Documentary:** Evidence of sample is collected such as labeling, photos, drawings, invoices, transportation records, inventory which may be used in investigations or connection to previously collected samples.

**Sample, Emergency Response/Outbreak:** Taken during an investigation for foodborne illness or in response to a foodborne emergency.

**Sample, Investigation:** Taken during a food safety inspection to document inspector observations, support regulatory actions or provide other information.

**Sample, Laboratory:** The sample or subsample(s) sent to or received by the laboratory.

**Sample, Law Enforcement:** Taken during a specific investigation by law enforcement to support possible legal action for non-compliance with federal, state or local regulations.

**Sample, Monitoring:** Used to collect information such as incidence, number and species of foodborne pathogens in food or the incidence, amount and frequency of chemical ingredients, additives, residues or contaminants but not intended to support regulatory action

**Sample, Official:** Sample taken in a manner that it can serve as the basis for enforcement and/or legal action and handled in a manner that preserves integrity as evidence including identity, ownership, traceability and a clear record of chain of custody.

**Sample, Sub-sample:** May be: (a) a portion of the sample obtained by selection or division; or (b) an individual unit of the lot taken as part of the sample; or (c) the final unit of multistage sampling.

**Sample, Surveillance:** Taken as part of routine inspections or surveys to identify any lack of compliance with state, federal or other laws and regulations.

**Sample:** A portion of material selected from a larger quantity of food or feed material.

**Sampling:** The process of collecting sample(s).

**Trace-back:** Information that identifies the firms that have handled or held ownership of a product from the time of production including cultivation and harvest through packaging, shipping, processing, and sale.

**Validation (method):** The process of defining an analytical requirement, and confirming that the method under consideration has performance capabilities consistent with what the application requires.

**Violation:** A sample found to be non-compliant with established food laws/codes/regulations.


Partnership for Food Protection
Federal, State and Local Collaboration