Human and Animal Food Laboratory Curriculum Framework

April 2019
Laboratory Framework

- Project involves:
  - APHL
  - AFDO
  - AAFCO
  - FDA OTED
  - IFPTI
  - Others

- Goal: A Competency-Based Curriculum Framework for Human and Animal Food Laboratory Professionals
Laboratory Framework (Current Version)
A curriculum framework is an illustration of the various topics in which an individual must be competent throughout a professional career.
<table>
<thead>
<tr>
<th>FDA/CFSAN/USDA</th>
<th>State</th>
<th>APHL/AFDO/AAFCO</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melissa Farrell</td>
<td>Reggie Blackwell (DC)</td>
<td>Cathy Johnson (APHL)</td>
<td>Hien Albright (OTED)</td>
</tr>
<tr>
<td>Brent Higgs</td>
<td>Jo Marie Cook (FL)</td>
<td>Louise Ogden (AAFCO)</td>
<td>Tony Barbagallo (Karna)</td>
</tr>
<tr>
<td>Cassandra Kontas</td>
<td>Virginia Greene (NY)</td>
<td>Robyn Randolph (APHL)</td>
<td>Will Bet-Sayed (OTED)</td>
</tr>
<tr>
<td>Christina Megalis</td>
<td>Gale Hagood (MS)</td>
<td>Reginald Richardson (APHL)</td>
<td>Deb Moir (CFIA)</td>
</tr>
<tr>
<td>Paul Morin</td>
<td>Maria Ishida (NY)</td>
<td>Yvonne Salfinger (AFDO)</td>
<td>Corinne Pequignot (CFIA)</td>
</tr>
<tr>
<td>Charles Pixley</td>
<td>Patty Lucas (FL)</td>
<td>Nancy Thiex (AAFCO)</td>
<td>Neil Vary (CFIA)</td>
</tr>
<tr>
<td>Dan Rice</td>
<td>Susan Murphy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Richelle Richter</td>
<td>Tom Phillips (MD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holly Rhodes</td>
<td>Dana Shell (GA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tom Sidebottom</td>
<td>Dirk Shoemaker (NE Rtd)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Steve Sobek (WI Rtd)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kathleen Wickman (OR)</td>
<td></td>
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</tbody>
</table>
By the End of 2016

- Competencies built out for all Entry Level content areas
- Course Design Documents (CDDs) delivered to APHL/FDA
Began competency development for Entry Level Program-Specific Content Areas
- Chemistry
- Microbiology
- Cross-cutting
- Built out competencies for Mid-Level core content areas
Nov 2018

- Finished building out competencies for all Entry Level Chemistry and Microbiology Content Areas.
• Built out competencies for Animal Food (Chemistry) and Dairy Regulatory Programs (Cross-cutting)
• Via webinars
Jan-Feb 2019

- Competency validation survey sent out.
- Approx. 235 respondents.

<table>
<thead>
<tr>
<th>Laboratory Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>State agricultural food or feed laboratory</td>
<td>32</td>
<td>13.7%</td>
</tr>
<tr>
<td>State public health laboratory</td>
<td>19</td>
<td>8.1%</td>
</tr>
<tr>
<td>Local public health laboratory</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Environmental health laboratory</td>
<td>1</td>
<td>0.4%</td>
</tr>
<tr>
<td>Federal laboratory</td>
<td>174</td>
<td>74.4%</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>8</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
Based on the survey results, some of the competencies were revised.

6. Basic Laboratory Math (9 competencies)

Reminder: these competencies apply to ENTRY LEVEL laboratory professionals (individuals who are newly hired with varying laboratory experience).

<table>
<thead>
<tr>
<th></th>
<th>1. Not At All Appropriate</th>
<th>2. Somewhat Appropriate</th>
<th>3. Appropriate</th>
<th>4. Extremely Appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Recognize how symbols are used in a mathematical operation.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>2.</td>
<td>Define key laboratory terminology.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>3.</td>
<td>Explain how constants are used.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>4.</td>
<td>Apply order of operations to perform calculations.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
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<tr>
<td>5.</td>
<td>Describe differences between various units of measure.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>6.</td>
<td>Illustrate the use of significant figures.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>7.</td>
<td>Perform unit conversion.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
</tbody>
</table>
Sample Handling renamed Laboratory Sampling
Currently …

- Incorporating new concepts from GOODSamples, GOOD Test Portions, and revised ISO/IEC 17025:2017 into Entry Level Content Areas
  - Accreditation/Certification
  - Chain of Custody
  - Regulatory Sampling
  - Sample Handling
Next Steps - 2019

- Develop performance indicators (PIs) for Laboratory Sampling
- Course development
• Continue buildout of Entry Level Program Specific Content Areas (competencies and PIs)
• Performance indicators for Advanced Level
Benefits & Utility of the Framework

1. Housing a national standard in one centralized location
2. Cataloging system for learning events, etc.
3. Assessment
4. Competency gaps
5. Learning plans
http://incs.ifpti.org/Frameworks/Home

Other Framework Development Projects

- Animal Food Framework
- Canadian Food Inspection Agency Frameworks
- Global Food & Medical Devices Framework
- Manufactured Food Framework
- Retail Food Framework
Identify Competencies

Content Area Definition:
Introductory knowledge, skills, and abilities related to food allergens, controls and regulatory requirements.

Broad Competency (Level 2):
Discuss the control of allergens in relation to food safety.

Narrow Competencies (Level 3):
- Explain the risks of allergen exposure.
- Identify major food allergens.
- Describe potential routes of allergen cross-contact.
- Use agency resources to evaluate allergen controls.
- Explain allergen labeling requirements.

Foundations
Click link to view topic files.

Topic Definition:
- Food allergens related to food programs.

Specific Competency (Level 4):
Discuss foundational information related to major food allergens.

Detailed Competencies (Level 5):
- Define relevant terminology.
- Differentiate food allergy from food intolerance.
- Discuss the prevalence of food allergy in the United States.
- Identify major food allergens as recognized by FDA and USDA.
- Give examples of foods deemed major allergens in non-U.S. countries.
- Discuss the public health significance of food allergens.
- Describe the symptoms of an allergic reaction.
- Discuss allergens in relation to recalls.
- Describe the treatment of an allergic reaction.
• Acts as a library or cataloging system for existing training and other learning events
B6 - Data & Information Systems

Content Area Definition:
Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to manage data and information.

Broad Competency (Level 2):
Provide examples of internal and external data and information systems.

Narrow Competencies (Level 3):
Describe data and information systems needed to perform your assigned duties.
Describe why data systems are important for regulatory activities.
Determine which systems are appropriate for the performance of duties.
Identify which organization is responsible for data and information systems needed to perform assigned duties.
Use data and information systems to perform duties.
B5 - Communication Skills

Performance Indicators (PIs)

- FDA CRA-U - PHDV60 - A Tour of FDA
- FDA CRA-U - PHDV76 - Meeting GMP Training Requirements
- FDA CRA-U - FOOD3 - Preventing Microbial Cross-Contamination
- FDA CRA-U - FOOD2 - Controlling Food Allergens in the Plant
- FDA CRA-U - EHS02 - Active Listening Skills
- FDA CRA-U - EHS16 - Diversity in the Workplace
- FDA CRA-U - EHS49 - Improving Productivity
- FDA CRA-U - EHS52 - Introduction to Information Systems
- FDA CRA-U - EHS50 - Making Meetings Work I: Purpose and Preparation
- FDA CRA-U - EHS61 - Making Meetings Work II: Leadership
- FDA CRA-U - EHS52 - Managing Conflict
- FDA CRA-U - EHS53 - Managing Job Stress
- FDA CRA-U - EHS54 - Managing Transition to Teams
- FDA CRA-U - EHS94 - Self-Motivation
- FDA CRA-U - EHS95 - Overcoming Negativity in the Workplace
- FDA CRA-U - FDA26 - FDA Establishment Inspection Report Writing
- FDA CRA-U - FDA27 - Interviewing Techniques
- FDA CRA-U - FDA46 - Courtroom Testimony
- FDA CRA-U - FDA47 - Photography for FDA Enforcement
- FDA CRA-U - PHDV65 - Principles of Good Documentation
- FDA - - Communication Skills for Regulators
Competency Assessment

B6 - Data & Information Systems

Course List  Performance Indicators (PIs)

Foundations  Collaborative Information Management Systems  Knowledge Management  Access/Control  Application Software  Policies  Resources

Click a topic above to move down to that topic.

Take Assessment

Content Area Definition:

Introductory knowledge, skills, and abilities related to systems used by regulatory agencies to manage data and information.

Broad Competency (Level 2):

Provide examples of internal and external data and information systems.

Narrow Competencies (Level 3):

Describe data and information systems needed to perform your assigned duties.

Describe why data systems are important for regulatory activities.

Determine which systems are appropriate for the performance of duties.

Identify which organization is responsible for data and information systems needed to perform assigned duties.

Use data and information systems to perform duties.
### Competency Assessment

**Assessee:** Chris Weiss  
**Assessor:** Self

#### Data & Information Systems

<table>
<thead>
<tr>
<th>Discuss data and information systems.</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐</td>
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</tbody>
</table>

**Average (Rating of 2)**
- The regulator has knowledge or awareness of information systems.
- The regulator is familiar with agency apps, programs, and data systems.
- The regulator can give examples of agency reports.
- The regulator can give examples of relevant databases.

**Outstanding (Rating of 4)**
- The regulator can utilize agency information systems.
- The regulator can use agency apps, programs, and data systems according to agency protocol.
- The regulator can prepare or interpret agency reports.
- The regulator can give examples of information found in relevant databases.

**Assessee Comments:**

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### Identify Training Gaps

#### Assessee versus Assessor

<table>
<thead>
<tr>
<th>Competency Statement</th>
<th>Assessor</th>
<th>Self</th>
<th>GAP</th>
<th>Need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss foundational information related to major food allergens.</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td>No</td>
</tr>
<tr>
<td>Discuss allergen labeling requirements.</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>Discuss control measures to prevent allergen cross-contact.</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>High</td>
</tr>
</tbody>
</table>
Informatics Framework

- 1-year project (CDC & APHL)
- SME Workshop held in Feb 2019 to build the framework
- Webinars being held to build out competencies

### Laboratory Informatics Curriculum Framework

<table>
<thead>
<tr>
<th>Level</th>
<th>Data Concepts</th>
<th>Data Systems</th>
<th>Interoperability</th>
<th>IT Infrastructure</th>
<th>Laboratory Activities</th>
<th>Policies and Regulations</th>
<th>Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>P5 (Go-to person)</td>
<td></td>
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<td>P4 (Doing on their own)</td>
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<td>P3 (Doing with supervision)</td>
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<tr>
<td>P2 (Some knowledge)</td>
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<tr>
<td>P1 An individual who needs or wants basic fundamental knowledge related to laboratory informatics.</td>
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</tr>
</tbody>
</table>

Laboratory Informatics Foundations
Questions?

Christopher Weiss, IFPTI

chris.weiss@ifpti.org