Global Context of Food Safety

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APEC FSCF PTIN Workshop
August 25, 2011
Bangkok, Thailand
First, some definitions…

- **Food safety** is about ensuring that food is free from microbiological or chemical contaminants - residues that might cause harm to human health.

- **Food security** is about ensuring a plentiful supply of safe food - energy and nutritional needs must be met.

- **Food fraud** is about deliberate adulteration of food to deceive consumers. Food fraud may not have food safety implications.
Recognized areas of food safety

- Pathogenic microrganisms
  - Salmonella, E-coli, Listeria, etc.

- Chemical residues & contaminants
  - Pesticides, vet drugs, mycotoxins, dioxins, melamine, etc.

- Radioactivity
  - Gamma, Beta, Alpha

- Physical
  - Glass, bone, metals, etc.
The global market drives food testing

- Consumer demand for imported seasonal products to be available all year-round.
- Consumer demand for processed food that is ready-to-eat and high in quality but low in cost.
- In developed countries food is sourced globally and international trade in food is substantial.
- A long food chain makes tracking and control over safety and quality of raw materials difficult to maintain – reliable analysis is critical.
The many roles of authorities in the food chain

- Feed people safely and grow economies (Agriculture Dept)
- Assess and manage food risks (Food and Drug Administrations, Health Dept)
- Manage trade (Commerce Dept)
- Set food safety standards, such as MLs, MRLs, and standardize validated testing methods.
- Work with food producers, IGOs (eg. Codex Alimentarius, OIE), industry associations (eg. GMA, AOAC), technology providers, and other governments to improve the global food safety.

*Risk Managers balance protection of human health with facilitating trade by establishing standards & putting them into food law.*
You cannot test your way to food safety!

Focus on Prevention

- Good Agricultural Practices (GAP)
- Hazard Analysis & Critical Control Point (HACCP) Plans
- One up/one down verification of suppliers/customers in the food chain.
- Industry Standards (ISO 22000, GFSI, etc)
- Quality Certification Programs (SQF, NSF, etc)

But be prepared to test reliably

- Laboratories need to be able to produce reliable results
  - Quality Assurance
  - Fit-for-Purpose Analytical Methods
  - Sampling, Data Analysis, and Data Interpretation

*Turn-Around Time for results is critical!*
The structure of food trade standards

- Codex Alimentarius Commission (CAC) provides the standards.
- These standards are accepted by the SPS and TBT Agreements of the WTO.
- Countries use these standards to conduct trade and solve trade disputes.
Codex plays a critical role

• Codex standards are considered scientifically justified and are accepted as the benchmarks against which national measures and regulations are evaluated.

• APEC has drafted a Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products. This calls for consistency with the requirements of the SPS and TBT Agreements and Codex standards.

• Codex has adopted protocol standards for
  (a) Proficiency Testing of Labs,
  (b) Design, Conduct and Interpretation of Method Performance Studies and
  (c) Internal QC in Analytical Labs.

• Codex has established guidelines for
  (a) Use of mass spectrometry,
  (b) Settling disputes over analytical test results,
  (c) Performance criteria and validation of methods, and
  (d) Measurement uncertainty.

Source: Understanding the Codex Alimentarius
Important government entities in food trade

- China
  - General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ): import and export
  - State Food and Drug Administration (FDA): domestic

- Japan
  - Ministry of Health Labor and Welfare (MHLW)
  - Ministry of Agriculture, Forestry and Fisheries (MAFF)

- USA
  - United States Department of Agriculture (USDA): meat, poultry and eggs
  - Food and Drug Administration (FDA): all other foods
  - Environmental Protection Agency (EPA): drinking water

- EU
  - EFSA: risk assessment (forms opinions)
  - DG SANCO: risk management (uses EFSA’s opinions)
  - National food safety agencies, eg. BfR in Germany

These entities have their own food testing protocols, trade agreements, MOUs, or they rely on WTO/Codex
Types of food testing labs

- In-House Industry Laboratory
  - Food Producers/Processors
  - Due diligence

- Government Laboratory
  - State Institute, National Reference Lab
  - For public health/consumer protection

- Contract Testing Laboratory
  - Independent testing laboratory
  - Offers services as a business

- University Laboratory
  - Conducts research
Food is a complex matrix for analysis

There are often different testing methods for different contaminants and for different foods (matrices):
So standards are critical!
Accreditation ensures mutual recognition

- 20% implementation cost & 10% maintenance cost (ISO/IEC 17025:2005)

- Need to ensure accreditation is ‘fit-for-purpose’ - NOT excessive - processes and procedures MUST be the minimum to satisfy assessors

- Need to maintain flexibility in operating laboratory

Accreditation adds to costs.
Method validation ensures mutual recognition

- In-house validation - ca. 15 days
  Cost: depends on matrix, analyte and techniques

- Interlaboratory validation - ca. 365 days
  Cost: depends on matrix, analyte and techniques

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<th>Characteristics</th>
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<th>Contract</th>
<th>University</th>
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<td>Using only validated methods</td>
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<tr>
<td>Accreditation to 17025</td>
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<td>Good performance in proficiency testing</td>
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<td>Reporting results on time – speed</td>
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*Method validation is slow and expensive but essential.*
Critical elements to enhance lab capacity

• Trained laboratory personnel
  • Laboratory techniques (sample preparation, enrichment, and analysis)

• Access to Fit-for-Purpose methods
  • Existing (AOAC, ISO, etc)
  • Develop new ones (Single Lab Validation, Multi-Lab Validation)

• Suitable analytical technology
  • Able to reach limits of detection
  • Targeted or non-targeted analyses

• Lab management tools
  • Lab Information Management Systems (LIMS)

• QA procedures
  • Method QA (% recoveries, Limits of Detection, Limits of Quantitation, Accuracy)
  • Quality standards (Sigma Aldrich, NIST, FAPAS, etc)
QA procedures - ISO/IEC 17025

• Main quality standard internationally used by testing laboratories
• 2\textsuperscript{nd} release 2005 aligned with ISO 9001
• Goal for the laboratory
  • Implement a quality system aimed to consistently produce valid results
  • Basis for accreditation from an Accreditation Body
• Comprises five elements
  • Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements
• Task of implementing a Quality Management System
  • Key: Responsibilities, SOPs, quality control
Case Study Pesticides Analysis

• International Regulations apply
  • Codex Alimentarius
    • collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety (1963 FAO, UN, WHO)
    • recognized by the WTO as an international reference point for the resolution of disputes concerning food safety and consumer protection
  • Japan Ministry of Health, Labour and Welfare (MHLW): Positive list system
  • US FDA - FFDCA Section 402(a)(1) (Federal Food, Drug, and Cosmetic Act)
Case Study Pesticides – Recommended Lab Setup

- Extraction and Clean-up
  - QuEChERS procedure for low fat food
  - DIN EN 12393-1-3 method using SEC (gel chrom.)
- Analysis
  - GC-ECD/NPD (requires 2 columns for confirmation)
  - GC-MS (for clean extracts, low matrix)
  - GC-MS/MS
  - LC-MS/MS
- Quality Control
  - External standard calibration
  - Confirmation approach (2 RTs, confirming ions)
  - QC check sample with each batch
- Reporting
  - Found and not-found compounds
  - CDS processing and LIMS administration

QuEChERS Sample Prep Procedure

GC-MS Laboratory
Summary

• Governments need to trade.
• They need to assure each other of safe food.
• Prevention is critical, but testing is also necessary.
• Food is chemically complex and requires robust testing procedures and trained personnel.
• Countries must recognize laboratory and testing protocols.
• They use their agencies and IGOs for standard protocols.
• Labs must provide reliable results.
Thermo Fisher Scientific: Products for Food Testing

We are an important part of the food testing community!