



● Global Context of Food Safety

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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 microorganisms
 - 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)

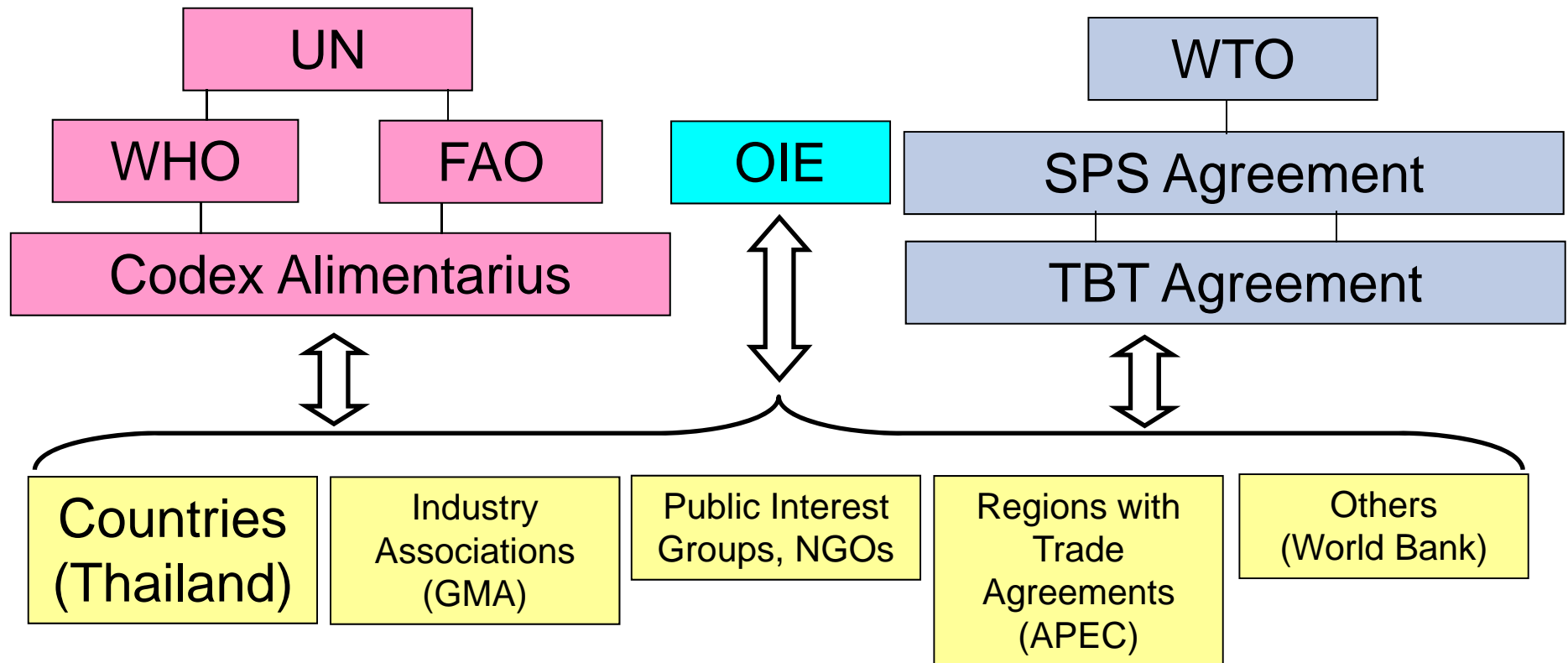
But be prepared to test reliably

- 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.

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



Cert #1586.01



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

Characteristics	Government	Contract	University
Using only validated methods	√√√	√√√	√
Accreditation to 17025	√√√	√√√	
Good performance in proficiency testing	√√√	√√√	√
Reporting results on time – speed	√	√√	√
Competitive price	√	√√√	√
Innovation	√√	√	√√√

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
- 2nd 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

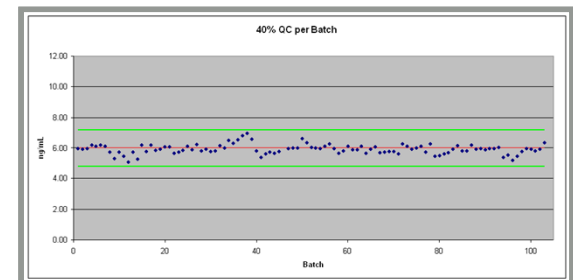
Environmental Biology	MTF SOP
Jackson State Laboratory	SOP #428-10 Rev. No. 4 Date: February 2007 Page 4 of 11

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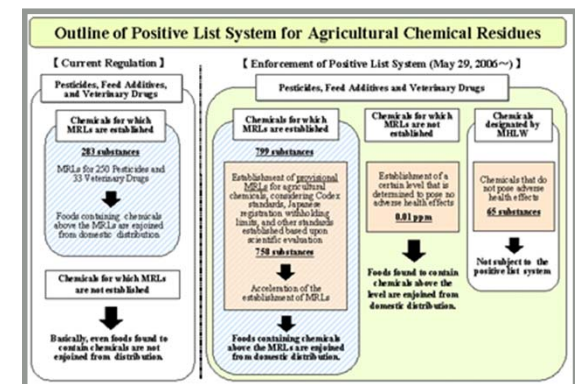
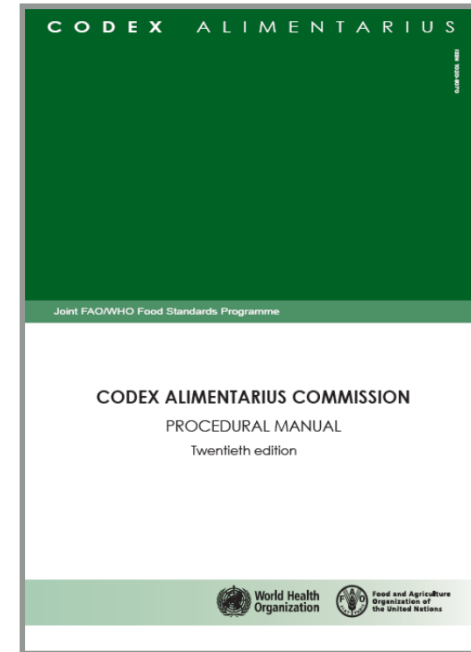
SOP Standard Operating Procedure



Quality Control Chart

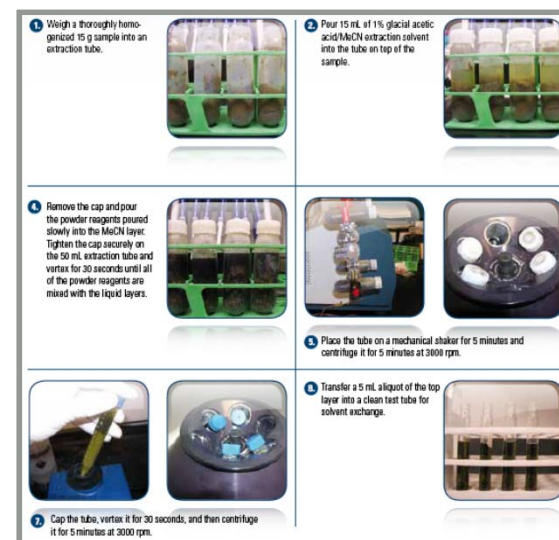
Case Study Pesticides Analysis

- 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
 - **EU** Pesticides Framework Directive 2009/128/EC
 - **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

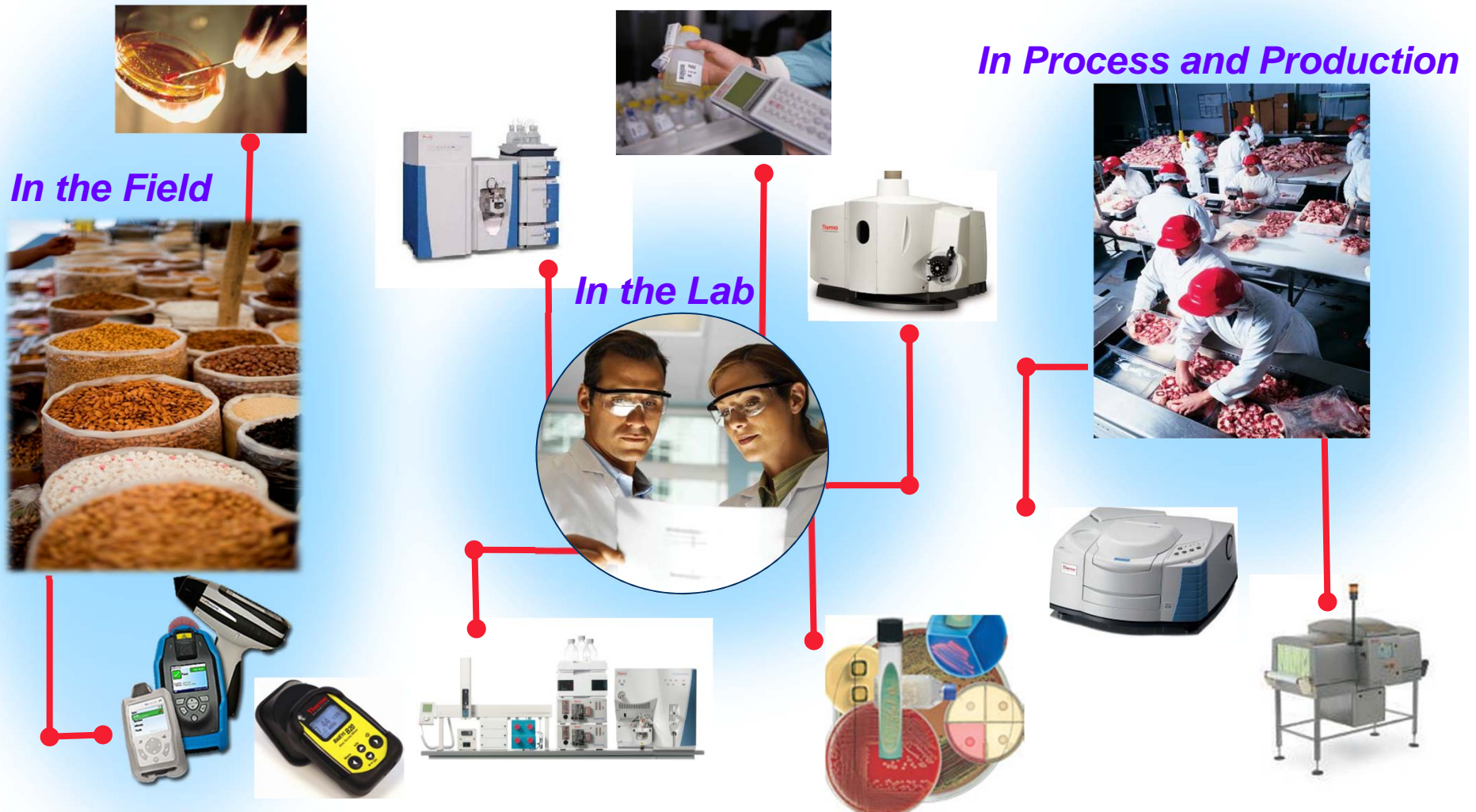


GC-MS Laboratory

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!