The Role of Microbiological Testing and Microbiological Criteria in an Evolving Regulatory Environment

International Commission on Microbiological Standards for Foods

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Microbial Testing

• Why test?
  – Safety of “batches”
  – Investigational sampling
  – Surveillance
  – Process control
  – Quality control/assurance
Microbial Testing

• Why test?
  – Safety of “batches”
  – Investigational sampling
  – Surveillance
  – Process control
  – Quality control/assurance

The “Poison Squad”
Microbial Testing

- Microbiological testing is almost always an important component of any integrated program to assure the safety of foods.
Testing for Safety

• Detection and identification

Testing for Safety

• Detection and identification
  – Traditional Plating
Traditional Microbiological Plating

- Plating on Sorbitol-MacConkey
  
  K-12
  Strain 868

- Plating on MUG for β-glucuronidase
Testing for Safety

- Detection and identification
  - **Traditional Plating**
  - “Rapid” Tests
    - Miniaturized tests
    - Gene probes
    - Enzyme-linked immunosorbant assays (ELISA)
    - Polymerase Chain Reaction (PCR)
    - Biosensors

![Diagram](Sample Biologically sensitive coating Sensor Transducer Output)
Testing for Safety

- Detection and identification
- Enumeration
  - Most probable number (MPN)
  - Plate counts
  - Instrumental methods
    - Flow cytometry
    - RT-Polymerized Chain Reaction (RT-PCR)

What does “the count” mean?
Testing for Safety

- Detection and identification
- Enumeration
- Attribution
  - Gram stain
  - Morphology
  - Biochemical tests
  - Immunological
    - Serotyping
    - ELISA
  - Molecular
    - Pulse field gel electrophoresis
    - Multilocus sequence typing
    - Cladistic analysis

Outbreak Response:

S. Agona in Cereal

Bacteria from the food and patients were the same

Matched using DNA fingerprint, which is read like a bar code (PulseNet)
Microbiological Criteria

What are “Criteria”?

• **Criterion**
  – **Standard**: Must meet, regulatory requirement
  – **Guideline**: Should meet, GHP
  – **Specification**: Expected to meet, generally used to describe an agreement between a supplier and a purchaser
Examples of Microbiological Criteria

• Indicator organisms
  – Presence or populations of organism statistically associated with a pathogen
    • Coliforms, fecal coliforms, *E. coli*

Examples of Microbiological Criteria

• Indicator organisms
• Target pathogens
  – None detected
    • “Zero Tolerance”
  – Attribute estimate (e.g. X positive samples in Y total samples)
  – Point value limit (e.g. 100 cfu/g)
    • “Bright Shining Line”
Microbiological Criteria

• Do the criteria have ANY theoretical or demonstrable relationship to public health?

• What qualitative or quantitative values best assure the safety of foods?
What does “the count” mean?

Perceived Prediction of Safety

UNSAFE

SAFE
Realistic Estimation of Safety

UNSAFE
Less Safe
Safer
SAFE

Defining Question

How Does One Choose the “Right” Value?
Changes in Philosophy to Assure Safe Foods

• Microbiological Testing for Safety

• Preventative Controls
Preventative Controls

• Good Manufacturing/Agricultural Practices
  – Minimum practices to reasonably assure sanitation, etc.
  – Foundation for HACCP

Preventative Controls

• Good Manufacturing Principals
• Hazard Analysis Critical Control Points (HACCP)
  – Focuses on identifying and preventing hazards from contaminating food
  – Based on sound science
  – Permits more efficient and effective government oversight,
  – Places responsibility for ensuring food safety appropriately on the food manufacturer or distributor
  – Reduces barriers to international trade.
Changes in Philosophy

- Microbiological Testing for Safety
- Preventative Controls
- “Outcome Based” Food Safety

– National Public Health Goals
Changes in Philosophy

• Microbiological Testing for Safety
• Preventative Controls
• “Outcome Based” Food Safety
  – National Public Health Goals
  – Risk Management Framework

Risk Management

• It is all about making decisions
  – Have to establish the level of protection deemed appropriate to safeguard the public
  – That level is both a scientific and a societal decision
  – Risk assessment is making it possible to link control measure to public health impact
Risk Management Concept

• The degree of “regulatory control” placed on a pathogen-food pair should be a function of the risk to public health.

“Outcome Based” Food Safety

• Quantitative Risk Assessments
  – *Salmonella* Enteritidis in Shell Eggs (USDA/FDA)
  – *Listeria monocytogenes* in Ready-to-Eat Foods (FDA/USDA, WHO)
  – *Vibrio vulnificus* in molluscan shellfish (FDA)
  – *Vibrio parahaemolyticus* in seafood (FDA)
Impact of Risk Analysis Framework

- Being able to better link food safety activities to public health outcomes via risk assessments has allowed:
  - **New concepts to be considered**
    - Food Safety Objective (FSO)
    - Appropriate Level of Protection (ALOP)
    - Performance Objective (PO)

Food Safety Objective

- An FSO can be viewed as a “bright shining line”
- By definition
  - Below is safe
  - Above is not safe
- PO is the equivalent at a specified point earlier in the food chain
Impact of Risk Analysis Framework

- Being able to better link food safety activities to public health outcomes via risk assessments has allowed:
  - New concepts to be considered
  - Old concepts to be put on a more scientific basis
    - Performance criteria
    - Process criteria
    - Product criteria
    - Microbiological criteria

The Evolving Regulatory Environment
The Evolving Regulatory Environment

- Massive and Revolutionary changes are occurring which affect Regulatory Policy

Change #1
Changes in Philosophy
Past Philosophy

• **Command and control**
  – Pasteurized Milk Ordinance (PMO) – 1924
  – Acidified Foods – 1979
  – Infant Formula Quality Control Procedures - 1982
  – Current Good Manufacturing Practice - 1986

New Philosophy

• **End results**
  – Preventative technologies
  – Food Safety Objectives
New Philosophy

• Performance standards
  – Focusing less on how outcomes are achieve
  – Focusing more on IS the outcome achieved
  • If the food safe?

New Philosophy

• Creativity on the part of the industry
  – Take risks in developing new technologies
  – Providing the scientific rationale and data for new processes
  • Importance of microbiological testing
Change #2
Changes in Knowledge

- Genetics
History of Microbial Identification

- Detection at Genus Level
History of Microbial Identification

- Detection at Genus Level
- Detection at Species Level

- Detection at Genus Level
- Detection at Species Level
- Detection at Subspecies Level
History of Microbial Identification

- Detection at Genus Level
- Detection at Species Level
- Detection at Subspecies Level
- Detection at Serotype or Serovar Level

History of Microbial Identification

- Detection at Genus Level
- Detection at Species Level
- Detection at Subspecies Level
- Detection at Serotype or Serovar Level
- Detection at Molecular Level
Changes in Knowledge

• Genetics

• Pathogenicity/Virulence
  – Identification of virulence factors
  – Role of extrachromosomal elements
    • Plasmids
  – What turns virulence genes “off” or “on”
    • Quorum sensing

Changes in Knowledge

• Genetics

• Pathogenicity/Virulence

• Ecology
Attachment and Survival of *E. coli* O157:H7 on Cut Lettuce

Internalization of Pathogens
Changes in Knowledge

• Genetics
• Pathogenicity/Virulence
• Ecology
• Growth and Survival in “Extreme” Environments
  – Microbial adaptation and change
    • Unrestricted use of antibiotics
    • Resistance to food processing technologies
      – Acid, redox potential, sanitizer, preservative adaptation

• New Foodborne Pathogens
  • New, more virulent strains
    – *E. coli* O157:H7, *S. Typhimurium* DT104, *S. Enteritidis* PT2
Emergence of Foodborne Pathogens

- **1942**
  - *Staphylococcus aureus*
  - *Salmonella*
  - *Clostridium botulinum*
  - *Streptococci*
**Emergence of Foodborne Pathogens**

- Campylobacter jejuni
- Clostridium botulinum (infant)
- E. coli 0157:H7
- Listeria monocytogenes
- Salmonella Enteritidis
- Vibrio cholerae (Latin America)
- Vibrio vulnificus
- Yersinia enterocolita
- Enterobacter sakazakii
- Norwalk and Norwalk-like viruses
- Rotavirus
- Cryptosporidium parvum
- Giardia lamblia
- Toxoplasma gondii
- Bovine spongiform encephalopathy prion

**New or Non-traditional Foods Associated With Recent Outbreaks**

- Mangos
- Puffer fish
- Almonds
- Potatoes
- Soft cheese
- Mamey
- Infant formula
- Dry Cereal
- Seed/bean sprouts
- Eggs
- Salsa
- Bean dip
- Cantaloupe
- Fruit juices
- Berries
Change #3
Changes in Society

Changes in Society

• Technology
Changes in Society

- Technology
  - Processing technology
    - Aseptic
    - High pressure
  - Transportation
    - Air freight
    - Refrigerated/MA trucking
  - Packaging
    - Extended shelf-life

- Technology
- Human Demographics and Behavior
Changes in Society

- **Technology**
- Human Demographics and Behavior
  - Age
  - Increased reliance on medicines
  - Purchasing and eating habits
  - Migrations to urban centers

Consumers are eating different foods
Changes in Society

20%-25% of the Population is At Risk

Changes in Society

More Food Prepared Outside the Home
Changes in the U.S. Population

• 17% of population is 60 or older
  – 4% of the population is 80 or older
• 64% of the adult population is overweight
• 5% of infants and young children and 2% of adults have food allergies
• 44% of the non-institutionalized population reports taking one or more prescription medications during the last month

Changes in Society

• Technology
• Demographics
• Travel and Tourism
Global Travel

- International travel is at an all time high and is expected to increase
  - Business
  - Tourism
- Travelers will be exposed to new types of organisms
  - E.g. Cyclosporiasis
- Once rare illnesses could become endemic in home country

Forecast of Inbound Travel to U.S.
Changes in Society

- Technology
- Demographics
- Travel
- Business
  - International trade
  - Economic development and land use
    - Consolidation of production and processing facilities

Changes in Society

More Food Now Comes From Distant Places
Imported Food Line Entries

![Imported Food Line Entries Chart]

Changes in Society

- Technology
- Demographics
- Travel
- Business
  - International trade
  - Economic development and land use
    - Consolidation of production and processing facilities
Future Trends Affecting the Regulatory Environment?

Future Trends

• Enhanced role of epidemiology
  – Role of traditional microbiological testing?
Future Trends

• Enhanced role of epidemiology

• Better attribution
  – Use of molecular biology to match outbreak strains to facility/line
  – Identification of “hot” strains

Future Trends

• Enhanced role of epidemiology

• Better attribution

• Importance of International Agreements
  – NAFTA-North America Free Trade Agreement
  – GATT-General Agreements on Tariffs and Trade
    • SPS-Sanitary and Phytosanitary Measures Provisions
Global Trade

- Harmonization
  - International Standards and Regulations
  - Methods of Analysis
  - Codex Alimentarius Commission
    - Standardizing body

Global Trade

- Harmonization
- Increased importance of International Scientific Bodies
  - Joint Expert Committee on Food Additives (JECFA)
  - Joint Expert Meetings on Microbiological Risk Assessment (JEMRA)
Summary

- Microbiological Testing will Continue to be a Fundamental Regulatory Tool
- Scientific and Social Changes will Impact the Role of Microbiological Testing
  - Changes in philosophy
  - Changes in knowledge
  - Changes in society
- Both Technology and the Regulatory Environment will change in response