

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

International Commission on Microbiological Standards for Foods

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Food and Drug Administration



## Microbial Testing

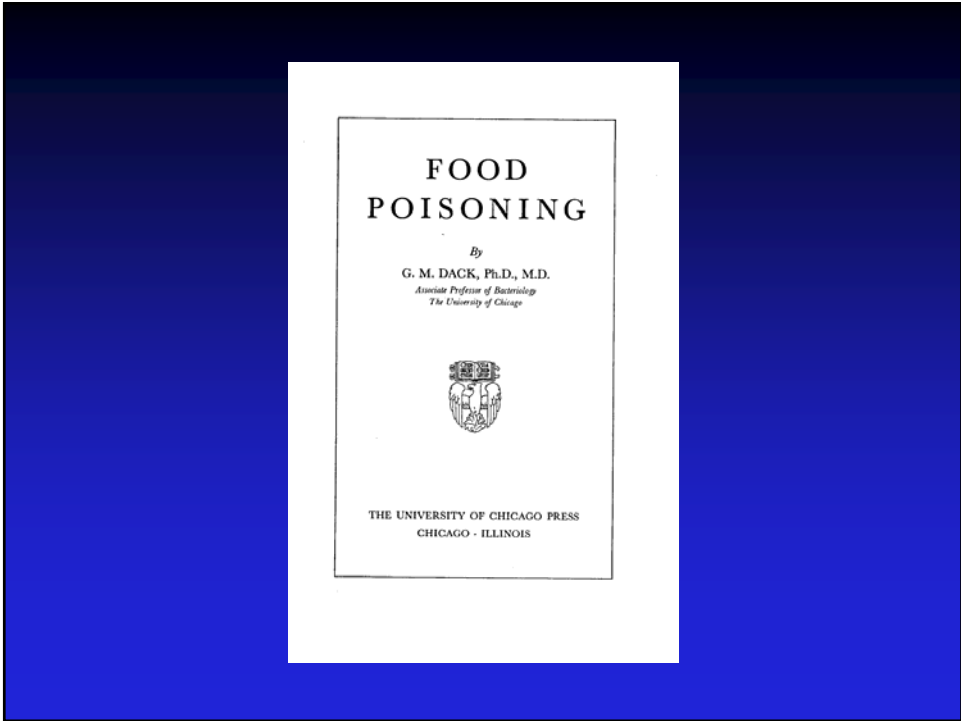
- Why test?
  - Safety of “batches”
  - Investigational sampling
  - Surveillance
  - Process control
  - Quality control/assurance

# Microbial Testing

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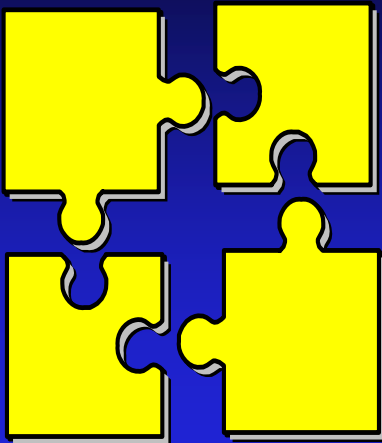
## The “Poison Squad”





# 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

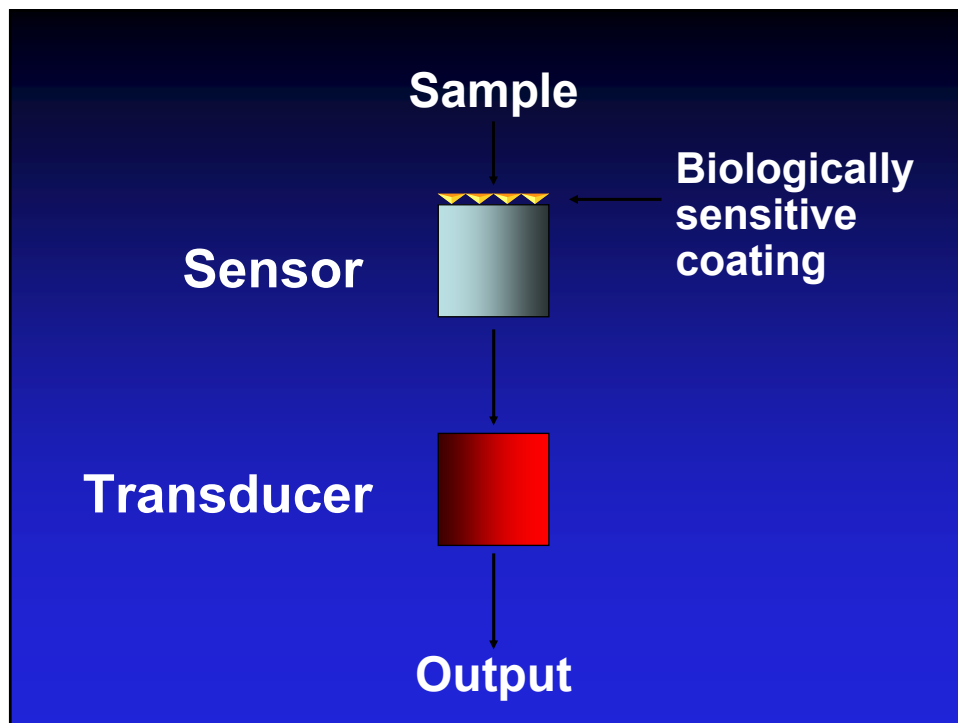
## Traditional Microbiological Plating

### ➤ Plating on MUG for $\beta$ -glucuronidase



## Testing for Safety

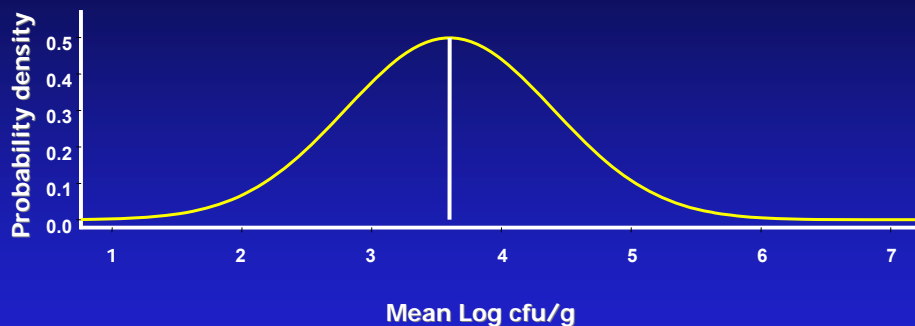
- **Detection and identification**
  - Traditional Plating
  - “Rapid” Tests
    - Miniaturized tests
    - Gene probes
    - Enzyme-linked immunosorbant assays (ELISA)
    - Polymerase Chain Reaction (PCR)
    - Biosensors



## 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?



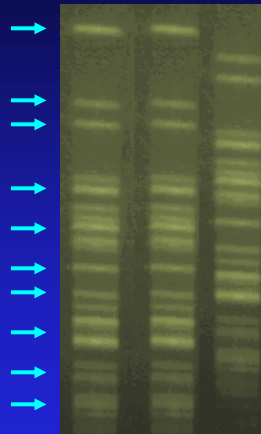
# Testing for Safety

- 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  
finger print, which is  
read like a bar code  
(PulseNet)



Patient Food Different  
Salmonella



## 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”

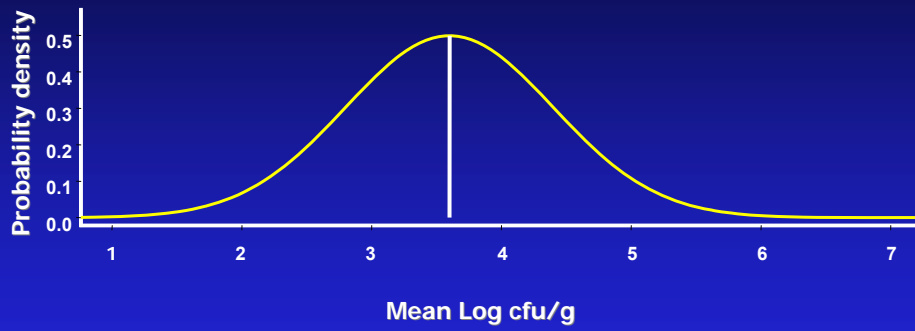
## **Microbiological Criteria**

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

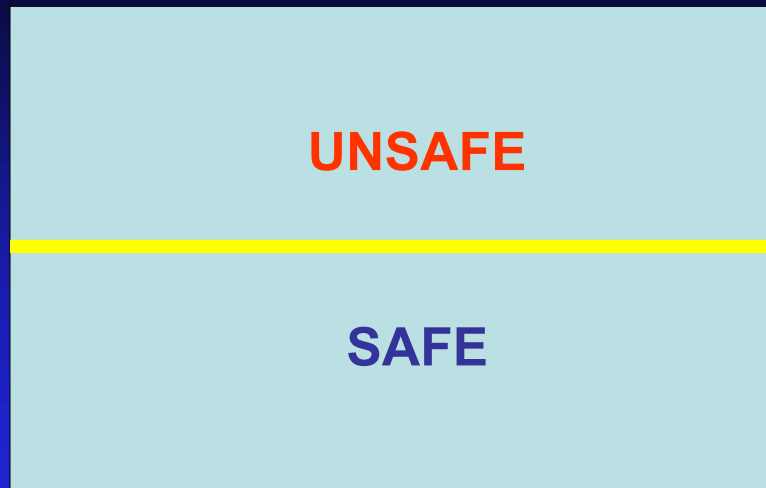
## **Microbiological Criteria**

- **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



## 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

## **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**

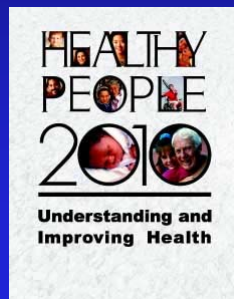
- **Good Manufacturing Principals**
- **Hazard Analysis Critical Control Points (HACCP)**
  - Focuses on identifying and preventing hazards from contaminating food
  - Based on sound science
  - Permits more efficient and effective government oversight,
  - Places responsibility for ensuring food safety 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

## Changes in Philosophy

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- “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**
  - **Low-Acid Canned Foods – 1973, 1979**
  - **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 achieved
  - 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**

## **Changes in Knowledge**

- **Genetics**





## **History of Microbial Identification**

- **Detection at Genus Level**
- **Detection at Species Level**

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

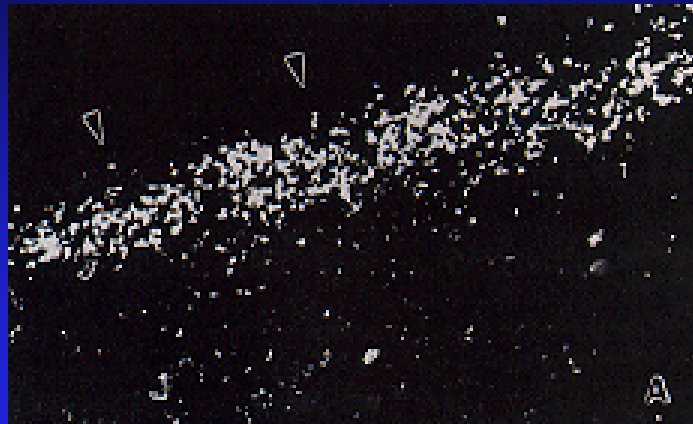
## Changes in Knowledge

- 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

## Changes in Knowledge

- Genetics
- Pathogenicity/Virulence
- Ecology
- Growth and Survival in “Extreme” Environments
- **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

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- 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

## Changes in Society

- **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

## Changes in Society



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**

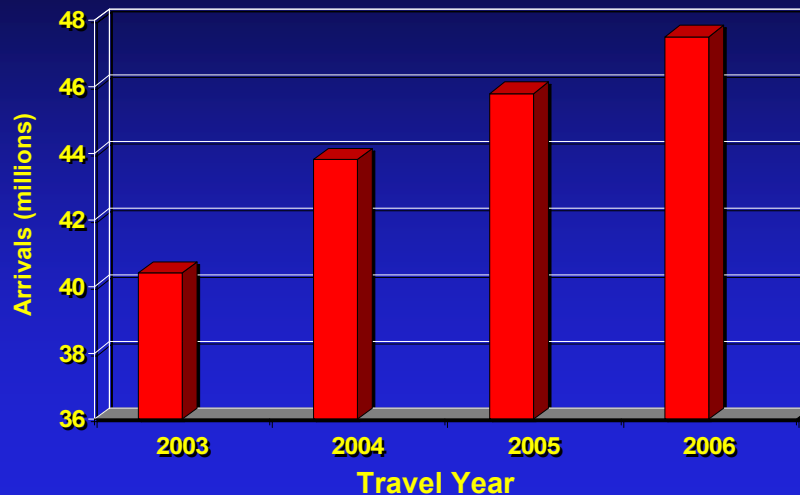
## **Changes in Society**

- **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

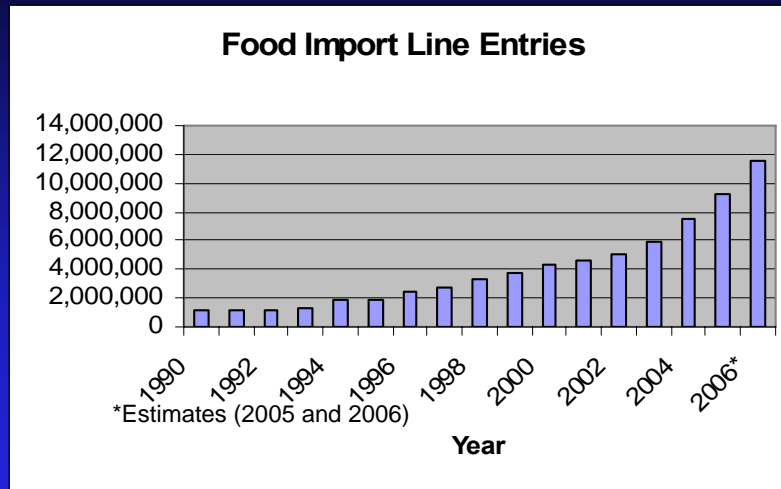
## Changes in Society

**More Food Now  
Comes From  
Distant Places**





## Imported Food Line Entries



## 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***