Adding Value by Achieving International Standards

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Why Is This Important?

• Everyone deserves safe and wholesome food
• Food that meet recognized standards get higher prices!
• International markets are moving to science based standards
  ▪ Improvements will happen only if positive change can be imposed upon current regulatory systems
Why Are International Standards Important?

- No country is completely self-sufficient in all of its food items
- Food imports/exports are global and consistent standards expedite trade
- Food exports are important for the balance of trade of developing countries
- New requirements are pending for international food trade
  - Food Safety Modernization Act (2011)
Why Are International Standards Important for Pakistan?

• Many of Pakistan’s key exports are fruits and vegetables.
• Most are consumed raw or with minimal processing
  ▪ New Food Safety Modernization Act is targeting the safety of fresh and minimally processed fruits and vegetables because of recent outbreaks in USA (spinach, Serrano peppers, lettuce, peanut butter, almonds)
Food Exports from Pakistan Have Potential to Increase

- Food exports should increase because of favorable exchange rate
- Overall, Pakistan exports are up
- Pakistan has the potential to export many different horticultural products
- Surplus of certain fruits and vegetable, high quality, and demand
  - Mango, citrus, vegetables
Why Are We Concerned with International Standards Now?

• Outbreaks and contamination incidents are global and wide reaching

• Microbial and chemical contamination risks—intentional and unintentional causes
  ▪ Failure to pull suspected or known contaminated foods from the market – Peanut Company of America

• Economic fraud
  ▪ China – melamine contaminated rice, wheat and milk powders; pet and animal feeds
Recent Issues

• Microbiological contamination
  ▪ Aflatoxin and other mold toxins
  ▪ *Salmonella* spp. and pathogenic *E. coli*

• Chemical contamination
  ▪ Dioxin
  ▪ Pesticides
  ▪ Drug residues
  ▪ Intentional additives (unapproved food dyes, melamine)
Recent Issues - Microbial Contamination

- Aflatoxin and other mold toxins
- Salmonella – wide reaching contamination in what were formerly considered to be low risk foods
  - Nuts – peanuts, almonds
  - Produce – green peppers, tomatoes
Emerging Issues - Microbial Contamination

• Prions (animal tissue – can these reach produce?)
• Antibiotic resistant bacteria
  • Environmental persistence
• Noroviruses – sources and controls
• New technologies for microbial control (nanoparticles – safety?)
Recent Issues - Chemical Contamination
Cases of Intentional and Unintentional Contamination

- Dioxin and other industrial chemicals
- Pesticides
- Drug residues
Dioxin
Recent Issues - Pesticides and Drug Residues

• Unintended use or wrong use (horticultural crops)
• Intentional contamination (food service)
• Unapproved drugs used (meat, poultry and fish)
  ▪ Lower tolerances for drugs and drug residues in certain markets as analytical detection methods get better
  ▪ Possible negative environmental impacts (antibiotic resistant bacteria)
  ▪ Non-tariff trade barriers
Recent Issues – Economic Fraud

• Economic fraud is a form of *intentional contamination*

  ▪ Intentional contamination of food with chemicals which will make the food or ingredient appear to be better than it is

  ▪ Contamination/adulteration is not intended to be harmful, just deceptive
Recent Issues – Economic Fraud, cont.

- Long term problem - Adulteration of consumer items, drugs with industrial chemicals (DEG etc.) by ‘low cost’ disreputable manufacturers.

- Counterfeit drugs

- Relative sophisticated fraud – compounds are hard or impossible to detect by conventional testing

- Compounds added are usually not acutely toxic making illness unlikely
Which Brings Us to Melamine

- Melamine – rice concentrate, wheat flour, milk powder
  - Intentionally contaminated protein ingredients exported from China since mid 1990’s
  - Only detected because contaminated ingredients were in a sole source food – pet food, infant formula
    - Plant protein products – 2007 adulterated pet foods
    - Milk powders – 2008 - hundreds of thousands of illnesses and numerous deaths
  - Chronic illness likely for affected children
Melamine

- Use – laminate board, plasticware, fire retardant
- Odorless, colorless, tasteless in foods
- Effects – potentially fatal kidney damage
- Detection is difficult
Melamine
Melamine Fraud and Its Impact

- A widespread practice with tacit government approval

- Legitimate producers were forced out of business by continuous undercutting

- Long term practice (melamine in animal feed since at least 1996)

- Fraudulent use continues

- Many products – 1800+ recalled foods in USA alone (dairy, bakery, beverages, dry mixes, soups, sauces, confections, meat, pet foods)
Melamine Fraud and Its Impact, cont.

- Global distribution
  - Geographically
  - Thousands of different foods

- Country of origin and source of materials made affected foods difficult to trace
  - Wheat and milk are a component in many blended ingredients
Melamine Fraud – Why it Worked

- Gullible regulators and ineffective food safety programs

- Melamine containing products were dumped onto markets which did not have ability to test
  - Testing remains expensive and is limited
Melamine Fraud and Its Impact, cont.

- Contamination would not have been detected if domestic animals had not been affected (2007)

- Use continued – widespread dried milk distribution detected in 2008
  - Public not notified until after the Summer Olympics
  - Several hundred tons repacked, relabeled, and sold (2010)
New FDA Import Requirements

• Exporting companies must have hazard analysis critical control point program (HACCP) for all foods
  ▪ **Documented preventive controls and monitoring**

• Standard Sanitation Standard Operating Procedures (SSOPs) and records

• Good Manufacturing Practices

• Recall or market withdrawal program

• Traceability program
Hazard Analysis

• Address both intentional and unintentional contamination – expanded list of hazards:
  biological  chemical
  physical    radiological
  natural toxins  pesticides
  drug residues  decomposition
  parasites    allergens
  unapproved additives
Importers - Foreign Supplier Verification Program

• Objective risk based assessment safety plan including intentional and unintentional contamination
• Compliant with US regulatory requirements
• Food is not adulterated or misbranded
• Supplier provides adequate assurance that food meet legal requirements
How to Meet Import Requirements

• Review of foreign manufacturer processes, procedures and risk based preventive measures
• Records for each shipment (2 year retention)
• Lot certification
• On-site inspections (annual)
• Check of HACCP plan
• Lot inspection
• Product testing
• Pre-shipment samples
Voluntary Qualified Importer Program (VQIP)

- Additional import requirements
- Expedited review and import clearance for products entering USA
- Additional requirements beyond foreign supplier verification program
- Facility certification
- Designated foods approved for VQIP (each food considered separately)
- Notice of intent by importer to participate
VQIP Requirements

• Compliant facility
• History of compliance of a particular facility
• Reliable export certification program in country of export
• Records
• Intentional contamination risk assessment and control program
VQIP Requirements

• Testing facility available
• Quality audits
• Traceability
• Temperature control and records
• Appropriate sourcing practices
• 3 year review with potential revocation by FDA
Import Certificates

• Shipment specific
• Known food safety risk of product or of foods from country of origin
• Government of exporting country has a reliable certification program
Prior Notification of Shipment

• Notice of incoming shipment must be received by FDA (since 2002)
• Can’t import product to USA if it has been rejected in another country
Other Requirements

• Importers are ultimately responsible for food
• Domestic and imported foods must meet same requirements
• Food must be safe, sanitary and labeled correctly
• FDA is not authorized to approve, certify license or otherwise sanction individual food importers, products, labels or shipments
• Foreign facilities must be registered with FDA
• All FDA regulated food subject to inspection at border
Impact of Food Safety Modernization Act on Food Producers Around the World

• HACCP requirement should increase overall food safety

• However, other provisions redundant with current laws - more requirements and records will lead to higher cost

• Pressure for additional product testing, environmental monitoring, and 3rd party audits

• Regulations and guidance are still to be drafted – Full funding is questionable

• FSMA will be considered a non-tariff trade barrier by other countries
WARNING!!!
URINATING ON THE WORK PLACE IS PROHIBITED
Anyone caught will be subject to instant dismissal.

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