

*Food Safety & Security in the Food Industry:
Regulations, Realities & Current Issues*

Presented by:
William E. Pursley
Vice President, Food Safety Education
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***“We are entering an era of
Globalization at a time when we
are undergoing profound societal
changes”***

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

20%-25% of the
Population is At Risk



Changes in Society

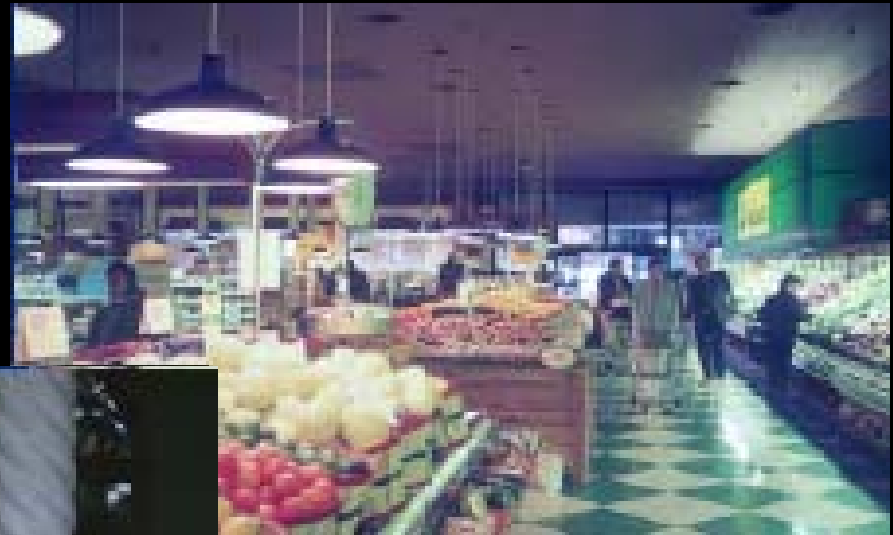


Consumers are eating
different foods



Changes in Society

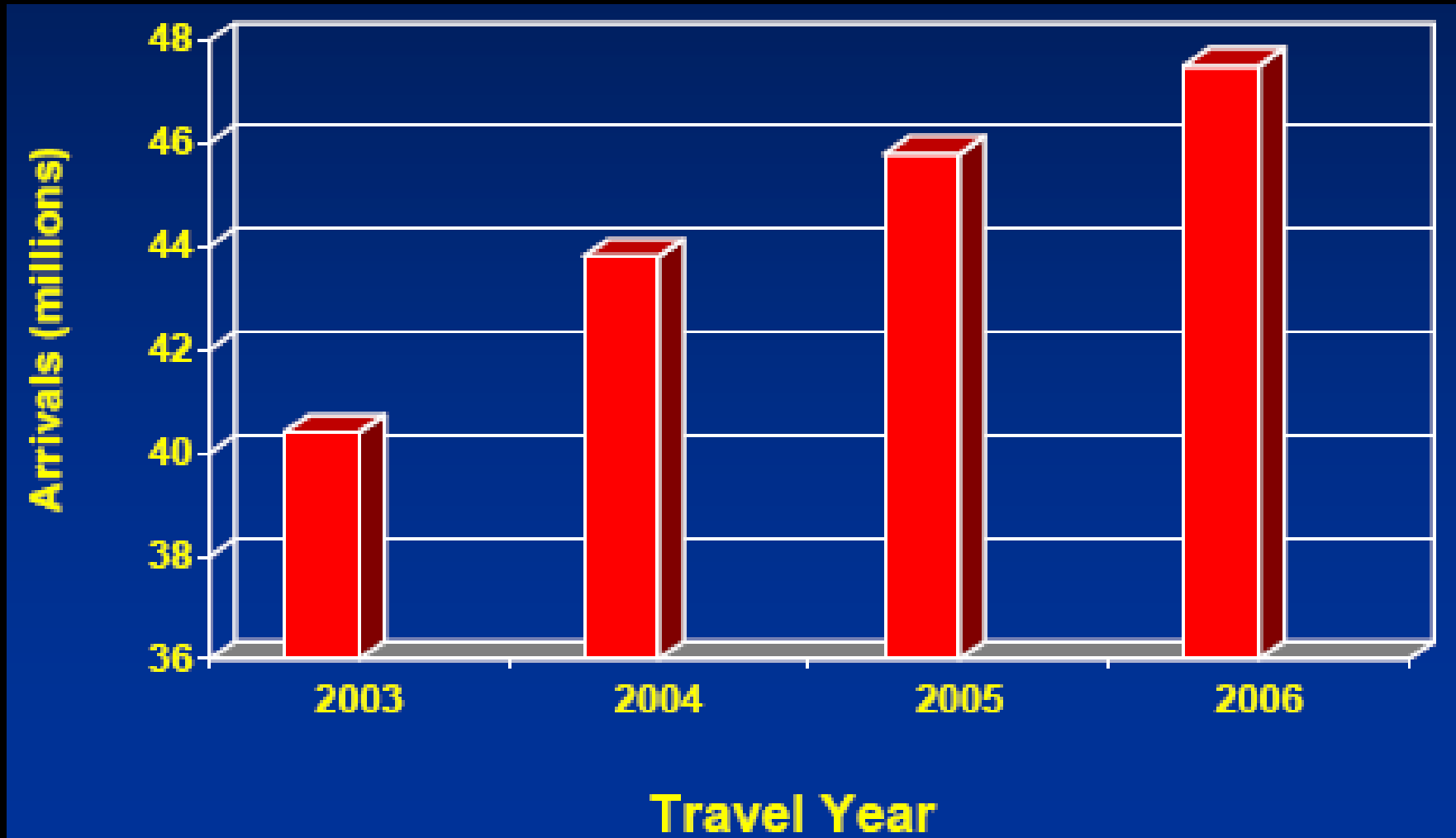
More Food Prepared
Outside the Home



Global Travel

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

Inbound Travel to U.S.

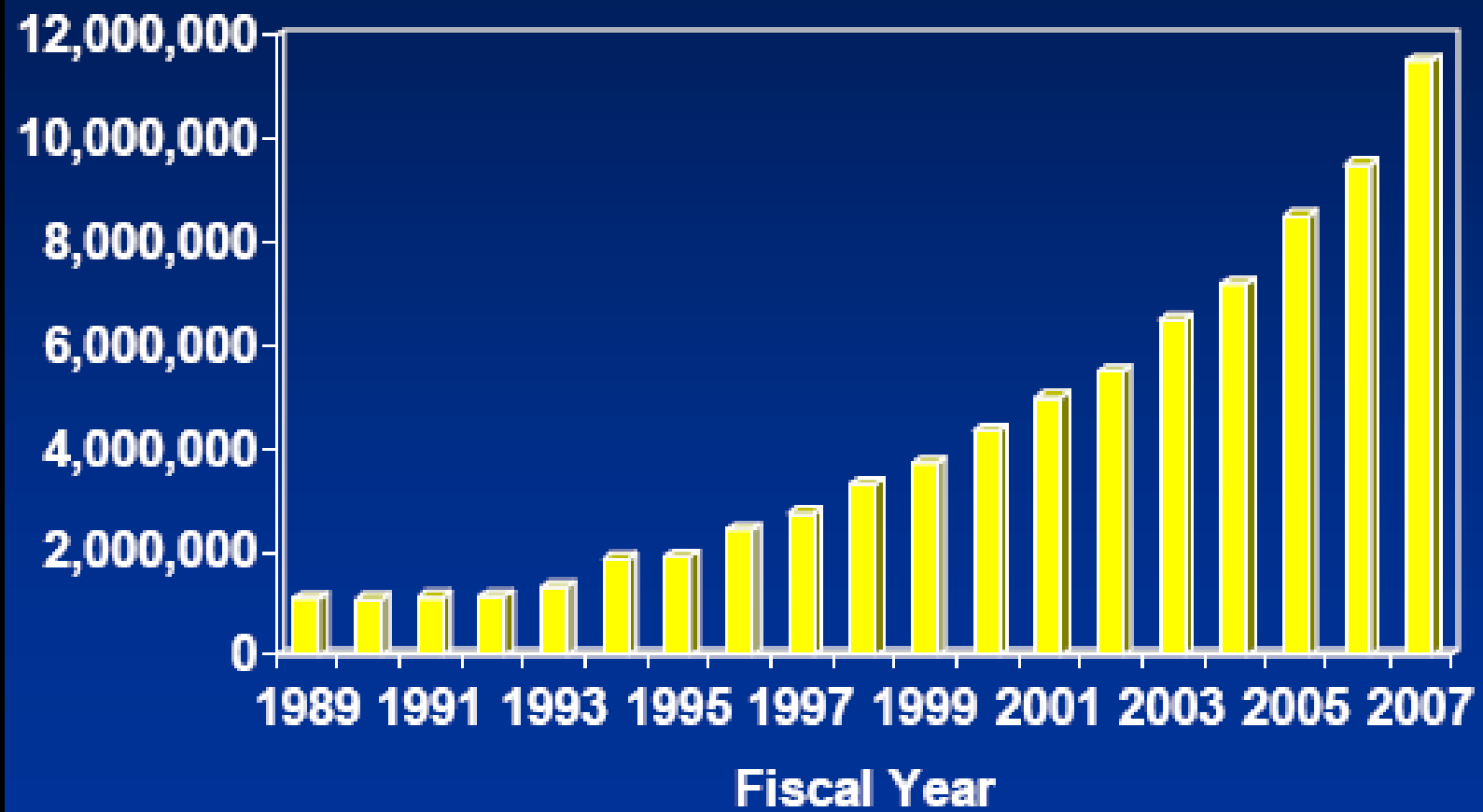


Changes in Society

More Food Now
Comes From
Distant Places



FDA Import Entries Foods Only



An Era of Globalization

- Americans are eating a greater *variety* of foods and desire a wide variety of foods year round
 - ◆ U.S. per capita consumption of fresh fruit and vegetables increased 36% from 1981 to 2000
 - ◆ Typical grocery store carried 173 produce items in 1987 and is now carrying 345 produce items
 - ◆ Retailers now routinely provide produce items that were once considered seasonal on a year-round basis
 - ◆ Total consumption of imported fish increased from less than 50% in 1980 to more than 75% today

What's New? How Are We Affected? Why Is It Important?

- Regulatory initiatives
- Food safety hazards
- Technology
- Competing audit/ guidance standards
- Health issues
- Recent recalls
- Miscellaneous

Background FDA Study 1999-2003

- Root cause analysis of Class 1 & 2 recalls
- 88% related to GMP (preventable) issues
- 34% undeclared allergen ingredient
- 28% undeclared/uncertified color
- Top 4 sector-bakery, seafood, bean/vegetable & multi-food dinner
- Only 14% of recalls initiated by company
- Conclusion-Need sector specific GMP improvement

www.cfsan.fda.gov/~dms/cgmps2.html



Center for Food Safety And Applied Nutrition (CFSAN) Objectives

- Ensuring Food Safety
- Ensuring Food Defense
- Improving Nutrition
- Improve Dietary Supplement Safety

New Approach...Focus on end results and apply risk based controls to the extent necessary.

Food cGMP Modernization

- First revision since 1986
- Behind schedule? FDA in disarray
- Likely to be out in 2007 or 2008?
- Main roadblock – mandatory environmental testing/ sampling
- Increase access to sensitive records

Food cGMP Modernization

Areas of Update:

1. Further define GMP/HACCP relationship for specific food types, e.g., produce, seafood, ready-to-eat (RTE)
2. Allergens
3. *Listeria Monocytogenes*
4. Sanitation procedures
5. Records availability

Food cGMP Modernization (Cont.)

Further review:

6. Remove exclusion for raw agricultural commodities
7. Time-temperature guidance

GMP Revision: Training

- Supervisors and workers
- Food hygiene
- Food protection
- Employee health
- Personal hygiene
- Training must be easily understood
- Records of training

GMP Revision: Allergens

- Big 8 Allergens (milk, egg, fish, shellfish, tree nuts, peanuts, wheat, soybeans)
- Training
- Segregation
- Validated cleaning
- Prevention of cross-contact
- Label review and control
- Supplier control

US Food Allergen Labeling and Consumer Protection Act of 2004

Updated 10/06

- Major food allergens remain the same:
 - ◆ Milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans
- Molluscan shellfish are not considered a major food allergen
- Tree nuts specified and coconut is now included

GMP Revision: Listeria

- Control for *Listeria monocytogenes*
- RTE Foods that support growth of L. mono
- Microbiological monitoring of environment
- Records to judge effectiveness of program
- Root cause of sanitation failures
- Documented corrective action

GMP Revision: Sanitation

- Written sanitation procedures
 - ◆ Scope
 - ◆ Objective
 - ◆ Management responsibility
 - ◆ Monitoring
 - ◆ Corrective Action
 - ◆ Recordkeeping
- All food contact equipment
- All food contact surfaces

GMP Revision: Records

- Maintain “critical records”
 - ◆ Provide evidence that firm is operating in compliance with cGMP
 - ◆ Consistent with Quality System principles
- Records available for review by FDA investigators

Items for Further Review

- Remove exclusion for raw agricultural commodities
 - ◆ 21CFR 110.19
 - ◆ “Farmer’s gate to consumer’s plate”
- Time-temperature guidance
 - ◆ Microbial growth models
 - ◆ Guidance for refrigerated storage
 - ◆ Guidance for hot holding
 - ◆ Make consistent with FDA Food Code
 - ◆ Avoid specific temperatures

Ensuring Food Defense

- Food Emergency Response Network (FERN)
- National Bio-Forensic Analysis Center (NBFAC)-referenced geographic collection of pathogens
- FDA model programs using Carver-Shock methods, risk modeling for sectors
- Research cost effective way to monitor foods for bio-terrorist attack, e.g., conductivity

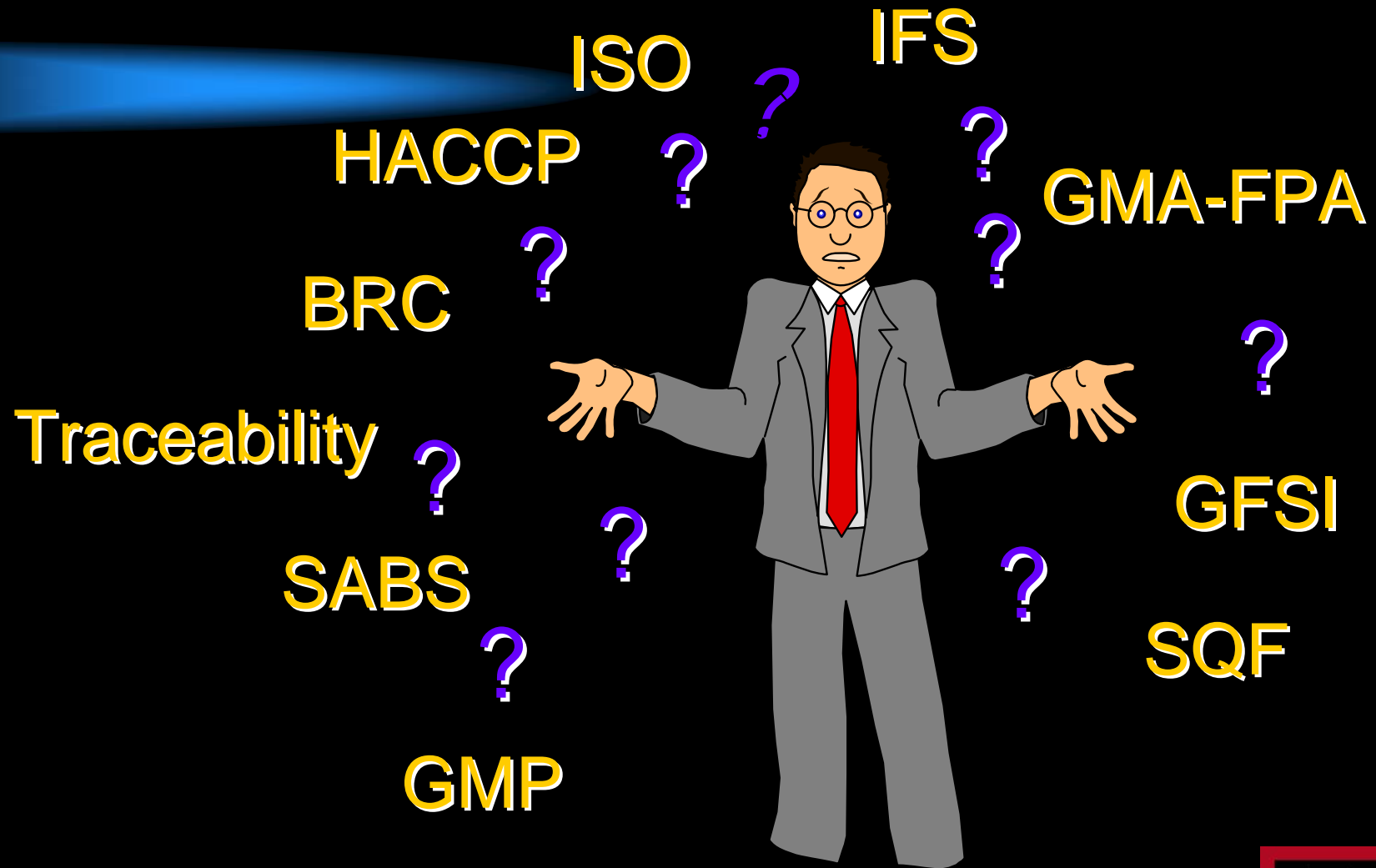
Records Maintenance

- Must keep records of receipt and delivery –
“One step forward and one step back”
- Must be able to track food contact packaging
 - ◆ Track the packaging specifically
 - OR
 - ◆ As part of tracking of food
- Applies in North America and Europe

Certification Audits

- The inspection / audit business is changing. Certification audits are becoming more common.
 - ◆ Require accreditation in many cases
 - ◆ More stringent requirements for proving competence
 - ◆ More document oriented

Making Sense of it All



System		Country	Summary
BRC	British Retail Consortium	Britain	HACCP, GMP, Quality
HACCP 0330	Hazard Analysis CCP's	South Africa	HACCP
IFS	International Food Standard	Germany France, other EU	EU equivalent to BRC
FPA	GMA-Food Processors Assoc.	USA	HACCP GMP, Quality, Bio-terrorism
GFSI	Global Food Safety Initiative	EU	HACCP GMP, Quality
SQF 2000	Safe Quality Food	Australia	Australian equivalent to BRC
ISO 9000	International Standards Org	Worldwide	Quality Management
ISO 22000	International Standards Org	Worldwide	Food Safety

Current Issues

MISCELLANEOUS



Organic & Cloning

- 12/06, FDA/USDA-Cloning OK, 90 day discussion
- Issues
 - ◆ Need for labeling
 - ◆ Cloned animals inconsistent with Organic Foods Production Act (OFPA)
 - ◆ Center for Food Safety petitions FDA for pre-market food safety review
 - ◆ State and Federal bills for labeling are forthcoming

Online Resources for Current Food Industry Issues

www.FDA.gov

www.USDA.gov

www.CDC.gov

www.FoodChemicalNews.com

www.FARRP.org

www.EPA.gov

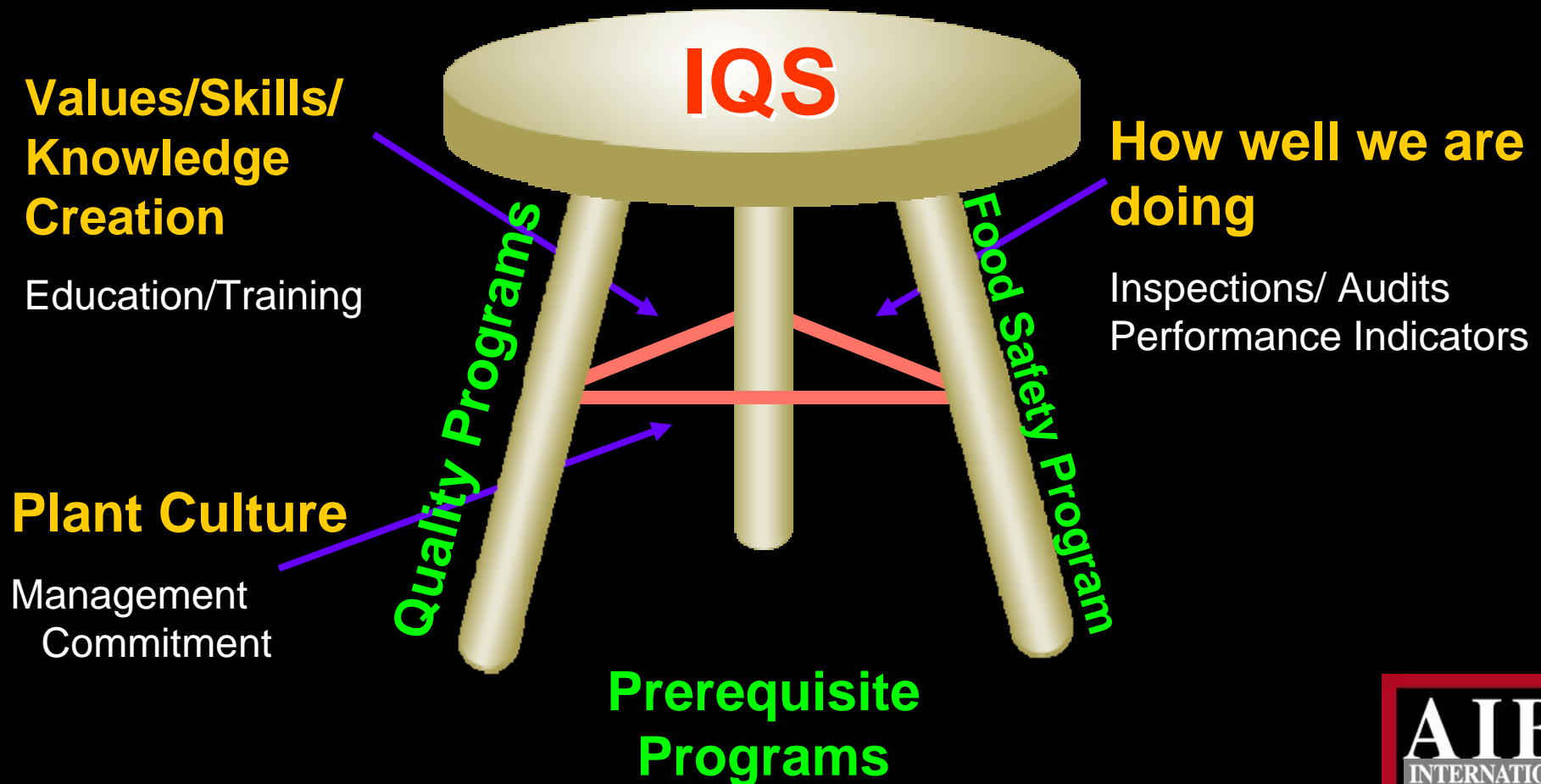
www.IFT.org

www.aibonline.org/newsletter

www.stagnitorollout.com



INTEGRATED QUALITY SYSTEM



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Director

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