THE AMERICAN SPICE TRADE ASSOCATION

Regulatory/Legislative Workshop

Thursday, November 2, 2006

Good Morning!

Welcome and Overview of ASTA Issues

Julia Bellinger
ASTA Government Relations Director

Regulatory/Legislative Workshop

Thursday, November 2, 2006

Goals for ASTA' s Regulatory/Legislative Program

1. Enhance regulatory resources for members

2. Increase ASTA's impact on regulations/legislation

3. Increase ASTA member participation in public policy arena

Regulatory Resources for Members

Additional regulatory resources on ASTA's new website in 2007

ASTA's new regulatory newsletter
ASTA Advocate

Web Seminars
Regulatory/Legislative Workshops

More active Government Relations Committee

Increase ASTA's Influence

- More active in Coalitions (GSP)
- More time spent developing relationships with federal agencies and policy makers
- Additional efforts communicating ASTA's position to decision makers
- GOAL: ASTA's position will be considered when regulatory/legislative policy is developed.

Increase ASTA Member Participation

- Policy makers are greatly influenced by constituents/the people they “serve.”
- Effective government relations programs use association members or “grassroots” to communicate with policy makers.
- Lots of opportunities for ASTA members to go to Capitol Hill and federal agencies to communicate ASTA’s position. (JBellinger@ASTAspice.org)
- Public Policy, regulations and legislation, affect your bottom line.
- In your best interest to know what regulations/legislation will be enacted, better yet, use ASTA to impact policy.

Current Issues Affecting the Spice Industry

- Generalized System of Preferences (GSP)
  - Sent letters to Capitol Hill
  - Sent comments to the U.S. Trade Representative
  - GR Committee met with Senate staffers
- The National Uniformity for Food Act
  - Sent Letter to Capitol Hill
  - More action in 2007
- SAFE Port Act (HR 4954)
  - Signed into law in October 2006
  - Expands the C-TPAT program
  - Look for detailed information in the ASTA Advocate in November

Update on Capital Hill Visits

Tim Sonntag

ASTA Government Relations Committee

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McDermott Will & Emery

ETHYLENE OXIDE USE ON SPICES

Regulatory Review and Update

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Presentation Overview

A. Project Goal and Objectives

B. Initiation of Special Review

C. First ASTA Residue Study

D. EPA Meeting of May 1996

E. Delaney Clause and Food Quality Protection Act

F. Second ASTA Residue Study

G. Anti-Microbial Regulation Technical Corrections Act of 1998

H. Reregistration Eligibility Decision ("RED")

I. Tolerance Reassessment Decision Document ("TRED")

J. Outstanding Issues

A. Project Goal and Objectives

"Ethylene Oxide is essential to providing safe spice products to the consumer. Consequently, all reasonable efforts should be made to assure the continued availability of this important health protection tool with minimal, acceptable limitations and regulatory restraints."

B. Initiation of Special Review

- Position Document 1 (PD1)
  - 1978 – Occupational exposure concerns
  - Reproductive toxicity and mutagenicity
  - 1980's – carcinogenicity concerns also raised
  - 1984 – EPA attempts to revise product label to increase worker protection
  - 1984 OSHA standard (Health Care Industry Use)
  - EPA defers to OSHA
- Position Document 2 to close out Special Review

C. First ASTA Ethylene Oxide Study

- Since 1978, the EPA has had concerns with the incomplete data base for many pesticides, including Ethylene Oxide (EtO).
- EPA has required the submission of various data, particularly data associated with residues of EtO and its metabolites in spices and black walnuts after treatment with EtO.
- Since the manufacturers were not willing to supply these residue data, ASTA developed and submitted these data to EPA in accordance with the schedule established by the Agency.

D. EPA Meeting of May 1996

- ASTA and EPA representatives met at the agency
- EPA provides a "back of the envelope" risk assessment of EtO use on spice based on ASTA residue study
- Good News – EtO itself is not a large concern
- Bad News – Agency concerned with the residues of ethylene chlorohydrin (ECH)
- Options:
  - Show ECH is not carcinogenic or
  - Reduce ECH residues

E. Delaney Clause and the Food Quality Protection Act

- Classification of EtO as a carcinogen generated problems
- Processed spices and the Delaney Clause
- Adoption of new standard in FQPA
- Applies to whole and processed or ground spices
- Risk only approach

E. Delaney Clause and the Food Quality Protection Act
(cont'd)

- **FQPA Standard for setting tolerances**
  - **The Administrator of EPA must determine that the tolerance is "safe"**
  - **"Safe" means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information**

F. Second ASTA Residue Study

- ASTA began testing various parameters for treating spices to determine whether residues could be lowered.
- Initially there was not a lot of success
- Lack of consistent results
- However, finally a new improved treatment method was developed
- This method resulted in initially eliminating EtO residues and substantially reducing ECH residues in treated spices
- Report was prepared for ASTA and submitted to EPA for consideration

G. Anti-Microbial Regulation

Technical Corrections Act of 1998

- **EPA prepares a draft rule which would result in transferring jurisdiction over EtO to the Food and Drug Administration (FDA)**
- **FDA made clear its position on EtO if the EPA rule was finalized**
- **ASTA encouraged Congress to step in and maintain the regulation of EtO as a pesticide at EPA where it appropriately belonged**

H. Reregistration Eligibility Decision

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires that registered pesticides be reviewed periodically to determine whether they meet current standards for continued registration
- The review leads to a reregistration eligibility decision (RED)
- The Agency must determine that the benefits of use outweigh its risks including risks to man and the environment

H. Reregistration Eligibility Decision *(cont'd)*

- **Federal Register Notice of February 22, 2006 – 71 Fed. Reg. 9110-12**
  - **EPA announces the availability of certain revised risk assessment documents associated with EtO**
  - **This is Phase 5 of a 6-stage public review process**

H. Reregistration Eligibility Decision *(cont'd)*

- **Issue of concern is Occupational Exposure for both spice and medical device use**
  - **Specific areas of concern are long-term non-cancer risks from occupational exposure to workers, as well as cancer risks from occupational exposure**
  - **These issues are most complicated and need additional time to complete**
  - **EPA agrees and extends the RED process for EtO**

I. Tolerance Reassessment Decision Document ("TRED")

- FQPA required that all food tolerance be re-assessed by August 2006 to determine whether they meet the new safety standards of the Act.
- EPA proceeded to evaluate the tolerances of EtO.
- EPA preliminarily determined that for all food uses, the acute (short term) exposure to ECH was of a concern.

Acute Dietary Exposure Profile

Traditional Treatment	ECH
General US Population	230% of the aPAD
Infants < 1 year old	480% of the aPAD
Children 1-2 years old	650% of the aPAD
Children 3-12 years old	540% of the aPAD
Youth 13-19 years old	130% of the aPAD
Adults 20-49 years old	130% of the aPAD
Females 13-49 years old	160% of the aPAD
Adults 50+ years old	120% of the aPAD

Acute Dietary Exposure Profile *(cont'd)*

*Improved Process	ECH
General Population	120% of the aPAD
Infants < 1 year old	160% of the aPAD
Children 1-2 years old	330% of the aPAD
Children 3-12 years old	250% of the aPAD
Youth 13-19 years old	140% of the aPAD
Adults 20-49 years old	80% of the aPAD
Females 13-49 years old	64% of the aPAD
Adults 50+ years old	36% of the aPAD

*Based on Second ASTA Study

I. Tolerance Reassessment Decision Document ("TRED") *(cont'd)*

- **EPA determined however that the use of EtO on Basil was the risk driver.**
- **If Basil was excluded, the dietary risks were acceptable.**
- **Consequently, the industry has recommended the exclusion of Basil from the label.**
- **EPA recommendations for a tolerance are as follows (parts per million)**

Chemical	Spices	Dried Vegetables
EtO	7	7
ECH	940	940

I. Tolerance Reassessment Decision Document ("TRED") *(Cont'd)*

- **EPA also required labeling directions for use to assure consistency in residues from treatment.**
- **ASTA provided use directories which would establish at least one method for applying the product to meet EPA requirements but which would also allow for other treatment regimens to also qualify.**

I. Tolerance Reassessment Decision Document ("TRED") (Cont'd)

- **ASTA's specific use directions are:**

  "Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then, introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 6 hours. Then evacuate the gas from the chamber using a sequence of not less than 21 steam washes (injections and evacuations) between 1.5 PSIA (27" Hg) and 5.0 PSIA (20" Hg) while maintaining a minimum chamber temperature of 115°F."

- **ASTA advised EPA that the industry needed at least two years to convert to the new or similar process. EPA has apparently agreed to that transition time.**

J. Outstanding Issues

- Final approval of tolerance and label directions.
- Approval of alternative treatment techniques.
- Completion of the RED
  - Addressing the Occupational Exposure issue associated with EtO use.
  - This applies to spices as well as use in the medical industry
  - Registrants are taking the lead on this issue.

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Keller and Heckman LLP

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GLOBAL REGULATORY STATUS OF PROPYLENE OXIDE USE ON SPICES: AN UPDATE

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REREGISTRATION OF PPO UNDER FIFRA

- EPA Issued the Reregistration Eligibility Decision for PPO on August 9, 2006 for a 60-day Public Comment Period, Which Closed on October 10, 2006
- No Adverse Comments Were Filed By Environmental Groups
- EPA Proposed to Reregister All Existing Uses of PPO Including Spices and Proposed New Tolerances for among other things Herbs (group 19), Dried Onions, & Dried Garlic. The PPO Registrant has asked that Dried Vegetables be Added.

DIETARY RISK ESTIMATES

- Spices are a Minor Contributor to Dietary Risk.
- For All Uses, Acute and Chronic Non-cancer Risk is Acceptable.
- For All Uses, Cancer Risk is 4×10^{-7} (1×10^{-6} is Acceptable).
- EPA Accepted Data Showing Rapid Hydrolysis of PPO to Propylene Glycol in the Human Stomach as a Factor in Adjusting the Dose from the Dunkelberg Rat Gavage Study

TOLERANCE REASSESSMENT DECISIONS ON SPICES

- For PPO

Commodity	Tolerance (ppm
Herbs and spices, group 19, dried	300
Onion, dried	300
Garlic, dried	300

- For Propylene Chlorohydrin (PCH)

Commodity	Tolerance (ppm)
Herbs and spices, group 19, dried, except basil	1500
Basil, dried	6000
Onion, dried	6000
Garlic, dried	6000

TOLERANCE REASSESSMENT DECISIONS (cont.)

- Propylene Bromohydrin (PBH) Tolerances Considered Unnecessary
- Data Requirements

For PPO:	
Chronic Toxicity (nonrodent)	In Reserve
For PCH	No Additional Data Needed

CHANGES TO THE PPO TOLERANCE EXPRESSION

- Old PPO Tolerance Contained Directions for Use established By FDA in the 1960s which included Outdated Provisions, such as a 4-Hour Treatment Time, Limitation to “Processed” Spices, and Requirement that “Bulk” Processed Spices “Be Further Processed into a Final Food Form.”
- EPA has Decided to Eliminate All Directions for Use from the PPO Tolerance
- PPO Label Will Need to Provide Detailed Directions for Use.

OCCUPATIONAL EXPOSURE

- PRA proposed OELs at:
  - 0.17 ppm for Chronic Non-Cancer Inhalation Effects
  - 0.11 (10^{-4}) to 0.0011 (10^{-6}) for Cancer Inhalation Effects
- EPA Credited Data from the ACC PO Panel Showing that PPO was a Threshold Inhalation Carcinogen
- RED Sets OEL at 2 ppm as an 8-hr TWA

LABEL CHANGES

- OEL at 2 ppm as an 8-hour TWA
- If PPO Levels Exceed 20 ppm at Any Time or 2 ppm as an 8-hour TWA, then Respirators are Required:
  - (1) Supplied Air Respirator (MSHA/NIOSH TC-19C)
  - (2) Self-contained Breathing Apparatus
- PPO Registrant has Proposed Use of NIOSH Approved Organic Vapor Cartridge Respirators

OTHER LABEL CONDITIONS

- Equipment “Specifically Designed” to Reduce PPO Emissions by 99%.
  - Note: “Specifically Designed” – No Monitoring Requirement
  - Note: No Specific Technology Required, i.e. Scrubbers or Acid Bubblers or Other Technology
- Registrant has Argued for 95% Design Efficiency with 10 Foot Stack for Large PPO Users and No Scrubber with Higher Stack (10-16 ft) for Small PPO Users Based on PERFUM Modeling and Revised Acute Risk Level of Concern

AUSTRALIA

- The Australian Pesticide and Veterinary Medicines Authority (APVMA) Issued an ADI for PPO of 0.006 mg/kg bw/d
- The ADI translates to > 50 ppm Residues of PPO in Spices Imported into Australia
- An Import Tolerance Petition for Spices Is Needed

JAPAN

- A Provisional MRL for PPO on “Other Spices” of 300 ppm has Issued
- “Other Spices” refers specifically to the following:
  - Hemp Seed, Asafetida Root, Asafetida Rhizome, Ajowan Seed, Anise Seed, Fennel Seed, Turmeric Root, Turmeric Rhizome, Allspice Fruit, Zedoary Root, Zedoary Rhizome, Chinese Pepper Fruit, Cassia Bark, Kaffir Lime Fruit, Galangal Root, Galangal Rhizome, Cardamom Seed, Cardamom Fruit, Licorice Root, Licorice Rhizome, Caraway Seed, Gardenia Fruit, Cumin Seed, Clove Bud, Poppy Seed, Caper Bud, Pepper Fruit, Coriander Seed, Saffron Pistil, Japanese Pepper Fruit, Japanese Basil Seed, Cinnamon Bark, Juniper Berry Fruit, Star Anise Fruit, Celery Seed, Tamarind Fruit, Dill Seed, Nutmeg Seed Kernel, Nutmeg Seed Skin (Mace), Nigella Seed, Basil Seed, Parsley Seed, Vanilla Fruit, Paradise Grain Seed, Rose Fruit (Rose Hip), Fenugreek Seed, Pink Pepper Fruit, Mustard Seed, Long Pepper Fruit

CANADA

- Petition to Issue a Food Additive Clearance for PPO has Been Filed with the Food Safety Directorate of Health Canada
- Canadian Counsel Retained
- Assistance by Almond Board of California

EU ACTIVITIES

- EU Clearance being Pursued for Imported Almonds with U.K. Food Safety Agency
- EU-wide Distribution will Rely on Mutual Recognition
- Why Almonds?
  - FDA Pasteurization Decision
  - Work toward an USDA Marketing Order

EU APPROACH

- PPO is Listed on the Codex Food Standards in the Processing Aid Category.
- Possible Regulatory Boxes:
  - Biocidal Products Directive
  - Plant Protection Products Directive
  - Food Additive
  - Preservative
  - Food Processing Aid

FOOD PROCESSING AID DEFINITION

- Directive 89/107/EEC concerning food additives authorized for use in foodstuffs intended for human consumption defines “Processing aid” as any substance:
  - ✓ ***(1) not consumed as a food ingredient by itself; and***
  - ✓ ***(2) intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and***
  - ✓ ***(3) which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product; and***
  - ✓ ***(4) provided that these residues do not present any health risk; and***
  - ✓ ***(5) do not have any technological effect on the finished product.***

SHOWING THAT PPO IS A PROCESSING AID

- Pasteurization Purpose May Be Unique to Almonds
- PPO Residues Significantly Reduced Over Shipment Time to Europe
- Low PCH Residues in Almonds
- EFSA Dietary Risk Assessment Shows Low Risk

ACKNOWLEDGMENTS

- ABERCO -- The PPO Registrant
- ASTA
- Almond Board of California
- California Walnut Commission
- Dried Fruit Association
- ACC PO Panel

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Thank you

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Legislative issues affecting the food/spice industry & getting involved in the legislative process

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American Spice Trade Association
2006 Regulatory/Legislative Workshop

November 2, 2006

James A. McCarthy
President and CEO
Snack Food Association

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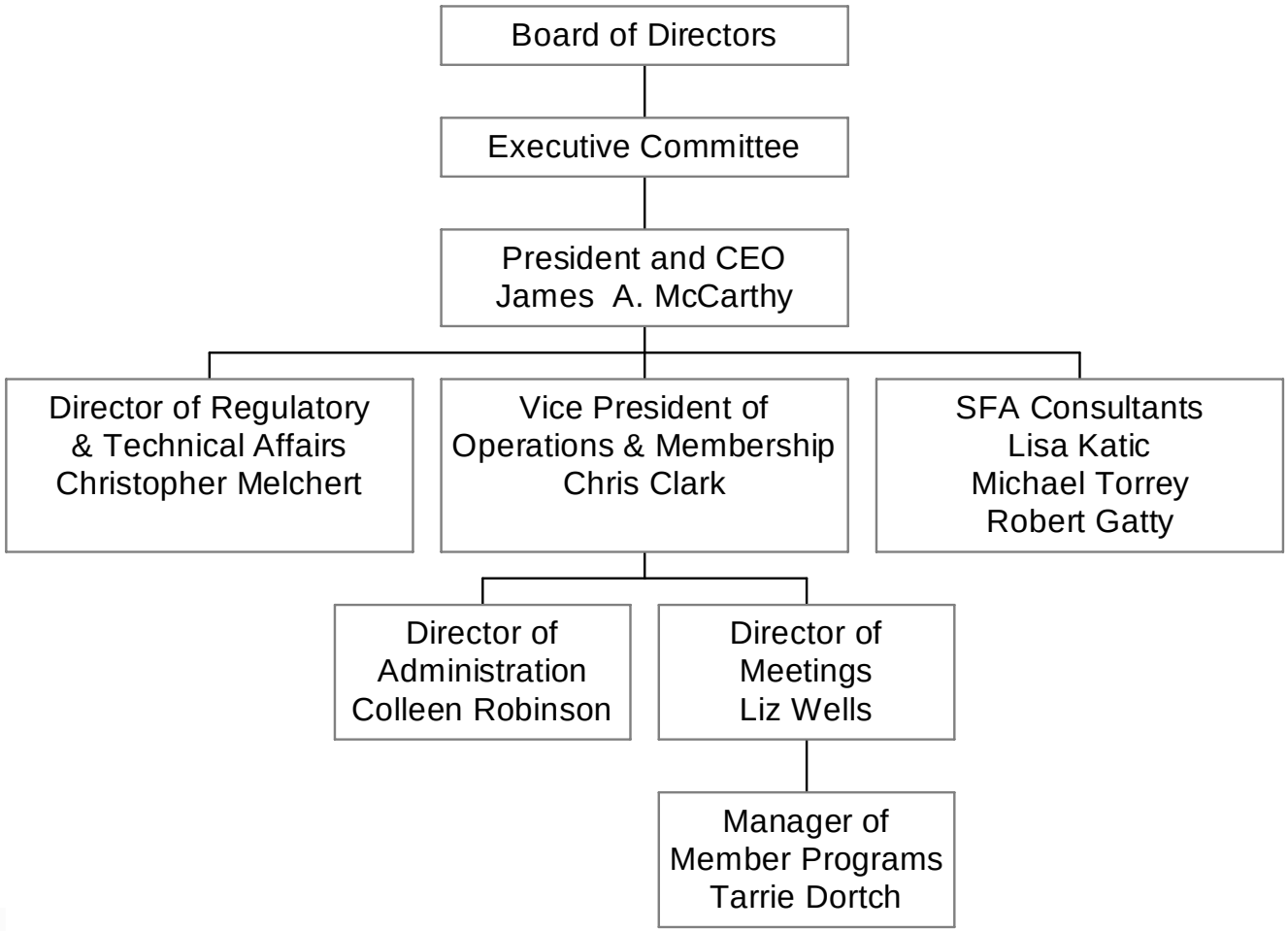
Organization Chart



i://JimMcCarthy/Organization Chart

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SFA Consultants:

Lisa Katic, RD; K Consulting LLC

Food Policy, Health & Nutrition and Communications Expert

Michael Torrey; Torrey Associates LLC

Government Affairs Consultant-Former U. S. Undersecretary of Agriculture

Bob Gatty; GattyEdits

Editor; *Snack Report*, SFA section of *Snack Food & Wholesale Bakery* magazine

Earl Eisenhart, Government Relations Services (GRS)

Dept. of Transportation/transportation & distribution policy issues

Government Affairs:

- Obesity
- Farm Bill/ Food Stamps
- Cheeseburger Bill
- Trans Fatty Acid
- Acrylamide/California Prop. 65
- National Uniformity
- Overtime for Driver/Sales Personnel
- Snack Taxes
- Diacetyl
- Sodium

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SEE *YOU* AT

SNAXPO® 2007

The World's Premier Event For The Snack Food Industry

March 24-27
Hollywood, Florida

www.SFA.org

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SFA Management Workshop
November 7-9, 2006
&
SFA Pretzel & Baked Snacks Seminar
November 9-10, 2006
Baltimore, MD

Texas A&M U./SFA Snack Food Processing Short Course
March 2007
College Station, TX

SNAXPO 2007
March 24-17, 2007
Hollywood, FL

2007 SFA Day in D.C.
May 2006 (TBD)
Washington, D.C.

SFA/CIFT/OSU Total Quality Management Seminar
September 10-14, 2007
Columbus, OH

SFA Top Management 2007
September 24-26, 2006
Laguna Beach, CA

All Candy Expo "Its All About SWEETS and SNACKS"
September 17-19
Chicago, IL

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Thank You!

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Legislative Issues Affecting the Food/Spice Industry

John Gay, Senior Vice President

Government Affairs and Public Policy

National Restaurant Association

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Regulations Affecting the Food/Spice Industry

American Spice Trade Association Workshop

November 2, 2006

Allen W. Matthys, Ph.D.
Vice President
Federal and State Regulations

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ASTA Workshop

- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- (Bioterrorism Act)
- June 12, 2002
- Title III – Protecting Safety and Security of the Food and Drug Supply

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Bioterrorism Act of 2002

- Administrative Detention
- Registration of Food Facilities
- Establishment and Maintenance of Records
- Prior Notice of Imported Food Shipments

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Registration of Food Facilities

Summary Report
September 2006

- Domestic 126,399 facilities
- Foreign 298,236 facilities

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Registration of Food Facilities

Compliance Evaluation

400 firms foreign/domestic

- **Notified facilities by e-mail, fax, or phone using primary mode of transmission**

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Bioterrorism Act of 2002

- Strategic Partnership Program – Agroterrorism (SPPA)

- FBI, DHS, USDA, FDA joint effort with States and private industry to secure the nation's food supply

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CARVER

- Criticality
- Accessability
- Recuperability
- Vulnerability
- Effect
- Recognizability

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Food Defense and Terrorism

ALERT
The Basics

Highlights

- **SPPA Initiative First Year Status Report September 2005 - June 2006**
- **Summaries of Competitive Food Defense Research Reports, 2005** - June 2006
- **Food Defense Awareness Webcast** - March 29, 2006
- **Food Defense Acronyms, Abbreviations and Definitions** - March 28, 2006

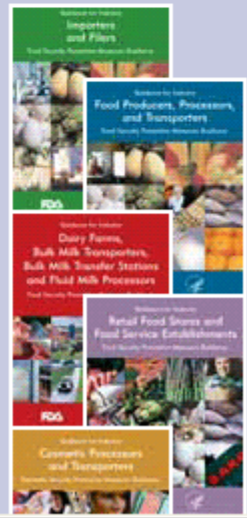
Upcoming Events

Overview

FDA works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply.

- **Food Defense Programs**
  Food Emergency Response Network, Strategic Partnership Program - Agroterrorism
- **Training Materials and Announcements**
  Training resources, upcoming courses, course registration
- **FDA Actions on Bioterrorism Legislation (Food Supply)**
  (Bioterrorism Act of 2002)
  - Administrative Detention
  - Registration of Food Facilities
  - Establishment and Maintenance of Records
  - Prior Notice of Imported Food Shipments
- **Food and Cosmetic Security Preventive Measures Guidance**
- **Consumer Information**

Food and Cosmetic Security Preventive Measures Guidance



ALERT: The Basics

- Assure
- Look
- Employees
- Reports
- Threat

- Be ALERT to protect your business

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ALERT: The Basics

- How do you ASSURE that the supplies and ingredients you use are from safe and secure sources?
- How do you LOOK after security of products and ingredients in your facility?
- What do you know about your EMPOYEES and people coming in and out of your facility?

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Alert: The Basics

- Could you provide REPORTS about the security of your products under your control?
- What do you do and who do you notify if you have a THREAT or issue at your facility, including suspicious behavior?

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ASSURE

- Know your suppliers
- Encourage your suppliers to practice food defense measures
- Request locked and/or sealed vehicles/containers/railcars
- Supervise off-loading of incoming materials

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LOOK

- Implement a system for handling products
- Track materials
- Store product labels in a secure location and destroy outdated or discarded product labels
- Limit access and inspect facilities
- Keep track of finished products
- Encourage your warehousing operations to practice food defense measures

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EMPLOYEES

- Conduct background checks on staff
- Know who belongs in your facility
- Establish an identification system for employees
- Limit access by staff
- Prevent customer's access to critical areas of your facility

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REPORTS

- Periodically evaluate the effectiveness of your security management system
- Perform random food defense inspections
- Establishment and Maintenance of Records
- Evaluate lessons learned

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THREAT

- Hold any product that you believe may have been affected
- FDA 24-hour emergency number at 301-443-1240 or local FDA District Office http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html
- Also notify appropriate law enforcement and public health authorities

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APHIS Import Fee

- Proposed user fee for inspection of all imported fruits and vegetables grown in Canada and entering the U.S.
- August 25, 2006; 71 FR 50320
- Comments due by November 24, 2006
- Effective date November 24, 2006

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GMP Regulations

- 21 CFR §110

- Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

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Food Labeling

- Food Allergen Labeling
- Gluten Free
- Trans fat
- Nutrition Labeling
- Food Standards
- Organic
- Country of Origin

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Food Contaminants

- Acrylamide
- Furan
- Perchlorate
- Heavy Metals (lead, cadmium)
- Aflatoxin

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Pandemic Preparedness

- CDC Checklist http://pandemicflu.gov/plan/pdf/businesschecklist.pdf
- Plan for the impact of a pandemic on your business
- Plan for the impact of a pandemic on your employees and customers

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Pandemic Preparedness

- Establish policies to be implemented during a pandemic
- Allocate resources to protect employees and customers during a pandemic
- Communicate to and educate your employees
- Coordinate with external organizations and your community

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Break

Status and outlook for the Generalized System of Preferences (GSP)

Laura Baughman, Director

Coalition for GSP

Angela Ellard, Majority Chief Trade Counsel

Committee on Ways and Means, U.S. House of Representatives

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Thank you for participating in today's workshop