

ASTA 2009
Annual Meeting and Trade Show

April 26-29, 2009
Loews Ventana Canyon Resort
Tucson, Arizona



American National Standards Institute



Private Standards for Food Ingredients - A Safety Perspective



Allen R. Sayler

VP, Regulatory Affairs & International Standards
International Dairy Foods Association
Washington, DC



International
Organization for
Standardization

FAO/WHO Food Standards

CODEX alimentarius

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International Dairy Foods Association Groups

- Regulatory Affairs
- Legislative and Economic
- Communications
- Education and Meetings
- International Trade
- Administrative



IDFA Regulatory Affairs Group

- **Clay Hough**, Senior Vice President, International & Regulatory Affairs, Chief Counsel
- **Cary Frye**: Vice President, Regulatory Affairs
- **Clay Detlefsen**: Vice President, Biosecurity & Environmental Affairs & Counsel
- **Allen Saylor**: Vice President, Regulatory Affairs & International Standards
- **Michelle Matto**: Asst. Director, Labeling & Food Technology
- Katie Sparrow: Manager, International Trade
- **Brian Fields**: Administrative Assistant
- **Kyle Stevens**: Administrative Assistant



IDFA Communications

- IDFA's Website: WWW.IDFA.ORG
- Weekly Electronic News Magazine(members only) subscribe by emailing newsupdate@idfa.org
- Weekly Electronic Food Industry Business Magazine (everyone)



<http://www.smartbrief.com/idfa/index.jsp>

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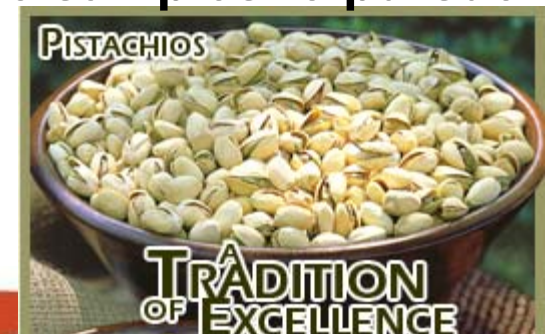
peanut
corporation
of America



AP



The FDA and the California Department of Public Health (CDPH) are investigating Salmonella contamination in pistachio products sold by Setton Pistachio of Terra Bella Inc, Calif. The company has stopped all distribution of processed pistachios and will issue a voluntary recall involving approximately 1 million pounds of its products. Because the pistachios were used as ingredients in a variety of foods, it is likely this recall will impact many products. In addition, the investigation at the company is ongoing and may lead to additional pistachio product recalls. The contamination involves multiple strains of Salmonella. Thus far, several illnesses have been reported by consumers that may be associated with the pistachios. It is not yet known whether any of the Salmonella strains found in the pistachio products are linked to an outbreak. The FDA is conducting genetic testing of the samples to pursue all links.





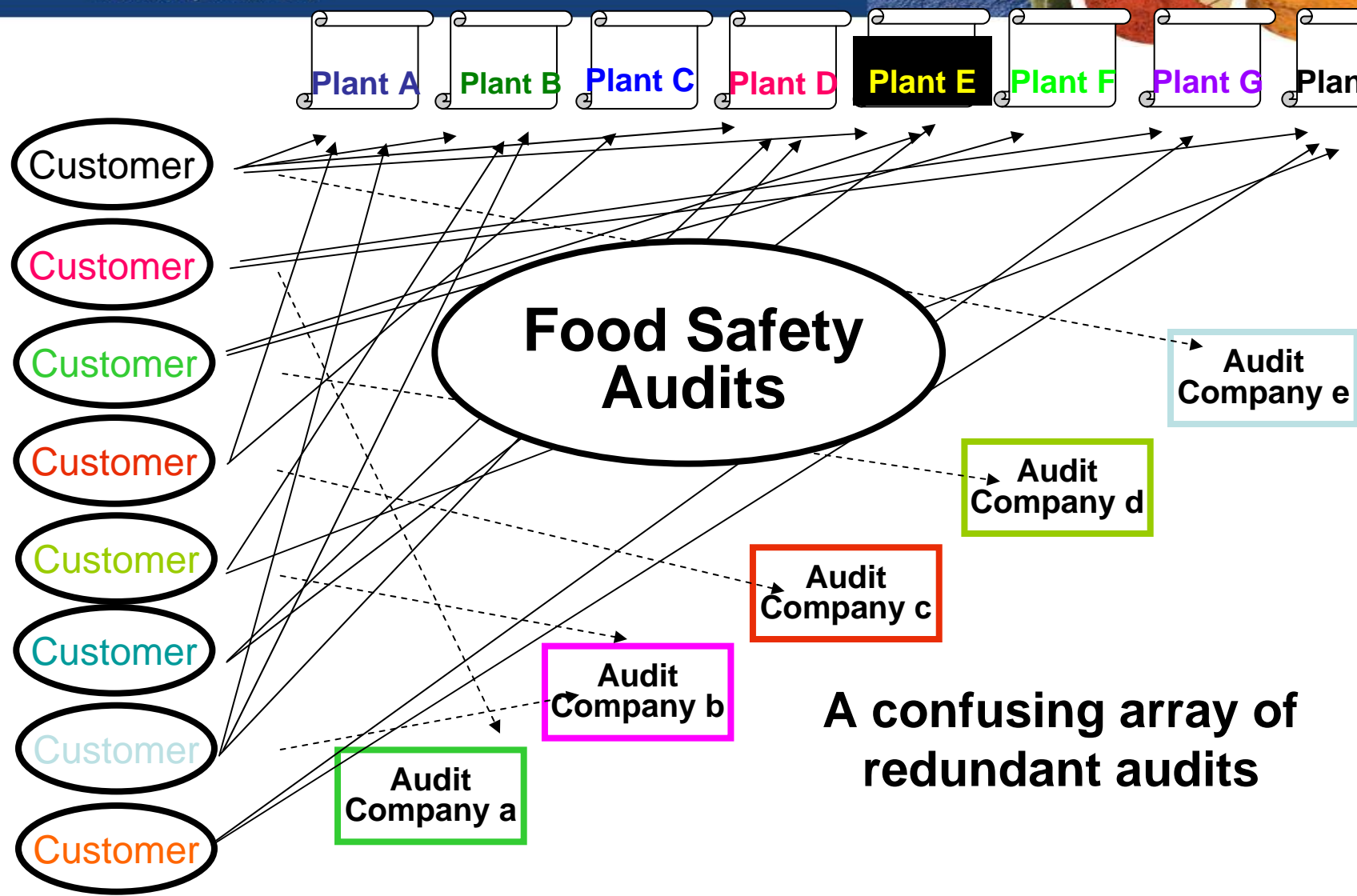
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How & Why - Food Industry

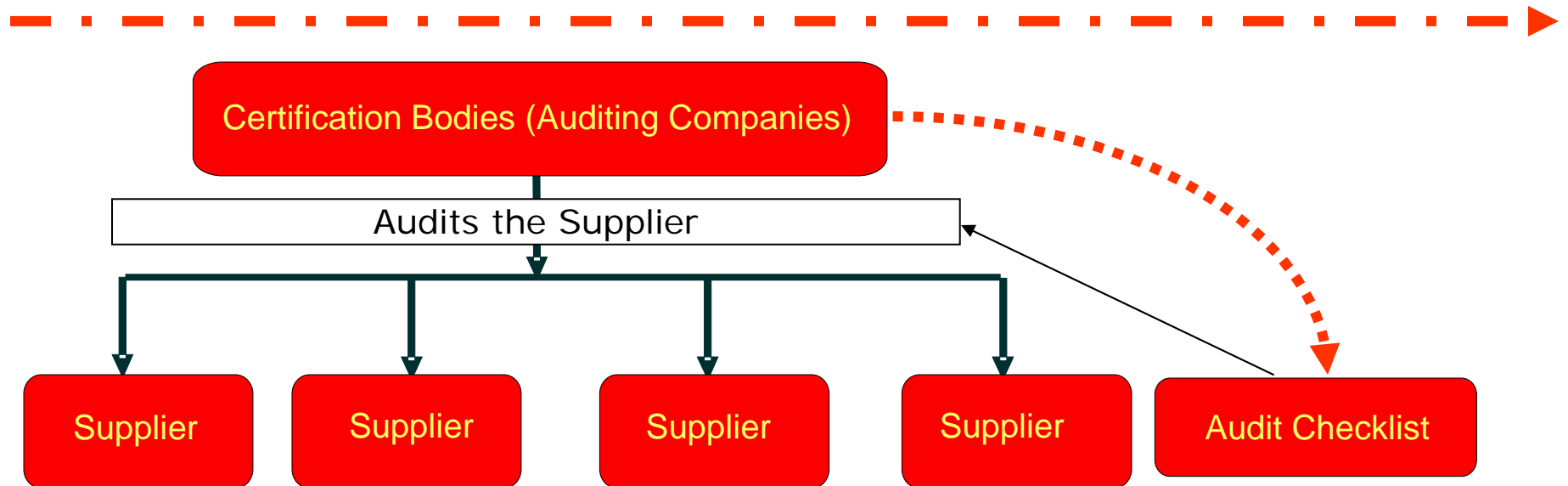
- **Pistachios - Setton Farms**
- **Peanut Products - PCA**
- **Tomato/Peppers**
- **Melamine in Infant Formula**
- **Melamine in Pet Food**
- **Spinach**
- **Ready-to-eat foods that required heating by consumer**

Current State of Audits & Standards

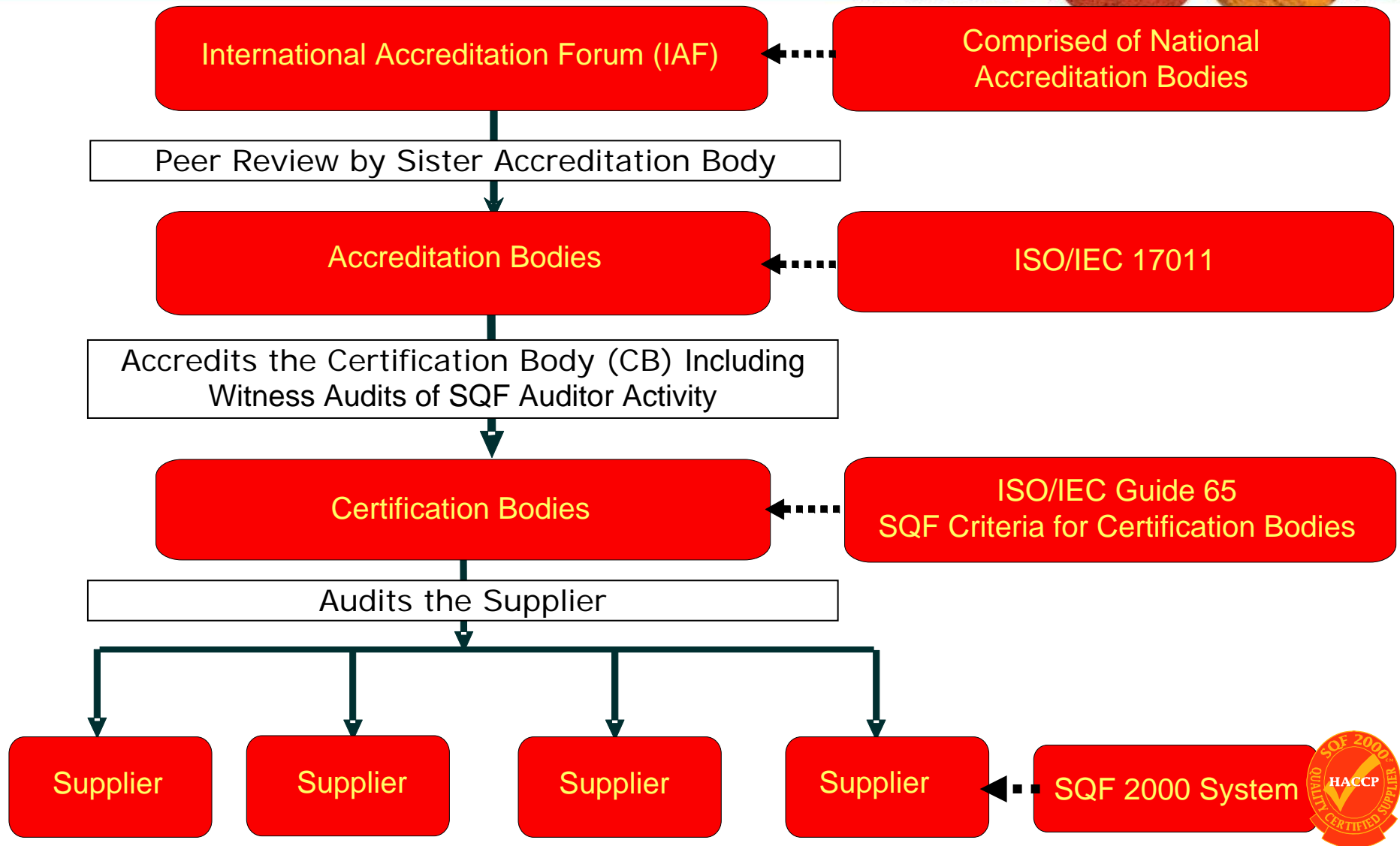




Current State of Audits & Standards



Accredited Third Party Certification



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How Is Washington Responding??



Recent Press Headlines

Food safety czar pleads for Congress to take up proposal
By Anna Edney [CongressDaily](#) January 25, 2008

While some government and industry officials had assumed FDA's plan to combat holes in the country's food safety system had been dismissed by Congress, it does appear one leading senator on the subject, who is also a Democrat, is giving it serious consideration.

FDA's food safety czar was exasperated Thursday that Congress hadn't moved to give the agency powers it sought in November. The proposal was meant to improve FDA's ability to police food, only to be told the ball is in HHS' court.

Recent Press Headlines

March 15, 2009: President Obama formed a Food Safety Working Group to “upgrade our food safety laws for the 21st century.” He named former New York City health chief Margaret A. Hamburg as his Food and Drug Administration commissioner.

<http://www.washingtonpost.com/wp-dyn/content/article/2009/03/14/AR2009031401600.html>

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U.S. Congress - New Legislation

- Rep. Dingell (?) FDA Globalization Act (H.R. 759)
- De Lorio (?)
- Senatory Durbin (?) - FDA Food Safety Modernization Act (S. 510)
- Costa (?) Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009 (H.R.1332)
- Waxman (?)

	<u>Existing Law:</u> <u>Food, Drug, & Cosmetic Act</u> ^[1]	<u>Dingell H.R. 759</u> <u>FDA Globalization</u> <u>Act of 2009</u>	<u>Durbin S. 510</u> <u>FDA Food Safety</u> <u>Modernization Act</u>
Records Access & Traceability	<p>FDA currently has access to records when there is reasonable belief that there is a threat of <u>Severe Adverse Health Consequences or Death (SAHCOD)</u> with written instruction from FDA District Director.</p> <p>FDA currently requires records tracing food <u>one step forward and one step back</u>, excluding restaurants and farms.</p>	<p>Gives FDA easier record access to <u>all records needed to determine if food adulterated or misbranded during routine inspection, no written request required</u>.</p> <p>Electronic records; Extend one-forward one-back to farms and restaurants; <u>Grower/lot/date for raw agricultural commodities</u></p>	<p>Closer to current law, <u>records access if threat of Severe Adverse Health Consequences or Death to Humans or Animals</u>.</p> <p>Traceability pilot project, then proposed rule; limited to produce</p>
Food Safety Plan	<p>Not required under existing law.</p>	<p>Requires <u>hazard analysis and food safety plan- no exemption for warehouses</u>.</p>	<p>Requires <u>hazard analysis and food safety plan</u>. FDA has authority to <u>grant exemption for warehouses and pet food</u>.</p>

	<u>Existing Law:</u> <u>Food, Drug, & Cosmetic Act</u> ^[1]	<u>Dingell H.R. 759</u> <u>FDA Globalization</u> <u>Act of 2009</u>	<u>Durbin S. 510</u> <u>FDA Food Safety</u> <u>Modernization Act</u>
Inspection frequency	Current law does <u>not</u> establish a <u>required frequency</u> of inspection.	Inspections are required <u>at least every 4 years</u> .	<u>Once every 4 years</u> for low risk facilities, <u>Annual inspections</u> required for <u>high risk facilities</u> .
Enforcement Authority			
<u>Subpoena authority</u>	None	Yes	No
<u>Mandatory recall</u>	None	Yes, for injury or illness	Yes, for Class I recall
<u>Civil penalties</u>	Limited to pesticides	\$100K individual; \$500K company; each day = separate offense; opportunity for a hearing	Only for <u>failure to comply with mandatory recall order</u> , 250K per entity not to exceed \$500K
<u>Suspension of Reg. Admin. Retention</u>	None Yes, if FDA has " <u>credible evidence</u> " or information indicating that a threat of SAHCOD exists.	Yes, if delay/deny/limit inspection Yes, if FDA has " <u>reason to believe</u> " that a food is adulterated or misbranded.	Yes, if " <u>reasonable probability</u> " of SAHCODA Yes, if FDA has " <u>reason to believe</u> " that a food is adulterated or misbranded.

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<u>Imports</u>			
Third Party Certification	None	Mandatory for imports; FDA would accredit third parties.	Required for imports <u>if FDA determines necessary</u> ; required to participate in fast lane.
Foreign Supplier Verification	None	No	<u>Yes</u> , each importer verifies that the imported food is in accordance with U.S. requirements.
User Fees	None	Registration; FDA would set fees to fund the cost of increased inspection. Importers would be required to pay an <u>annual fee of \$10,000</u> . Requires fees to cover mandatory export certificates.	No registration fees; but <u>fees would be imposed to cover the costs of reinspection and recalls</u> . Voluntary fee for Qualified Importer Program Voluntary fee to cover export certificates

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Country of Origin Labeling (COOL)	Customs law currently requires every imported food to indicate country of origin, except agricultural products. USDA law requires retailers to list COOL for produce, peanuts, fish, beef, lamb, and pork - processed food products are exempt.	Expands COOLs. <u>Requires FDA approved label to indicate where final processing was conducted.</u> Requires company website to list country or origin for each ingredient.	No new requirements
Reportable Food Registry	In 2007, the Bioterrorism Act requires registered food facilities to report when there is a reasonable probability that food will cause serious adverse health consequences or	Expands the registry to require that <u>any person, other than an individual consumer</u>	No new requirements

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Lab Testing	None	<u>Federal labs, labs certified by FDA or certified by third parties must be used for all required food testing (including import certificates, to comply with an FDA order or as otherwise required by FDA).</u> <u>Lab results would have to be transmitted to FDA in electronic format.</u>	<u>Either federal labs or accredited by a registry created by FDA must be used for all required food testing (including when FDA issues an Import Alert or FDA suspects a food safety problem).</u> <u>Lab results must be provided directly to FDA.</u>

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What Should the Spice Industry Do?

- Wait for Federal Food Safety Legislation - Dingle, Durbin, Waxman, Costa, De Lorio, Oh My
- Accept individual company standards for Production, Transport, Processing and Packaging Criteria - example - McCormick
- Utilize Existing Private Standards Bodies to Establish Production, Transport, Processing and Packaging Criteria - ANSI, USP, ISO, etc
- Develop Internal Industry Standards to Establish Production, Transport, Processing and Packaging Criteria - ASTA

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What Does ASTA Have to Offer?

- Defect Action Levels
- Spice Grinding & Drying for Noxious Weed & Insect Control
- Uniform Analytical Methods
- ASTA Approved Laboratory Program for detection of adulteration
- ASTA Standardization Contracts
- ASTA Cleanliness Specifications

GAPS:

- **Reconditioning**
- **Non-ASTA Compliant Imports**

Global Food Safety Initiative (GFSI)



American National Standards Institute



What Do They Have
to Offer



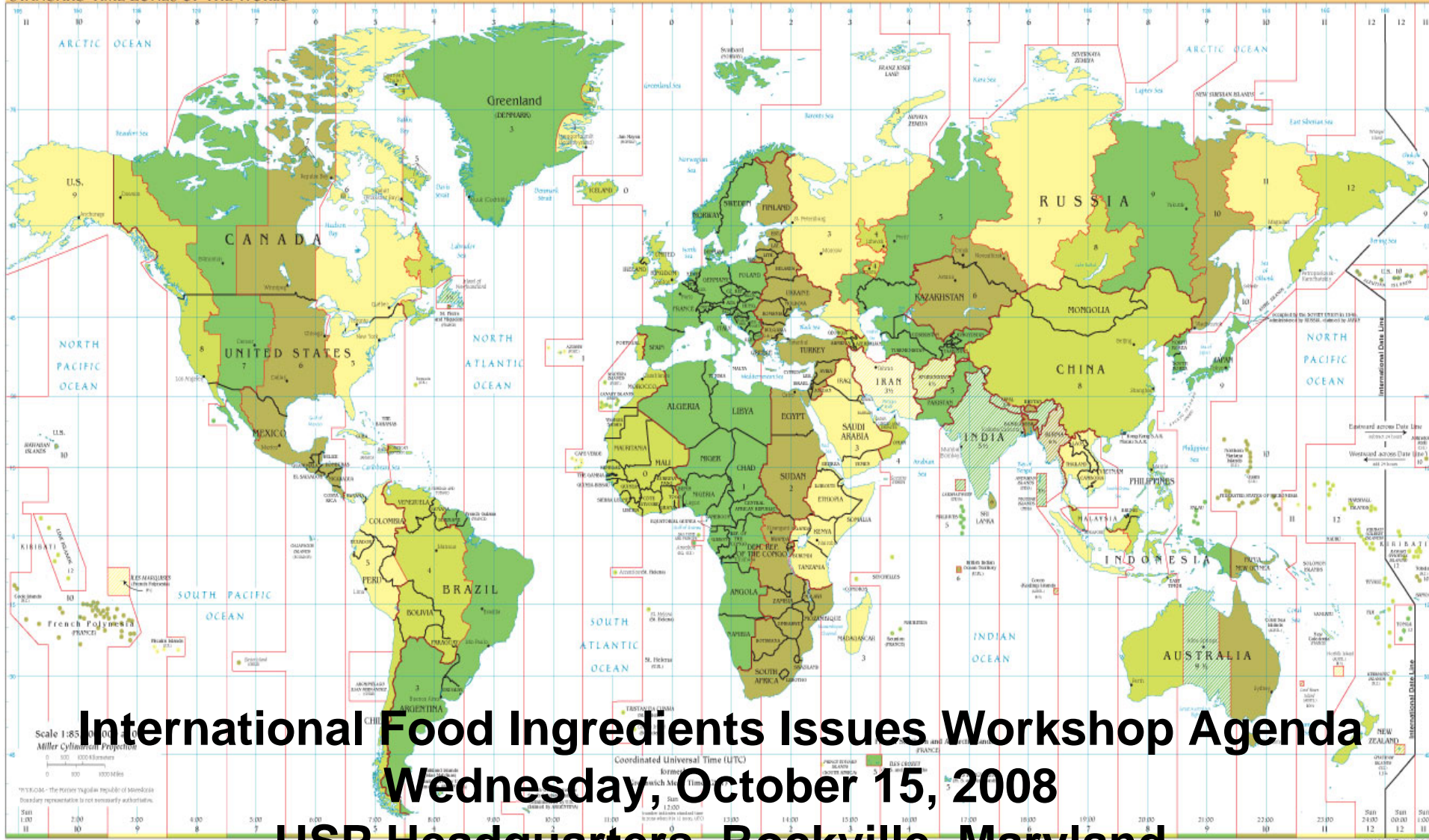
U.S. PHA



FAO/WHO Food Standards

CODEX alimentarius

STANDARD TIME ZONES OF THE WORLD



International Food Ingredients Issues Workshop Agenda

Wednesday, October 15, 2008

USP Headquarters, Rockville, Maryland

<http://www.usp.org/meetings/agendas/foodIngredientsWorkshop2008-10-15.html>

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EUROPE



What Do They Have to Offer

International Food
Ingredient Issues:

Europe

Manfred Lützow, saqual
GmbH

*Rockville, MA, October 15,
2008*

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What Do They Have to Offer

MERCOSUR

Challenges to Achieving a
Harmonized Regulatory
Framework

*Susana Socolovsky, Ph.D.
Pentachem SRL*

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What Do They Have to Offer



www.theodora.com/maps

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Regulations

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UNIVERSITY

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www.theodora.com/traps

What Do They Have to Offer

Current Food
Issues -
Australia
Dr. Simon Brooke-
Taylor, Australia

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Any Offers??

Thank
You

