

Regulatory Update

IDFA's Ice Cream Technology Conference

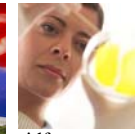
February 26-27, 2009

Cary Frye

Vice President, Regulatory Affairs

International Dairy Foods Association

Washington, DC



www.idfa.org

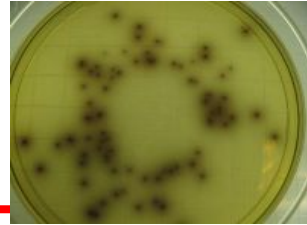
Agenda

- Status of FDA Draft Guidance for the Industry Control of *Listeria monocytogenes*
- Possible Food Safety Legislation
- Labeling of Carmine and Cochineal Extract
- Allergen Advisory Statements
- Opinion on "natural" claims for HFCS



FDA Guidance on *L. monocytogenes*

- FDA announcement Feb 7, 2008
- Draft FDA Compliance Policy Guidelines - Guidance for FDA Staff *Listeria monocytogenes*
- Draft Guidance for the Industry Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods



FDA Guidance on *L. monocytogenes*

- Draft FDA Compliance Policy Guidelines - Guidance for FDA Staff *Listeria monocytogenes*
 - A RTE food **does not support the growth** of *L. monocytogenes* if the food:
 - pH that is less than or equal to 4.4; or
 - customarily held and consumed in a frozen state; or
 - water activity that is less than 0.92; or
 - processed using an effective listeristatic control measure (e.g., an antimicrobial substance or a combination of factors such as pH, water activity, and antimicrobial substances)
 - FDA may regard a RTE food that does not support the growth of *L. monocytogenes* to be adulterated within the meaning of when *L. monocytogenes* is present at or above **100 colony forming units per gram of food (cfu/g)**



FDA Guidance on L. monocytogenes

- Draft FDA Compliance Policy Guidelines - Guidance for FDA Staff *Listeria monocytogenes*
 - A RTE food that **do not support the growth** of *L. monocytogenes*
 - **Ice Cream and other frozen desserts**
 - **Does not included ice cream mix until frozen for consumption**
 - **FDA will review available evidence on a case-by-case basis to determine proper classification of food**
 - **Enforcement could still result if food is deemed to be prepared, packed or held in unsanitary conditions**
 - A RTE food that **supports the growth** of *L. monocytogenes* will continue to be subject to 1cfu/25 grams or .04 cfu/gram level



FDA Guidance on L. monocytogenes

- Draft Guidance for the Industry Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods
 - Compliments Current Good Manufacturing Practices (cGMP)
 - Applies to both foods that support and do not support the growth of Lm.
 - Although Draft guidance is considered nonbinding recommendations, FDA explicit connection to specific GMP regulations could result in potential enforcement for non compliance



FDA Guidance on L. monocytogenes

- Draft Guidance for the Industry Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods
 - Formulation of RF-RTE foods;
 - Listericidal measures
 - Controls for ingredients and raw materials
 - Storage practices
 - Personnel practices including recommended training
 - Design, construction, and operation of plants and equipment
 - Sanitation controls
 - Transportation controls
 - Monitoring critical surface areas
 - Sampling of finished RF-RTE foods
 - Corrective actions
 - Record retention.



FDA Guidance on L. monocytogenes

- Draft Guidance for the Industry Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods
 - Monitoring critical surface areas
 - Written Plan
 - Critical Food-Contact Surfaces
 - » Once per week so all areas are tested monthly - min. 5 sites in each production line
 - » Prior to clean up, but not earlier than mid prod.
 - Critical Non-Food-Contact Surfaces
 - » All areas once every two weeks so each areas is tested quarterly - min 5 sites each area
 - » Taken any time

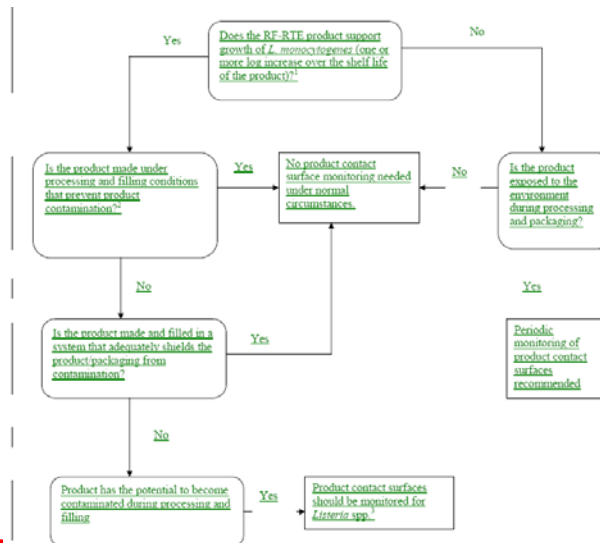


FDA Guidance on *L. monocytogenes*

- Draft Guidance for the Industry Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods
 - Sampling of finished RF-RTE foods
 - Written plan
 - Periodic collection for historical reference and validation
 - Corrective actions
 - *Listeria* species = further testing or assume Lm
 - Conduct additional sampling and testing
 - Clean and sanitize surface or area
 - Determine if food support growth of Lm
 - Reprocess, animal feed, destroy, recall if distributed
 - Record - retain for two years

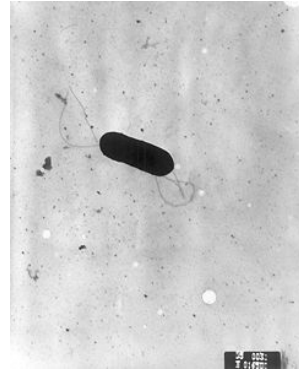


FDA Guidance on *L. monocytogenes*



FDA Guidance on *L. monocytogenes*

- IDFA worked with food trade associations to provide suggested risk based edits to FDA Guidance
- Final guidance pending



Food Safety Legislation

- HR 759 - Food & Drug Administration Globalization Act
 - Third party certification
 - FDA would accredit foreign governments, states and third parties to certify food facilities - audited 4 yrs
 - User fees
 - Flat registration fee \$2,000 per facility in registration
 - Importers fee \$10,000
 - Records Access
 - Access to copy records during an inspection “needed to assist” in determining whether food is adulterated or misbranded.” without written request



Food Safety Legislation

- HR 759 - FDA Globalization Act
 - Trace back
 - Standardized electronic records for the record keeping provisions of the Bioterrorism Act.
 - Source identification (including grower, lot, and harvest and packing dates) would be required for raw agricultural products.
 - Lab Results
 - Require testing (where problems previously have been identified) be conducted by certified labs and all results sent to FDA



Food Safety Legislation

- HR 759 - FDA Globalization Act
 - Administrative detention
 - Lower legal standard from “credible evidence or information indicating [that the article of food] presents a threat of serious adverse health consequences or death” to “reason to believe [that the article of food] is adulterated or
 - Preventative Controls
 - Required the hazard analysis to identify preventive controls - recall and traceback procedures, supply chain management. Give FDA authority to evaluate the effectiveness of these plans and to establish/enforce



Food Safety Legislation

- HR 759 - FDA Globalization Act
 - Certified Labs
 - FDA to establish a program for the certification of laboratories (not third parties)
 - Risk Based Inspections
 - Establish a risk-based inspection schedule - requiring facilities to be inspected at least once every four years
 - Country-of-Origin Labeling
 - On the product label for a finished food and on the company's website for all ingredients.



Food Safety Legislation

- HR 759 - FDA Globalization Act
 - Notification/Mandatory Recall
 - Notification of recall to FDA
 - Mandatory recalls if a voluntary recall is refused
 - Standard for notification and mandatory recall would be tied to if food product “may result in illness or injury,” without regard to its seriousness
 - Import restrictions
 - Deny entry to any import - facility or foreign government refuses to consent to an investigation where food from the facility or country is linked to a foodborne illness outbreak or is otherwise adulterated



Carmine and Cochineal Extract

- FDA is aware of 35 cases of hypersensitivity, including anaphylaxis, to carmine or cochineal extract
 - FDA believes labeling is necessary to protect public health
- Under the authority granted to FDA by FALCPA, FDA has finalized that all products, including ice cream, containing these color additives list them by their common and usual name, "carmine" or "cochineal extract"
 - Cannot use generic "artificial color" or "color added"
 - no need to declare "color additives are derived from insects" as petitioned by CSPI



- Final Rule issued 1/5/09 - Effective 1/5/2011
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Allergen Advisory Statements

- FDA held public meeting on Sept 2008
- Solicit views from consumers and industry on Current Trends in the use of allergen advisory labeling
 - Use
 - Effectiveness
 - Consumer Perception
 - "may contain___" "Produced on equipment/in a facility with___"



- IDFA comments - allergen advisory labeling should be strictly voluntary
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Allergen Advisory Statements

- IDFA urged - allergen risk assessment to determine what levels of allergenic protein can cause reactions in allergic individuals and use the risk assessment results as the basis for threshold levels
- Validated analytical testing is needed
- **No indication if FDA might proceed with proposed rules**



Natural Labeling Claims

- FDA issued an opinion letter - term "natural" can be used to describe products containing High Fructose Corn Syrup (HFCS)
 - Means nothing artificial (including artificial flavors) or synthetic (including all colors, regardless of source)
 - Enzyme used to make HFCS uses synthetic fixing agent "glutaraldehyde" which is further removed in processing
- FDA would not object to foods using HFCS being "natural" depending on acids used and formulation



Questions

