GMA

Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

GMA's Role in FSMA Rulemaking

Warren Stone, MBA
Senior Director of Science Policy,
Compliance & Inspection
Grocery Manufacturers Association

www.gmaonline.org

GMA History with FSMA

- Jan. 21, 2010: **GMA Urges Senate to Vote on Food Safety Bill**
- In a ... letter to Senate Leadership, GMA ... today urged the Senate to quickly schedule a vote on S. 510, the FDA Food Safety Modernization Act of 2009.
- Aug. 24, 2010: **GMA Urges Senate to Vote on Food Safety Bill** GMA today urged the Senate to schedule a vote on S. 510, the FDA Food Safety Modernization Act, as soon as possible.
- Nov. 24, 2010: **GMA Calls for Passage of Food Safety Bill** GMA ... on behalf of America's food retailers and manufacturers, called for the passage of S. 510, the FDA Food Safety Modernization Act.
- Nov. 30, 2010: **GMA Applauds Senate for Passage of Food Safety Bill**

Grocery Manufacturers Association Applauds President Obama for Signing Food Safety Legislation

1/5/2011

(WASHINGTON, DC) The Grocery Manufacturers Association (GMA) today issued the following statement in response to President Barack Obama signing The FDA Food Safety Modernization Act:

"On behalf of GMA, … I would like to thank President Obama for his leadership and dedication to strengthening and modernizing America's food safety system," said GMA President and CEO Pamela G. Bailey. "Today's bill signing marks a historic moment for our country – as it represents the most comprehensive reform of our nation's food safety laws in more than 70 years. This landmark legislation provides FDA with the resources and authorities the agency needs to help strengthen our nation's food safety system by making prevention the focus of our food safety strategies..."

Pamela Bailey, CEO GMA

Industry Food Safety Practices:

INFORMING THE FDA
FSMA RULE MAKING PROCESS

Contains comments from GMA members on suggested successful industry approaches to food safety.

Published pre-proposed rules.

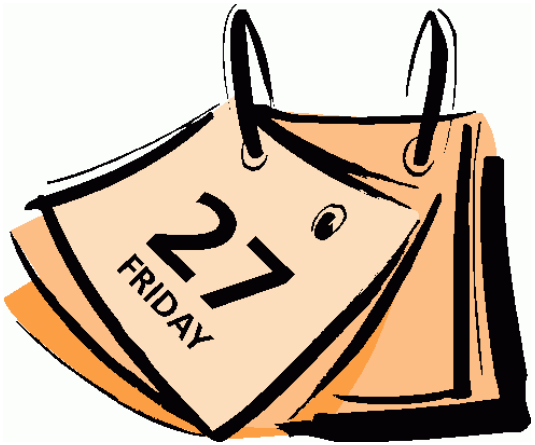
Transparency & Interaction

- FDA listened
- Responded to GMA/Industry concerns

Jan 2013 to September 2015: GMA FSMA senior management and SMEs hold approximately 70 face to face meetings with FDA FSMA Leadership Team.

To date, probably 100.

Fast Forward Three Years



The GMA FSMA Team Doth Decree

1. Preventive controls are general, flexible, and not necessarily CCP-based
2. Oversight of preventive controls shalt be flexible, incorporating a "sliding scale"
3. Thou shalt conduct zone-1 testing only when appropriate
4. Supply chain management shalt focus on both ingredient risk and supplier risk
5. Thou shalt not have Part 11 compliance, remote access to records, or facility profiles
6. Supplier verification audits shalt not trigger bells and whistles of 3PAC.
7. Thou shalt exempt warehouses from 117 requirements,
8. Thou shalt modify warehouse requirements for TCS foods
9. Requirements for diversion to animal feed shalt be minimal
10. Management oversight for PCs shalt be commensurate with their roles in the facility's food safety system

And 20 More

20. Replace “significant hazards” with “hazards requiring a preventive control”
21. Add to management oversight, “and its roles in the facility’s food safety system”
22. Allowance for “Exception” monitoring
23. Corrective actions tied to both nature of the preventive control and the “nature of the hazard”
24. No requirement to review consumer complaints
25. Routine testing by accredited labs does NOT trigger direct reporting to FDA
26. No validation for sanitation, allergen controls, supply chain management or recall plans
27. Corrections (slightly expanded)
28. Flexibility to not have annual supplier audit for SAHCODHA hazards if justifiable
29. No FDA access to audit reports, just significant findings and corrective actions

30. No supplier verification for R & D samples
31. Permissible role for brokers, distributors and aggregators in supplier verification
32. GMPs use term “allergen cross-contact” for food allergens
33. No “protection” needed for RACs stored in outside vessels destined for further processing
34. No “zero tolerance” for allergen control in plant
35. Recognized flexibility to use dry cleaning methods with no sanitizing steps
36. Warehouse exemption (TCS narrowed)
37. Exemption for certain storage facilities, such as grain elevators and warehouses, that store only RACs (other than fruits and vegetables)
38. Animal food diversion does NOT apply to facilities that are registered ONLY with FSIS
39. Compliance dates for supplier verification staggered to take into account when smaller companies become subject to the new requirements

Food Defense/Intentional Adulteration

Mitigation Strategies To Protect Food Against Intentional Adulteration

GMA Recommendations in Final IA Rule

1. Rule deals with MS. No FMS, no BMS. Title change eliminated FMS.
2. MS are the product of a vulnerability assessment
3. Flexibility: rule includes in many places the terminology, "as appropriate to …, taking into account the nature of each such mitigation strategy and its role in the facility's food defense system."
4. No codified Key Activity Types – available through guidance.
5. Rule no longer focuses on acts of terrorism and broad economic disruption. Has broader focus on widespread public health harm.
6. Other facility programs such as personnel safety may be included as part of vulnerability assessment (with some limitations).
7. FD monitoring may employ exception reporting
8. No Part 11 recordkeeping requirements
9. Removed term "reasonably foreseeable" and indicate in preamble that it does not apply to food defense.
10. Holding, warehousing, is exempt (except for bulk liquids).

Future opportunities

- "Tiered Inspections"
- 21 CFR Part 117.136 – written assurances

QUESTIONS???