Hogan Lovells

What's Safe? What's Natural?

International Sweetener Colloquium

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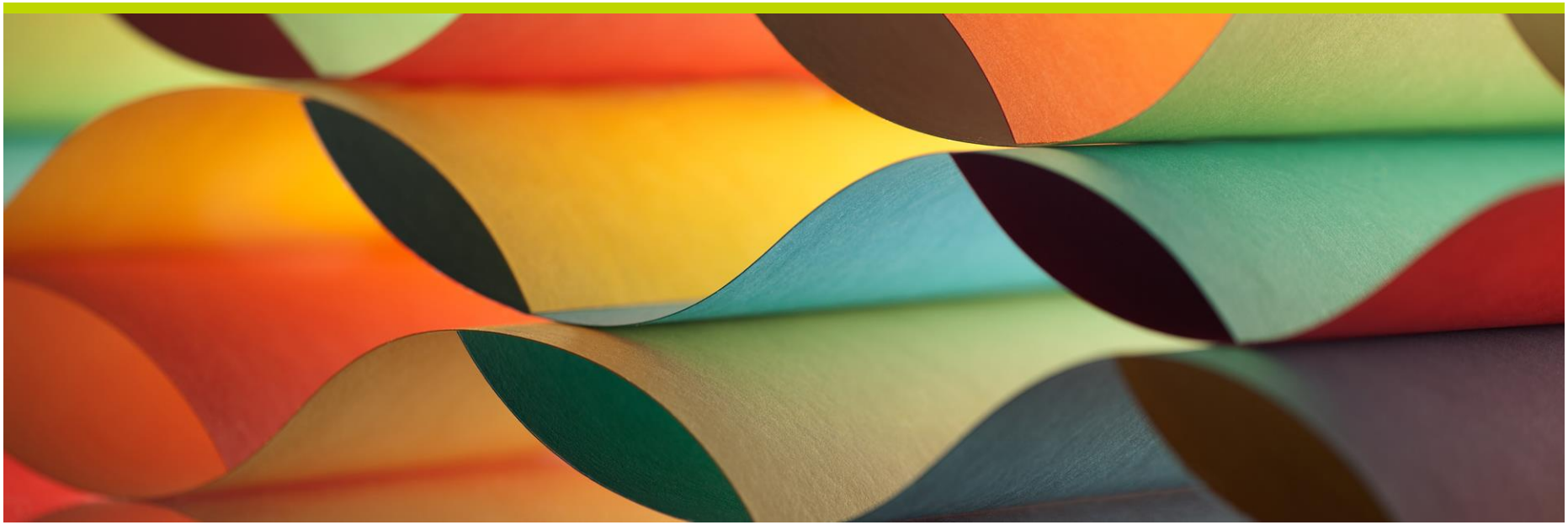


Agenda

- Overview of FSMA
- Summary of Major Provisions
- “All Natural” Update
- Questions and Discussion

FDA Food Safety Modernization Act (FSMA)

Background

- FDA Food Safety Modernization Act (FSMA) became law January 2011
  - Adopted following several high profile foodborne illness outbreaks
- FDA is charged with implementing the law
  - Issues proposed regulations (tentative conclusions)
  - Then issues final regulations (rules you must comply with)

Key Themes

- Modernization
  - Preventive controls (built on HACCP principles)
  - Updated GMPs
  - Food defense plans
- Accountability
  - Greatly increased records access by FDA
  - Supply chain management of domestic and foreign suppliers
  - Reinspection fees
- Oversight
  - More frequent government inspections, both in the U.S. and internationally
  - FDA authority to suspend registration (shutting down operations) and require recalls

Status of FSMA Implementation

- FDA has issued 5 final rules:
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Produce Safety
  - Foreign Supplier Verification Program
  - Accreditation of Third-Party Auditors
- There are 2 more to come:
  - Sanitary Transportation of Food
    - Expected in early April 2016
  - Food Defense/Intentional Adulteration
    - Expected in early June 2016

Timeline

- March 31, 2016
  - FDA must issue final rule for sanitary transportation of food
- May 31, 2016
  - FDA must issue final rule for food defense
- **September 19, 2016**
  - **Compliance required for preventive controls for companies with 500+ FTE employees**
- **Late May 2017**
  - **Compliance required for FSVP**

Overview of Major Regulations

Preventive Controls for Human Food

- Updates and revised the cGMPS in part 110
- Creates new regulations requiring food safety plans (based on HACCP principles)
  - Hazard Analysis
  - Identify and implement preventive controls to “significantly minimize or prevent” (SMOP) “significant” hazards
  - Management components
    - Monitoring
    - Verification
      - Validation
      - Testing
    - Validation
    - Corrective actions
    - Reanalysis
  - Supplier verification
- Everything documented in records for FDA review

Preventive Controls for Animal Food

- Manufacturers of animal food need to
  - Follow new GMPs for animal food
  - Implement food safety plans, just like preventive controls for human food
- Human food by-product diverted to animal food
  - Follow human food requirements up to diversion
  - Follow certain holding and distribution GMPs for diverted by-product (modified requirements)
  - Modified requirements would not apply to adulterated product or product subject to processing (heat, drying, pelleting)

Foreign Supplier Verification Program

- Parallel to supplier verification requirements under preventive controls
- Applies to “importers” of “food” when a food has a “hazard requiring a control” controlled by the supplier
  - US owner or consignee of the food when imported
- Importer determines appropriate verification activities based on a risk evaluation that considers both risks associated with the food and the supplier
  - Activities could include audits, testing and sampling, review of food safety records
  - Default use of annual onsite audits for SAHCOHA hazards
- All activities would be documented and subject to FDA review

Produce Safety

- Rather than issue standards for categories of produce considered high-risk, applies to almost all produce, except:
  - Specific commodities rarely consumed raw (e.g., potatoes)
  - Produce subject to a kill step through commercial processing, so long as documentation kept (e.g., oranges for juice)
- Sets standards to control specific hazards
  - Worker Training and Health and Hygiene
  - Agricultural Water
  - Biological Soil Amendments
  - Domesticated and Wild Animals
  - Equipment, Tools, and Buildings
  - Sprouts
- Generally, more like cGMPs than HACCP

Accreditation of Third Party Auditors

- Would create an auditing system for importers using the Voluntary Qualified Importer Program (VQIP) or for imports that must be accompanied by Mandatory Import Certification

Food Defense/Intentional Adulteration

- Would require food defense at registered food facilities
  - Warehouses expected to be exempt
- FDA is trying to target the sophisticated insider – someone with legitimate access to the facility
- Significant revisions to proposed rule are expected in the final rule

Sanitary Transportation of Food

- Establishes good transportation practices applicable to all transportation operations
- Sets more specific obligations for shippers, carriers, and receivers in their respective roles
- FDA is particularly focused on:
  - Temperature control
  - Proper cleaning between loads (for both sanitation and allergen control purposes)
  - Protecting food during transport (e.g., preventing contamination from cross-contact)
  - Any adulteration, including spoilage
- Exempts shelf-stable fully enclosed food
- FDA views the proposal as consistent with current industry practices

Which Rules Apply?

- Registered Food Facilities (manufacturers, processors, warehouses, re-packers, distributors, ingredient suppliers)
  - Preventive Controls
  - Food Defense Plans
- "Importers"
  - FSVP
- Farms
  - Produce Safety Rule
  - Preventive Controls (sometimes)
- Shippers, Carriers, Receivers
  - Sanitary Transportation of Food

Preventive Controls Compliance Dates

Business Type	Time Until Compliance Date	Compliance Date
Businesses with 500+ FTE Employees	1 year	September 19, 2016
Small Businesses (<500 FTE Employees)	2 years	September 18, 2017
Facilities subject to the PMO	3 years	September 17, 2018
Qualified Facilities (including very small businesses)	3 years	September 17, 2018

Preventive Controls Supplier Verification Compliance Dates

Business Type	Compliance Date
Businesses with 500+ FTE Employees	The later of: • March 17, 2017, or • 6 months after a supplier is required to comply with PC/produce rule (if applicable)
Small Businesses (<500 FTE Employees)	The later of: • September 18, 2017 • 6 months after a supplier is required to comply with the PC/produce rule (if applicable)
Facilities Subject to the PMO	September 17, 2018

FSVP Compliance Dates

- Importers need to comply by the latest of the following dates:
  1. 18 months after publication of the final rule (May 2017);
  2. For importation of food from a supplier subject to PC or the produce rule, 6 months after the foreign supplier is required to comply with the relevant regulations; or
  3. For an importer that also is subject to the supply-chain program provisions in the PC rule, the date the importer (as a receiving facility) is required to comply with the supply-chain program provisions of the PC regulation

The Future is Now!

- Most significant food safety regulations of our professional lifetime – affects every food company
- Establishing and maintaining a food safety culture is essential in today's environment
- Get help from legal counsel
- Key Steps:
  - Educate your company leadership and employees
  - Conduct gap analyses
  - Train for and implement good recordkeeping practices
  - Self-audit before the FDA comes

“All Natural” Update

FDA Considers Defining “Natural”

- In response to citizen petitions and requests from courts that FDA define the term “natural,” FDA issued a notice in Nov. 2015 seeking comment on whether/how it should define natural
- FDA plans to coordinate with FSIS
- Comments originally due Feb. 10, 2016
- Deadline extended to May 10, 2016

Key Questions in Notice

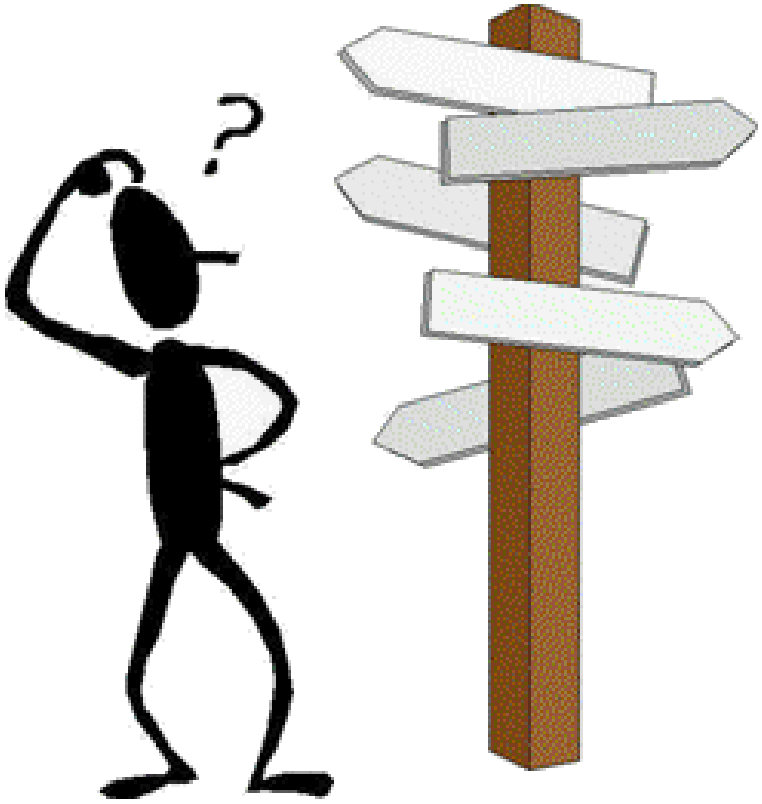
- Should FDA define “Natural” through rulemaking?
- Should FDA prohibit “Natural”?
- Should only raw agricultural commodities or single ingredient foods or unprocessed foods be able to bear the term?
- If multi-ingredient foods should qualify, what ingredients should disqualify a food from bearing the term?
- Should FDA consider production practices used in agriculture (e.g., genetic engineering, use of pesticides, animal husbandry)?
- Should FDA consider the manufacturing process or the manner in which an ingredient is produced or sourced?
- What does natural mean? Healthy? Nutritional benefit?
- Do consumers confuse “Natural” with “Organic”?

Challenging Issues Raised

- How should FDA treat:
  - A food that is or contains an ingredient(s) derived from GE crops?
  - More than minimally processed ingredients?
  - Synthetic vitamins and minerals?
  - Pasteurization, fermentation, irradiation, hydrolysis?
  - Foods derived from crops treated with pesticides, or that may contain low levels of pesticide residues?
- What is synthetic?
- What is more than minimal processing?
- Does natural mean unprocessed or raw?

Can We Align on a Common "Natural" Definition?

- Already 4,500+ comments received
- Diverging points of view
  - Conventional food industry perspective
  - Organic food industry perspective
  - Natural food industry perspective
  - Consumer group perspective
- Expect FDA to require substantial time to consider comments



Effects on Current Lawsuits

- Numerous lawsuits underway challenging the use of “All Natural” claims
- Defendants might use FDA notice to raise “primary jurisdiction” challenges
  - At least one such motion is already pending
  - Others likely to follow
- Anticipate mixed court rulings
- Similar experience with evaporated cane juice litigation

Questions?

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