Assuring Safety in Petfood Ingredients: New Requirements Under the Food Safety Modernization Act

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FSMA Topics of Interest

- Hazard Analysis and Preventive Controls
- Foreign Supplier Verification Program
- Supplier Approval and Verification
- High-Risk Foods
- Traceability

Hazard Analysis

- Identify known or reasonably foreseeable hazards for each food type to determine whether there are hazards that are reasonably likely to occur.
- Must consider hazards that may occur naturally or may be unintentionally introduced

Hazards

- Biological e.g., parasites, environmental pathogens and other microorganisms of public health significance
- Chemical e.g., pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens
- Physical and Radiological

Hazard Analysis

- Determine whether the hazards are reasonably likely to occur including an assessment of the severity of the illness or injury if the hazard were to occur
- Must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging

Preventive Controls

- Process controls
- Sanitation controls Cleanliness of food contact surfaces; prevention of cross-contact & cross-contamination
- Recall plan

Recall Plan

- Written procedures that describe steps to *directly* notify the direct consignees of the food being recalled;
  - Notify the public when appropriate to protect public health;
  - Conduct effectiveness checks to verify that the recall is carried out; and
  - Appropriately dispose of recalled food

Preventive Controls

- Must be written
- Must include, as appropriate to the facility and the food: Parameters associated with the control of the hazard, and
- The maximum or minimum value, or combination of values

Monitoring

- Facility must have written procedures, including frequency they are to be performed, for monitoring the preventive controls
- Monitoring must be documented in records subject to verification

Corrective Actions

- Facility must establish and implement written corrective action procedures to identify and correct a problem with implementation of a preventive control
- Ensure affected food is evaluated for safety
- Ensure adulterated food is prevented from entering into commerce

Verification

- Confirmation that:
  - Monitoring of preventive controls occurred
  - Corrective actions were taken if preventive control failed
  - Preventive controls were validated

Validation

- Collecting and evaluating scientific and technical information (or conducting studies) to demonstrate the preventive controls are effective in controlling the hazards
- Must be performed prior to implementation or within 6 weeks of production

Reanalysis of the Food Safety Plan

- At least every 3 years
- Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is ineffective

Required Records

- Written food safety plan
- Records that document monitoring of the preventive controls
- Records that document corrective actions
- Records that document verification
- Records that document training for the “qualified individual”

Foreign Supplier Verification Program

- Proposed rule to be published soon
- Requires importers to verify that their foreign suppliers produce food at the same level of public health protection as required by domestic producers by:
  - Monitoring records for shipments
  - Lot-by-lot certifications of compliance
  - Annual on-site inspections
  - Checking the hazard analysis and risk-based preventive control plans
  - Periodically sampling and testing shipments.

Import Certification

- Requires that certain imported foods and ingredients which pose a safety risk must be accompanied by an ***Import Certification***
- Risks include
  - Inherently risky foods
  - Country/region of origin
  - Comparability of food safety regulation in country of origin to US
- Certifying official can be
  - Representative of the foreign government
  - Agency of the foreign government
  - Third party accredited to certify

Import Certification
Impact on Industry

- Loss of foreign suppliers that cannot obtain certification
- Potential disruption to multiple supply chains

Supplier Approval and Verification Program

- Not required under FSMA
- FDA requesting comments whether to require supplier approval and verification as part of preventive control regulation

Supplier Approval and Verification Program

- Facility receiving raw materials or ingredients ensures that supplier has implemented preventive controls to prevent hazards reasonably likely to occur
- Supplier controls not required if hazard is controlled by receiving facility

Supplier Approval and Verification Program

- Costs per supplier
  - Annual audit: $0 - $5,000
  - Testing raw materials and ingredients: $7,000 - $90,000

Supplier Approval and Verification Program
Comments Requested

- When is supplier approval and verification appropriate?
- Should requirements be general or specific?
- Should SAVP require a written list of approved suppliers?
- Should SAVP consider regulatory history of suppliers? *e.g.* warning letters, import alerts, recalls, etc.

Supplier Approval and Verification Program
Comments Requested (cont.)

- Are there circumstances when a SAVP should not be required because receiving facility controls identified hazards?
- Should the level of verification be commensurate with the risk?
- Should the requirements for audits be specified including qualifications of auditors, content of the audit, compliance with receiving facility's food safety plan?

Supplier Approval and Verification Program
Comments Requested (cont.)

- Should verification activities take place at predefined frequencies, *e.g.* initially, annually, or periodically?
- Should different requirements apply to suppliers that are “qualified facilities”?
- Should the records requirement for suppliers be specified?
- Can an FDA or State inspection substitute for a third party audit?
- Should the receiving facility be required to take corrective actions if the supplier is not controlling hazards?

High Risk Foods

- Requires facilities to keep additional records for foods designated high-risk by the FDA
- FDA must publish proposed and final rules before requirement goes into effect (2-4 years)

High Risk Foods Designation

- High-risk designation is based on:
  - Safety risks of the food including history and severity of outbreaks
  - Likelihood of contamination due to the nature of the food or processes used to produce food
  - Point in the manufacturing where contamination is most likely to occur

High Risk Foods Designation (cont)

- High-risk designation is based on:
  - Steps in manufacturing to reduce the possibility of contamination
  - Likelihood that consumption will result in illness
  - Severity of illness, including health and economic impacts

High Risk Foods Recordkeeping

- Recordkeeping requirements shall:
  - Relate only to information that is reasonably available and appropriate
  - Be based on science
  - Not prescribe specific technologies for records maintenance
  - Ensure health benefits outweigh costs of compliance

High Risk Foods Recordkeeping (cont)

- Recordkeeping requirements shall:
  - Be scale appropriate for facilities of various sizes regarding costs and recordkeeping burdens
  - Not require creation of duplicate records
  - Minimize number of different recordkeeping systems for facilities processing 2 or more types of food
  - Not require a change of business systems to comply with recordkeeping mandates
  - Allow storage of records at a central or reasonably accessible location

High Risk Foods Recordkeeping (cont)

- Recordkeeping requirements shall ***not require***:
  - A full record of the complete previous distribution history of the food from the point of origin
  - Records of recipients beyond the immediate recipient
  - Product tracking to the case level

Traceability

- FSMA requires FDA to conduct pilot projects to rapidly identify recipients of food that may cause illness
- Pilots designed to explore and evaluate methods and technologies for tracing foods
- FDA will use the pilot project data to initiate rulemaking on record requirements for “high-risk” foods

Traceability

- Pilots must:
  - Reflect the diversity of the food supply
  - Be practical for facilities of varying sizes, including small businesses
  - Include different types of FDA-regulated foods that have caused significant outbreaks from 2006-2010
- FDA must:
  - Consult with USDA, state public health agencies, food industry, and consumer organizations
  - Assess the costs and benefits of traceability systems

Traceability

- Institute of Food Technologists (IFT) conducted pilot projects under FDA contract
  - Tomatoes grown in fields and greenhouses
  - Frozen Kung Pao-style dishes that contain peanuts, red pepper, and chicken
  - Jarred peanut butter and dry, packaged peanut and spice
- Foods in pilots have caused numerous outbreaks from domestic and imported products and represent complex food supply chains

Traceability

- Pilot projects have been completed and published
- FDA is required to report to Congress on the findings of the pilot projects with recommendations for improving tracing of food

Traceability Systems

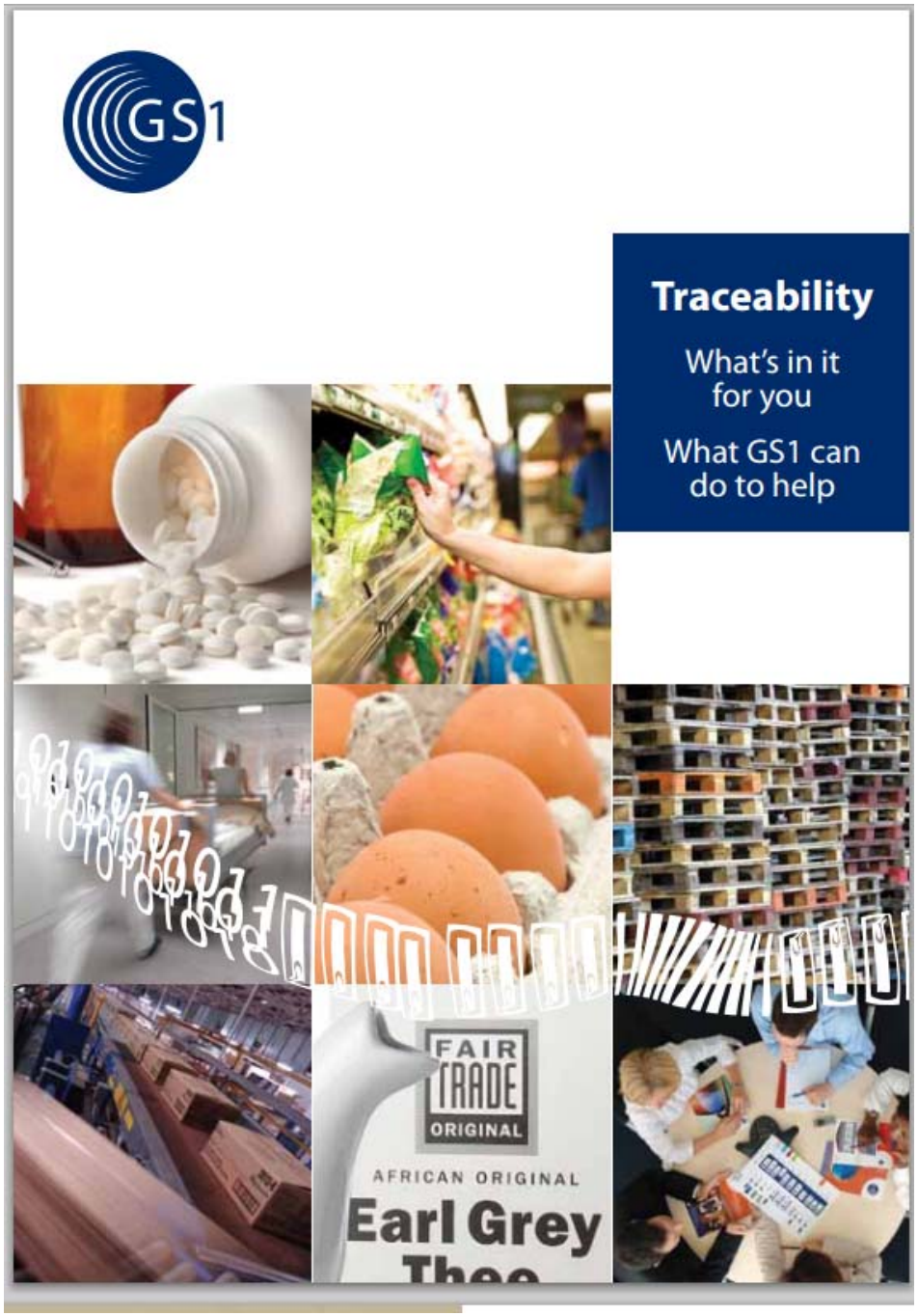
- Internal Traceability = each facility's own system
- External Traceability = data exchange between facility and suppliers
- Whole-Chain Traceability = Internal + External traceability

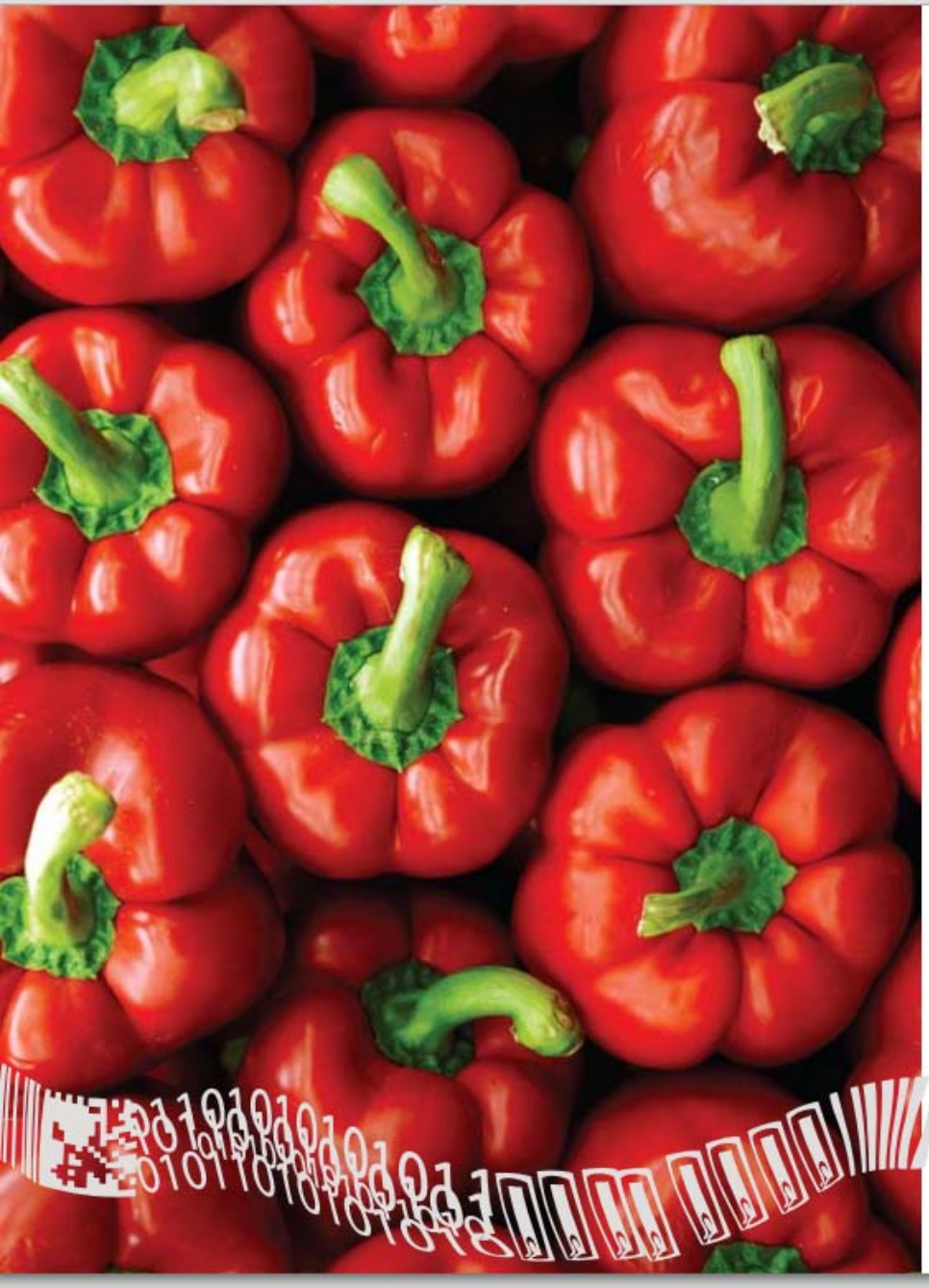
Characteristics of Ideal Traceability Systems

- Uses existing global, market-proven standards (*e.g.* GS1)
- Uses existing technologies: Barcodes
- Uses existing information:
  - Unique company identification number
  - Lot #
  - Production date
  - One-step-up, one-step-down
- Augments (not replaces) internal systems

Key Components of Ideal Traceability Systems

- Unique identifiers – human readable (numbers) and electronic (bar codes)
- Connects each link in the supply chain
- Allows automation, eliminates manual activity
- Increases productivity, ensures consistency
- Allows database storage, information management
- Allows for quick access and analysis


GS1
Traceability
What's in it for you
What GS1 can do to help
FAIR TRADE ORIGINAL
AFRICAN ORIGINAL
Earl Grey



Ensuring food safety

Where does the food your family eats come from? How did it get to your supermarket? What route did it take to get there? The label says "organic", but is it really? Does it contain anything your daughter is allergic to? Is it grown and harvested in an eco-friendly, sustainable way?

The ability to answer these questions lies in traceability applications and systems.

In order to work, traceability systems need to know everything that happens, at every step of the way, from the farm to your kitchen table. But with the increase in extended and highly global supply chains and the growing use of contract manufacturing, tracing food products from end of end has become more difficult.

GS1 standards make traceability systems possible, on a global scale – no matter how many companies are involved or how many borders are crossed as food and food ingredients travel from one end of the supply chain all the way to the consumer.

Traceability is especially important if something goes wrong and food products must be recalled. Recent legislation in the European Union obliges manufacturers to inform authorities and consumers of any potential risk to consumers from their products. Many other countries are reviewing their own legislation on this same theme. Individual growers, producers and manufacturers, eager to protect their brands from the harm done by tainted materials or poorly-managed recalls, are boosting their own internal recall policies and methodologies.

GS1 standards can play a vital role in product recalls. Because they are global, reaching from one end of the supply chain to the other, they ensure immediate access to accurate product information, which enables swift, comprehensive recalls.

But perhaps more importantly, our standards also facilitate quality assurance and accurate inventory control. And that contributes to making recalls as unnecessary and as infrequent as possible.

Summary

- The Food Safety Modernization Act imposes new requirements on petfood manufacturers, ingredient suppliers, and importers
- Although the Preventive Controls regulation for animal food has yet to publish, it will likely track the human food regulation

Summary (cont)

- Foreign supplier verification and import certification requirements could lead to loss of suppliers
- Domestic supplier approval and verification may be mandated in the final rule

Summary (cont)

- Additional recordkeeping will be required for “high-risk” foods and ingredients
- Supply chain traceability systems for “high-risk” foods and ingredients may be required in the future

Don’t wait until the last minute

- Start preparing now!
  - Implement hazard analysis preventive control systems
  - Ensure key personnel are adequately trained
  - Develop a food safety plan for each facility
  - Make sure your suppliers will meet the new FSMA standards
  - Consider adding traceability systems to your production

Petfood Workshop

Questions?

Petfood Industry

WATT