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

Definition of High Risk in the Food Safety Modernization Act

ASTA Regulatory/Legislative Workshop

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www.gmaonline.org

Agenda

- Risk-related terms used by FSMA
- Risk related Industry presentations to FDA:
  - Risk based inspections and targeted records access
  - Risk Assessments for FSVP and VQIP
  - High risk in context of Food Defense

"Risk-related" Terms used by FSMA

- FSMA contains a number of "risk-related" terms
  - "high risk facilities"
  - "high risk of intentional contamination"
  - "low risk"
- There are different usages of "risk-related" terms depending on the context the term is being used
- Therefore, a single definition of "risk" is not feasible

A. Inspections

1. Domestic – “high risk facilities”

   - FDA must identify *high-risk facilities*, based on the following factors:

     - Known safety risks of the food
     - Compliance history of a facility
     - Rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls.
     - Receipt of a certification
     - Other criteria may be identified

A. Inspections

2. Imports at port of entry: “known safety risks” of imported “food”

- FDA must allocate resources to inspect *imported food* according to the *known safety risks* of the food, based on the following factors:
  - Known safety risks of the:
    - Food imported
    - Countries or regions of origin and countries through which such article of food is transported
  - Compliance history of the importer
  - Rigor and effectiveness of the activities to satisfy the requirements of the foreign supplier verification program

B. Import Controls

1. Mandated Import Certifications: “risk of the food”

- FDA must base its determination that an imported food is required to have a certification on the following factors involving the *risk of the food*:
  - Known safety risks associated with the:
    - Food;
    - Country, territory, or region of origin of the food;
  - A finding by the Secretary, supported by scientific, risk-based evidence, that the food safety programs are inadequate

B. Import Controls

2. Voluntary Qualified Importer Program – "risk of the food"

- When determining eligibility for the VQIP, FDA must consider the *risk of the imported food*, based on the following factors:
  - Known safety risks of the food.
  - Compliance history of foreign suppliers
  - Capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.
  - Compliance of the importer with the requirements of FSVP
  - Recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.
  - Potential risk for intentional adulteration of the food

C. Prevention

1. Food Defense: “high risk of intentional contamination”

   - Food defense regulations will apply only to food for which there is a *high risk of intentional contamination* that could cause serious adverse health consequences or death to humans or animals.
     - Criteria listed in the statute: short shelf-life or susceptibility to intentional contamination at critical control points, and foods in bulk or batch form

C. Prevention

2. Preventive Controls (for very small businesses): "low risk" activities and "low risk foods"

- Analysis of on-farm manufacturing, processing, packing and holding activities that are *low risk* as they relate to specific foods.

- FDA can modify/exempt preventive controls requirements and inspection frequency requirements for farms engaged in low risk activities for low risk foods

C. Prevention

3. Produce Standards (general) – “those types” of fruits/vegetables where standards “minimize risk”
   - FDA must prioritize the regulations for those fruits and vegetables based on known risks, which may include a history and severity of foodborne illness outbreaks.

4. Produce Standards (for very small businesses) -- “low risk” activities and “low risk foods”
   - FDA can modify/exempt the standards for produce safety for small businesses producing/harvesting *low risk* fruits and vegetables. (FDA can also decide not to issue regulations for such fruits and vegetables).

D. Traceability

- Any additional recordkeeping requirements only will apply to ***high-risk*** *foods*. This designation will be based on:
  - Known **safety risks of a particular food**
  - Likelihood that a particular food has a **high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;**
  - Point in the manufacturing process of the food **where contamination is most likely to occur;**
  - **Likelihood of contamination** and steps taken during the **manufacturing process** to reduce the possibility of contamination;
  - **Likelihood** that consuming a particular food will result in a **foodborne illness** due to contamination of the food; and
  - Likely or known **severity**, including health and economic impacts, of a **foodborne illness** attributed to a particular food.

Risk Presentations from the Inspections and Enforcement WG at GMA

Risk Based Inspections
&
Targeted Records Review During Inspections

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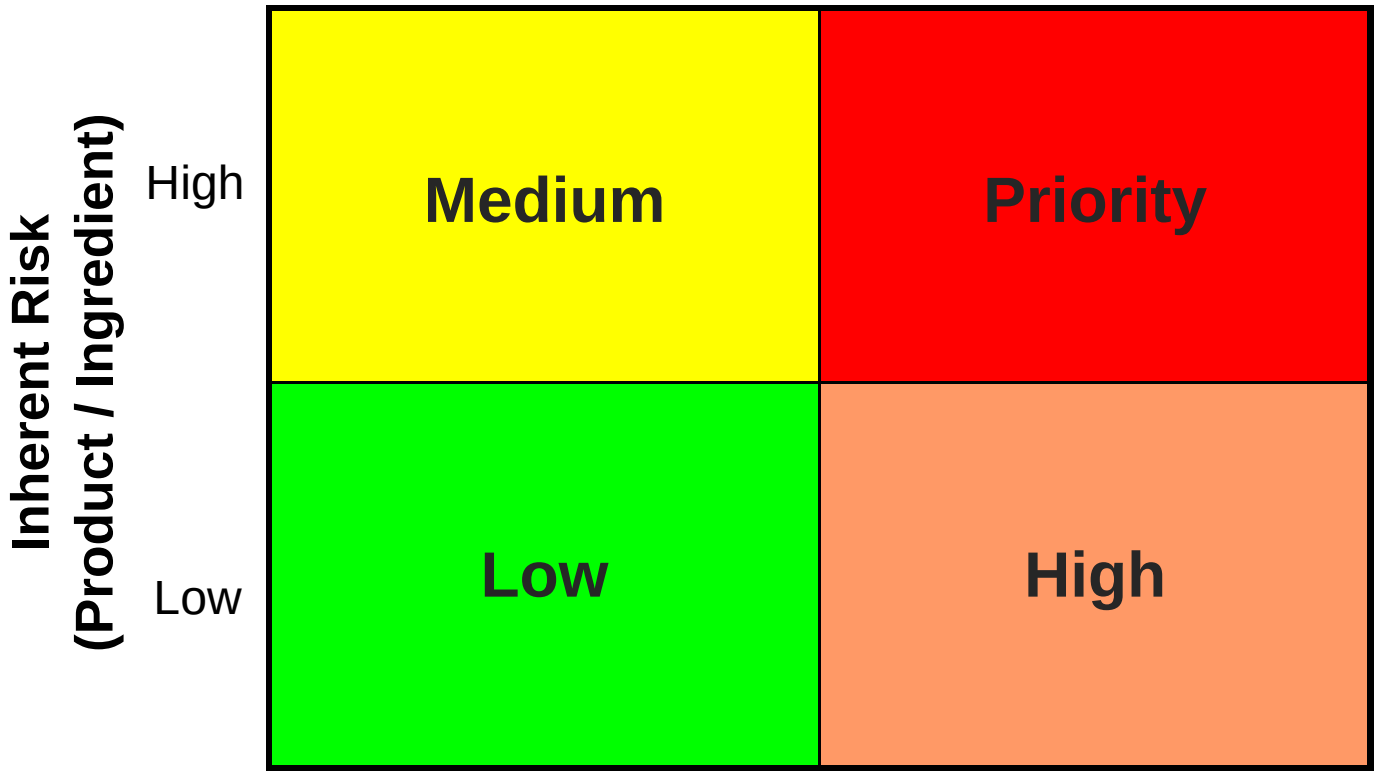
Risk–Based Inspections: Key Principles

- Any effort to define “high risk” must consider both inherent product risk and facility risk (refer to proposed risk matrix examples)
- Inherent product risk generally does not change over time unless there is a new linkage to foodborne illness
- A number of products, such as seafood, juice, and low acid canned foods are covered under specific HACCP or HACCP-like regulations and inspections should follow the requirements identified in those programs

Risk–Based Inspections: Key Principles

- Facility risk may change over time based on a variety of factors (as outlined in Sec. 201):
  - Compliance history of the facility, including food recalls, outbreaks of foodborne illness, and violations of food safety standards
  - The rigor and effectiveness of the facility's hazard analysis and risk–based preventive controls
  - Whether the food manufactured, processed, packed, or held at the facility:
    - Meets the criteria for priority under Section 801 (h)(1)
    - Has received certification as described in Section 801 (q) or 806, as appropriate
  - Any other criteria deemed necessary and appropriate

Example 1: Proposed Inspection Risk Matrix



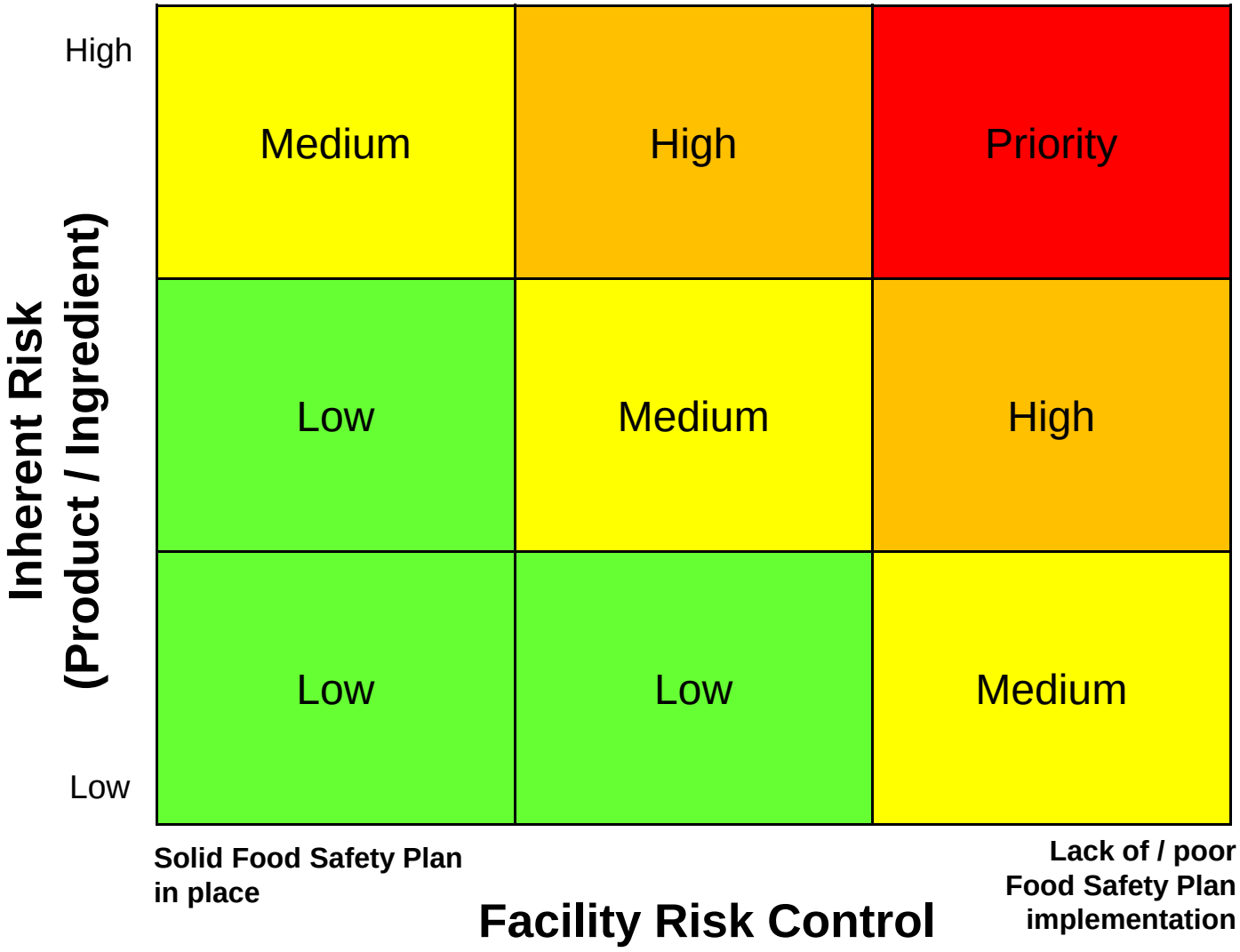
Priority = comprehensive inspection in depth and scope

High = focused inspection to address gaps in Food Safety Plans

Medium = targeted inspection to assure proper, on-going implementation of Food Safety Plans

Low = confirmation inspection

Example 2: Proposed Inspection Risk Matrix



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Targeted Records Review During Inspections

- To ensure effective and efficient inspections, FDA should conduct targeted records reviews

- Due to the volume of records maintained, FDA should:
  - Work cooperatively with the facility to pinpoint information responsive to the inspector's interests

  - Streamline the records review portion of inspections

    - Initial review of a sampling of records followed by review of additional records as dictated by initial findings, rather than universal review of a larger volume of records, would be most efficient and effective

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Risk Presentation from the Supply Chain Management WG at GMA

Foreign Supplier Verification Program (FSVP) & Voluntary Qualified Importer Program (VQIP) Risk Assessments

Statutory Language – FSMA §301

- Each importer *shall* perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the supplier is:
  - Produced in compliance with the Food Safety Plan requirements
  - Produced in compliance with produce safety regulations to be promulgated by FDA
  - Not adulterated or misbranded due to the presence of undeclared allergens

- Verification activities *may* include (but are not limited to):
  - Monitoring records for shipments
  - Lot-by-lot certification of compliance
  - Annual on-site inspections
  - Checking the hazard analysis and risk-based preventative control plan of the foreign supplier
  - Periodically testing and sampling shipments

Supplier Risk

- Examples/Types of items to evaluate

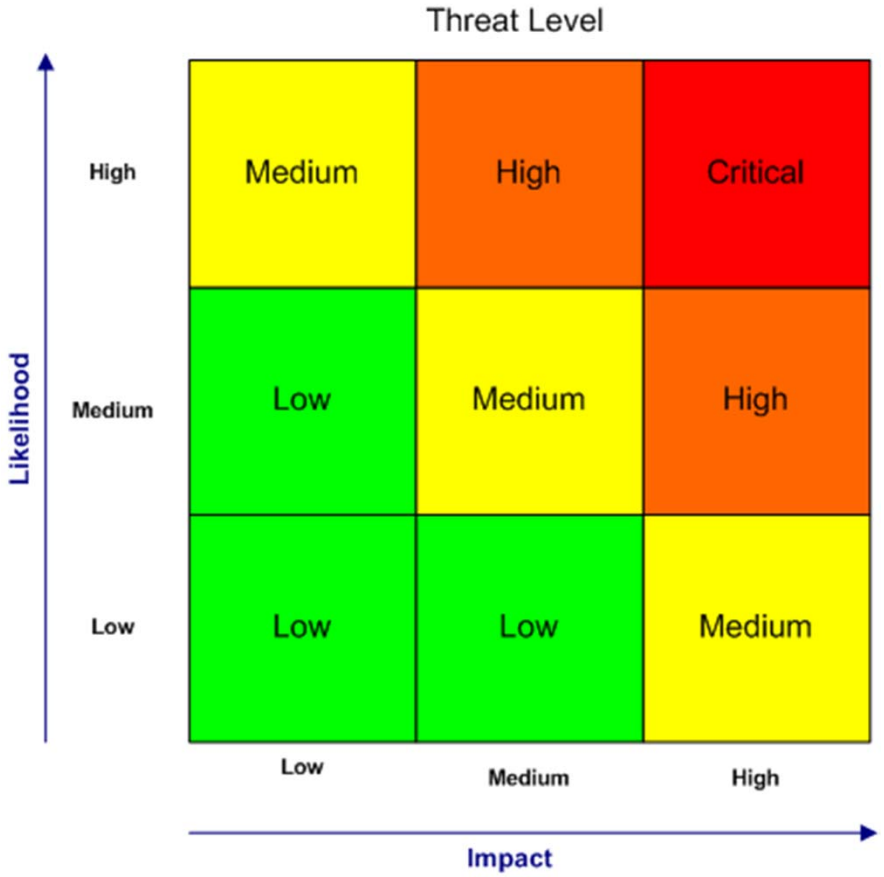
  - Country of Manufacture (*i.e.,* origin)
  - Performance history of supplier
  - Supplier's culture of food safety and quality management
  - Stability of supply chain
  - Location of manufacturing facilities
  - Sourcing options available
  - Quantity involved for purchase or use in finished product
  - Infrastructure of supplier or country
  - Food Defense capability (*i.e.,* security and integrity of supply chain)
  - Volatility of business activities in region
  - Changes in risk profile of material (*e.g.,* Japan)

Ingredient Risk

- Types of items to evaluate

  - Material is a known source of potential contamination
  - Vulnerable consumer base for finished product
  - Lack of kill step in material or finished product
  - Inconsistent quality of material
  - Material may support survival/growth of pathogens
  - Source of allergens
  - Packaging/transportation/storage

Supplier Verification – Real World Business Examples

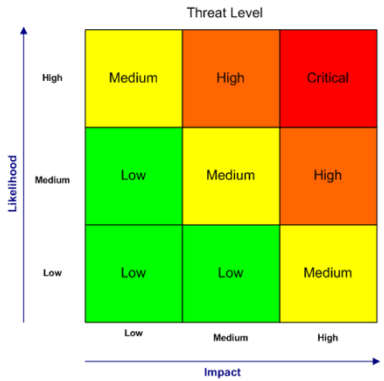


Different approaches can be used to evaluate a supplier's risk.

For example, materials sourced at a supplier could be placed in a risk matrix and evaluated according to the context of the supplier, application and programs utilized.

Hypothetical Supplier – High Risk

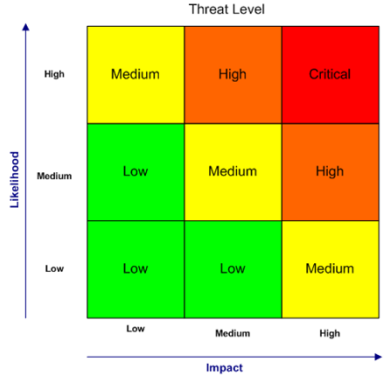
- Whey Protein Concentrate
  - Supplier
    - Chinese company with five years of manufacturing operation
    - Some history of quality issues
    - Inconsistent performance record
  - Ingredient application
    - Potential high risk consumer base
    - High usage in formulation for finished product
    - Large distribution



  - Conclusion: This ingredient would receive a high level of scrutiny. Most likely a site visit would be necessary for qualification and pre-shipment lot approval would be required for materials

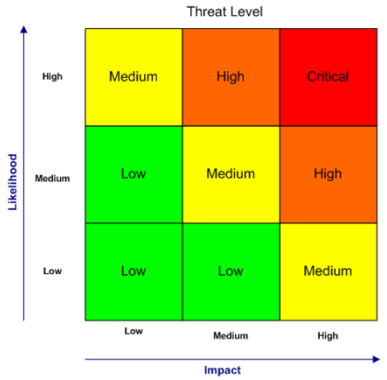
Hypothetical Supplier – Medium Risk

- Ready-to-eat (RTE) Individually Quick Frozen (IQF) Vegetables
  - Supplier
    - Chilean company is a leader in fruit and vegetable canning
    - 20 plus years as reputable food manufacturer
    - Expanding in IQF Vegetable Market
  - Ingredient application
    - Steam pasteurization process for CCP
    - Post heat treatment processes for controlling contamination are not robust so recontamination is possible
    - Mixed with other RTE materials to form finished product that undergoes minimal re-thermalization



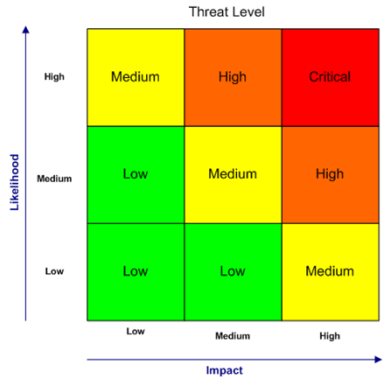
Hypothetical Supplier – Medium Risk

- Conclusion: Combination of factors results in a medium risk supplier/material that requires further systems-based consideration to ensure the supplier understands risks for recontamination post heat treatment and has robust control programs. Site visits, COA's, GFSI certification, and/or random sampling of incoming materials may be advised.



Hypothetical Supplier – Low Risk

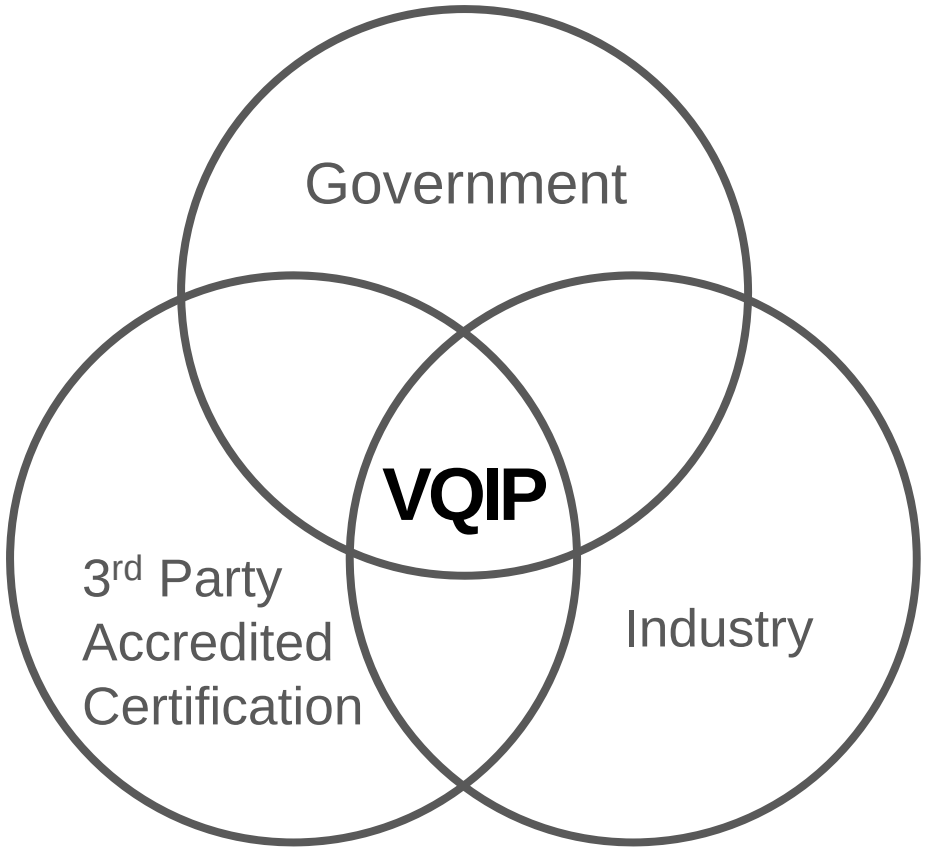
- Salt for Seasoning Mix
  - Supplier
    - Business partner for 10+ years
    - Excellent third party audits with GFSI certification
    - Stable region with strong food safety regulation
  - Ingredient application
    - Inherent low risk material for contamination
    - Intended for consumption by the general public
    - No history of foodborne illness contamination
  - Conclusion: Low risk supplier that will be a minimal risk to manufacture. Review paperwork (including Food Safety plan) to approve and monitor every other year.



Verification Activities

- Verification activities differ depending on the risk assessment and vary over time.
  - Activities may include:
    - Monitoring records for shipments
    - Lot-by-lot certification of compliance
    - On-site inspections
    - Checking the hazard analysis and risk-based preventative control plan of the supplier
    - Testing and sampling shipments
    - Accredited third-party audits
    - Customer audits

Voluntary Qualified Importer Program (VQIP)



VQIP Industry Principles: Benefits

- **Industry funds the value that VQIP will deliver**
  - ***Key Benefits***
    - Advanced paperwork review before port arrival resulting in early or immediate "may proceed" at point of entry, optimize FAST lane use
    - Priority testing and review when random sampling is done
    - Improved communication between Industry & FDA to clear goods
      - i.e. FDA HQ/field VQIP Account Mgr, regional accountability structure at FDA similar to CBP, Helpline, direct email from FDA, timeline commitments, etc.
  - ***Reduced***
    - PREDICT score
    - Foreign inspection frequency (per FSMA § 307)
    - Random sampling
- **FDA effectively allocates resources based on risk and performance**
  - Compliance confidence through 3rd party accredited certification
  - Independence & transparency via 3rd party accredited certification

VQIP Industry Principles: Application

- Application Process
  - *Prerequisites for application (section 301):*
    - Demonstrated compliance of qualifying 3rd party accredited certification & FSVP
  - *Advice to FDA*:
    - Seek “LESSONS LEARNED” from CBP border program application processes
    - Incorporate INFORMATION PREVIOUSLY SUBMITTED to FDA (e.g. facility registration)
    - FLEXIBILITY – allow applicants to choose how they want to apply (by product line, or as a company)
    - Be TRANSPARENT about the methodology to be developed for scoring admission into the program and share “risk scores”

VQIP Industry Principles: Integration

- Integration with CBP Border Programs
  - Integration with existing CBP programs is appropriate to extent necessary to reduce DUPLICATIVE data entry requirements
  - Risk score for VQIP should be positively influenced if applicant is already C-TPAT member
  - Violations in CBP border program should only impact VQIP membership if violation is RELEVANT AND MATERIAL for VQIP purposes

VQIP Industry Principles: Assessing Risk

- Assessing Risk for VQIP Membership
  - Importer Practices that are CONTROLLABLE should be predominate factor to determine risk score (recordkeeping, testing, inspections and audits, temperature controls, etc.)
  - Imports with known food safety risks should not be precluded from admissibility in VQIP program so long as risks are controlled (don't punish good actors)
  - FDA BENEFITS from VQIP by partnering with best industry performers and safest import compliance performers thereby enabling effective application of FDA resources
    - To achieve maximum utility for industry AND FDA VQIP admission standards should be rigorous yet achievable

Conclusions

The management of suppliers, both foreign and domestic, must take a risk-based systems approach. Manufacturers will need to demonstrate to FDA by manufacturing location that appropriate verifications were performed to mitigate risk to the consumer. Risk for the same material sourced from the same supplier can vary by manufacturing location.

- Food Safety Plans are the best method to evaluate risk to products from incoming materials
- Supplier qualification is the best method to evaluate risk to supply
- Evaluation of Suppliers and Materials is contextual and multi-layered
- Different situations require different tools/approaches to determine acceptability
- Many different approaches to evaluating risk can all lead to the production of safe food.

*"…with the signing of the law, FDA will for the first time have a congressional mandate for **risk-based inspection** of food processing facilities."*

– Margaret A. Hamburg M.D., Commissioner of Food and Drugs

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High Risk in context of Food Defense

General Application of the Terms Hazard and Risk:

- In general:
  - A possible or potential food defense “hazard” is a threat when its potential is restricted to the facility
  - The Hazard can be “controlled” through mitigation strategies and subsequent specific mitigation protocols
  - It becomes a risk when it reaches the marketplace and can impact the public health.

Food Defense Definition:

- Typically a facility undertaking food defense activities will take the following steps:
  a) conduct a threat assessment
  b) conduct a vulnerability assessment
  c) conduct a risk assessment to identify the potential impact of a threat(s) and vulnerability if it is not addressed
  d) implement mitigation strategies.

Threat Assessment:

- The identification and evaluation of types of threats of intentional contamination that a facility, product, or process may reasonably be exposed to.

Vulnerability Assessment:

- The process of collecting and evaluating information on the susceptibility of a particular facility, product, operation, and environment to potential threats, identified in the threat assessment.

Risk Assessment:

- The process of assessing the public health impact of a threat and vulnerability if not addressed.

Mitigation Strategies:

- Preventive measures to reduce the probability of, or lessen the impact of, an identified vulnerability.

Impact on Spice Trade Association

- Educate their members on FSMA
- Train members on how to generate and implement a good Food Safety Plans
- Have members understand their supply chain
- Identify the potential food safety issues; e.g., micro contamination, use of unapproved pesticides, possible allergens, etc. and ensure that member put mitigation plans in place. Especially for the spice industry – may want to consider irradiation to prevent micro contamination
- Spice Trade Association members are invited to attend GMA training courses
- Recommend looking at the seafood programs as a means to predict how FDA views a high risk commodity

Thank you for your time!

Questions?

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