

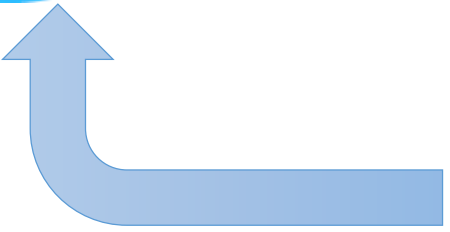
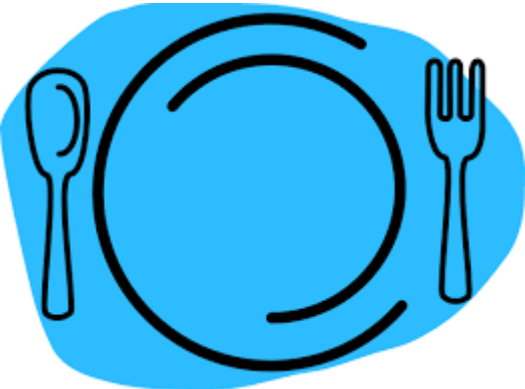
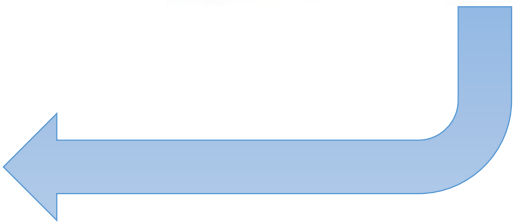
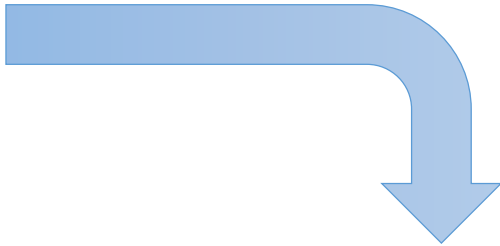
Risk Assessment of Suppliers & Materials

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Risk Assessment of Suppliers & Materials

- Agenda
 - Overview
 - Why do we need risk assessments?
 - What is the risk?
 - Quality Risk Management / Basic Risk Assessment
 - Material Risk Assessment
 - GFSI Rules
 - New HARPC Rules

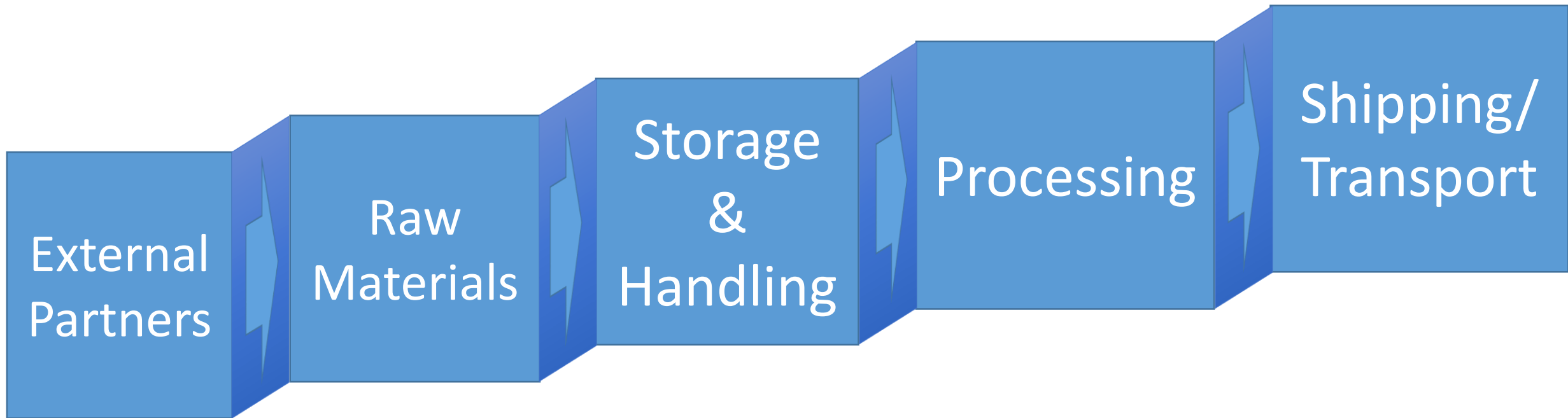
Supply Chain



Supply Chain

- A Supply Chain has many vendors that need to be assessed for the risk they pose to the organization
- A vendor risk analysis process should be in place to determine where weaknesses are from a technical point of view in the supply chain

Risk Assessment in the Supply Chain



Why Risk Assessments?

- Managing vendor risk is an ongoing process
 - You want to get the biggest bang for your buck from your program
 - You want to ensure that the information you learn is used to make better decisions

Why Risk Assessments?

- Organizations implement vendor risk management programs as a formal way to evaluate, track and measure third-party risk
 - To assess its impact on all aspects of the business
 - To develop compensating controls of mitigation to lessen the impact on your business should something happen

Supply Chain Challenges



Supply Chain Challenges

- Suppliers pose a challenge to any organization
 - People: Contractors in and out of the company
 - Reliance of Supplier background checks
 - Process: Each department can manage the Supplier relationship differently
 - Essentially, you are assuming the liability of a 3rd party!

What is the risk?

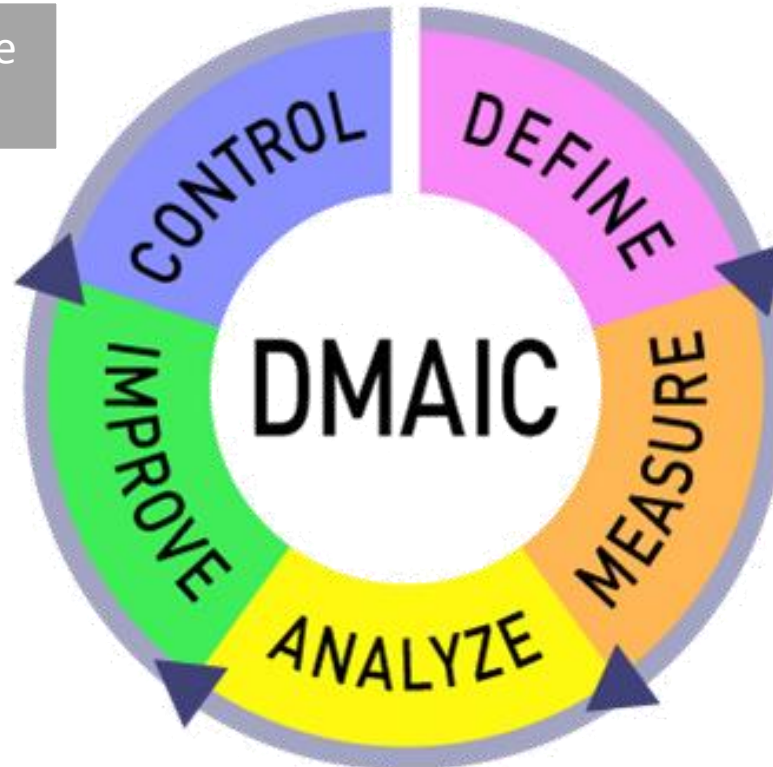
1. Supplier Management Systems are frequently inaccurate if no ownership
2. Manual Processes are prone to error (Emails, Word documents, Phone Calls, Snail Mail)
3. Inconsistent cataloging of data
4. Large companies have particular challenges with many business units, time zones, varying regulatory requirements
5. Lack of consistent testing methods

Quality Risk Management Process

Control – Monitor compliance of risk mitigation plans

Define quality risks and owners of risks

Improve risk mitigation guidance and processes



Measure and rank risks (Complete gap analysis)

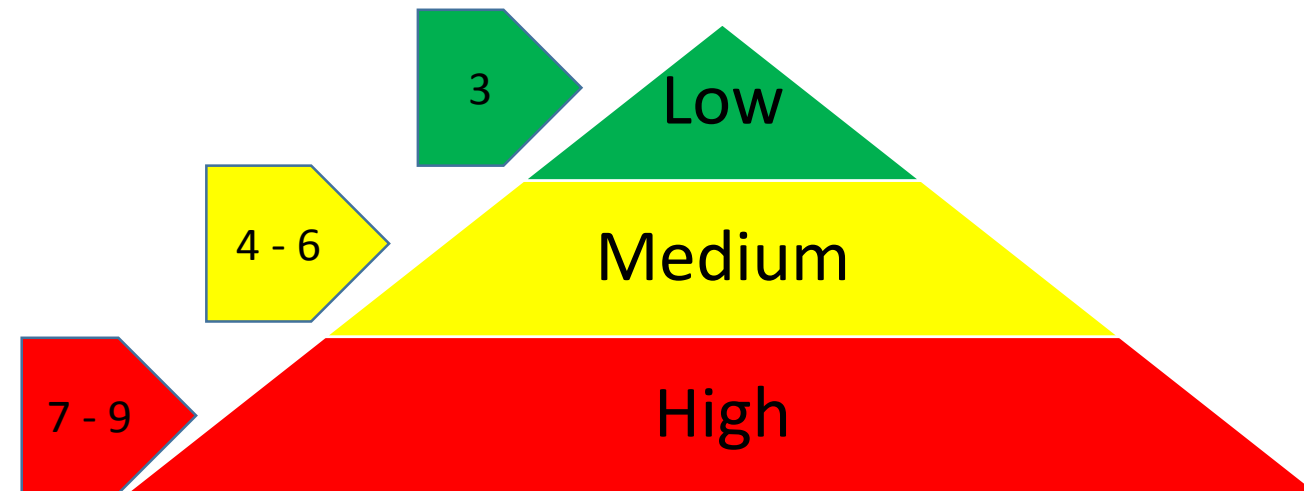
Analyze current risk mitigation processes in place for key risks

Basic Risk Assessment

1. Inherent Risk of Ingredient, Materials, or Service
2. Volume of ingredients or materials supplied
3. The supplier history and performance

| | | Severity | | |
|------------|----------------|-----------|--------------|-----------|
| | | Minor - 1 | Marginal - 2 | Major - 3 |
| Likelihood | Minor - 1 | Low | Med | High |
| | Occasional - 2 | Med | High | High |
| | Frequent - 3 | High | High | High |

Low = 1
Medium = 2
High = 3



Basic Risk Assessment

Based on the RA a decision can be made on the:

- Method of supplier approval
 - Questionnaire, Supplier Audit, 3rd Party Certification
- Method of supplier monitoring and degree of monitoring
- Type and frequency of raw material sampling and testing required

Material Risk Assessment

- Many hazards can be introduced into a facility through raw materials
- Some hazards to assess:
 - Pathogens, Allergens, Chemical Residues, Pests, Foreign Material

Material Risk Assessment

- *Be clear on the hazards*
 - Identify what can go wrong (hazard)
 - Assess that hazard (likelihood / severity)
 - Basic hazards to address:
 - Allergens, microbiological, chemical, and physical
 - Regulatory, intrinsic hazards (pitts in fruit, bones in chicken), geographical origin, purchase format



Demo

- Dashboard
- HACCP
- Management
- PRP Control
- Monitoring
- Master Data**
- Utilities

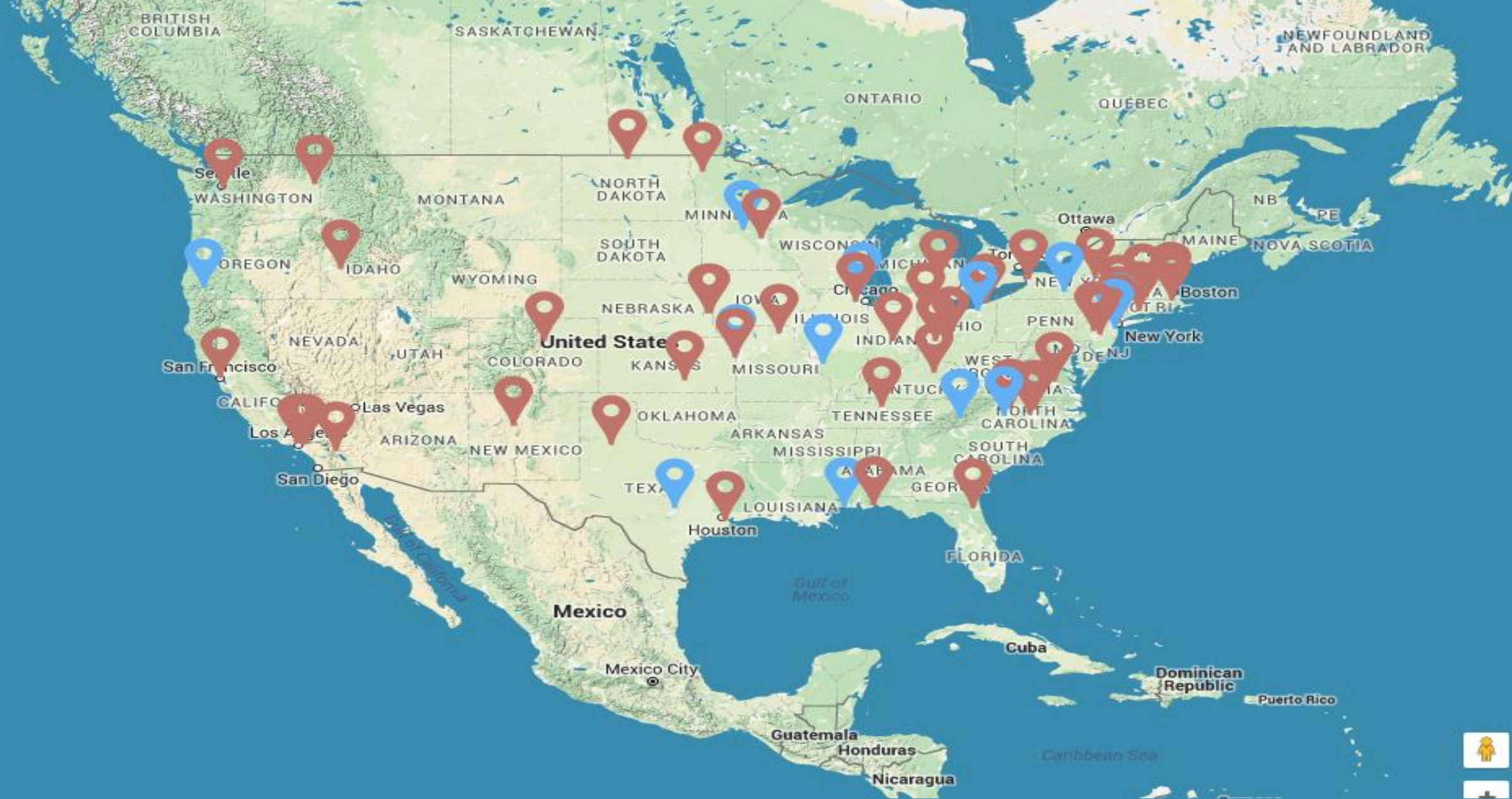
Contact

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- Customers
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|------------|------------|-----------------------------------|-------------------------------|----------------|-----------------------|------------------|
| 107 | 04/10/2015 | 4 Earth Farms | | Jennifer Brown | jbrown@4earthfams.com | |
| 99 | 08/01/2014 | A.EASTLAND | | | | |
| 39 | 02/02/2012 | A.K.M. Cashews | Ingredient - Manufacturer | Nissamudeen . | | +914743249765 |
| 41 | 02/02/2012 | A.M. Cashews | | Nisam . | amcashews@gmail.com | +914742727297 |
| 108 | 05/13/2015 | AA Supplier | AA Supplier | Barack Obama | | |
| 69 | 03/27/2012 | abc | Ingredient - Manufacturer | | | |
| 42 | 02/02/2012 | Alfiya cashew Company | Ingredient - Manufacturer | | | |
| 5 | 04/02/2011 | Allpure Ingredient Providers Inc. | Ingredient - Agent / Importer | Jenny McArthy | jenny@allpure.com | 1800 555 893 299 |



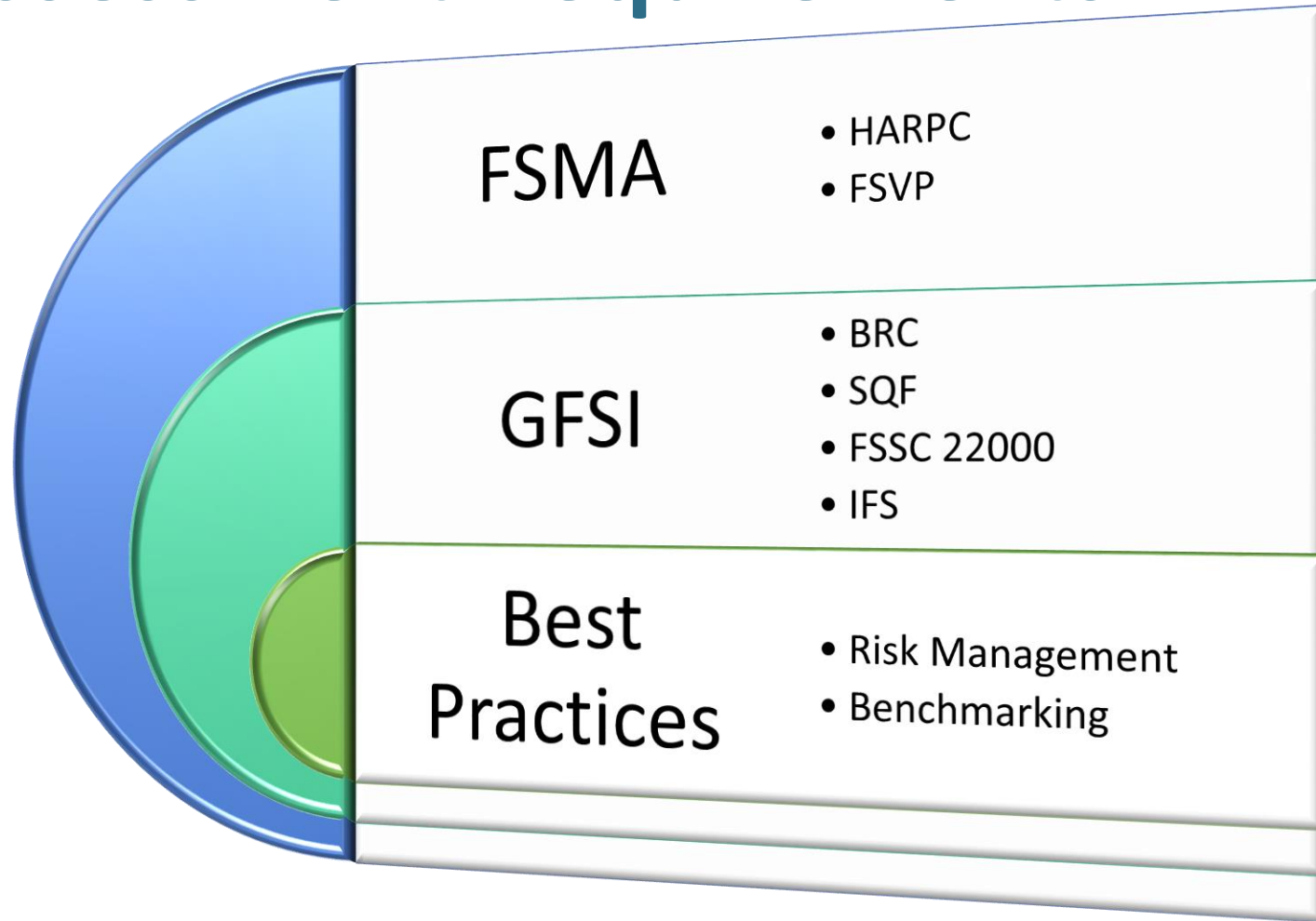
Material Risk Assessment

- *Define risk assessment ratings*
 - Have clear definitions associated with your likelihood and consequence ratings
 - If something is rated "medium" – what does that actually mean in relation to the hazard you have identified?
 - What is the impact on both the consumer and the business?

Material Risk Assessment

- *Research your hazards*
 - The more thorough your raw material risk assessment the better
 - Identify threats to your business and food consumers
 - Resources: recall databases, FDA raw material profiles, your own experience, government food importation department

Risk Assessment Requirements



GFSI

- GFSI to require specific food fraud mitigation strategies in 2016
 - GFSI Board believes mitigation of Food Fraud is an integral part of a company's FSMS
- GFSI to support SSAFE (Safe Supply of Affordable Food Everywhere)
 - Developing guidelines for companies on 'how' to assess and control food fraud vulnerabilities within their organization and supply chain

GFSI : British Retail Consortium (BRC)

- BRC: Fundamental Requirement
 - Increased requirements for supplier Risk Assessments
 - Sites required to verify an effective traceability system for all suppliers
 - Verify traceability to the last manufacturer, packer, or grower when raw materials are packaged and purchased from an agent or broker

GFSI : British Retail Consortium (BRC)

- BRC: Section 3 – Authenticity of Food (Food Fraud)
 1. Economically motivated adulteration
 2. Ingredient substitution
- Risk Assessment that includes Food Fraud and Material Substitutions is now required ANNUALLY
 - (Must be reviewed by Management during the management review process!)

FSMA

- FSMA implementation will be the largest change in the food industry in its implementation as well its enforcement
- Implementation processes and compliance tools will be the largest investment many companies will make over the next 5 years

FSMA

- The rules require a supplier approval and verification program
 - This applies to each buyer along the supply chain up to but not including retail/foodservice and sales establishments

FSMA : Food Safety Plan Requirements

- Written supplier approval and verification program
 - A risk based approach to ensure suppliers are not providing food facilities with raw materials or ingredients that pose a significant risk to the final product made by the facility

FSMA

- Processors must conduct a hazard analysis of all their raw materials, ingredients, and packaging materials
 - Incorporate the material in question as well as the manufacturer and country of origin
- For food processors that have made the commitment to pursue and implement a GFSI audit scheme, this assessment will be an essential element of their program

FSMA : HARPC

- The scope of your risk and hazard analysis includes a full supply chain evaluation
- Broader spectrum of hazards and their source (natural/manmade, intentional/unintentional)
 - Biological, Physical, Chemical, and Radiological
 - Natural Toxins, Pesticides, Drug Residues, Decomposition, Parasites, Allergens, Unapproved Food and Color Additives

FSMA : HARPC : Hazard Analysis

- Hazard Analysis to identify and evaluate 'reasonably foreseeable hazards'
 - 'Intentional Hazards' include *acts of terrorism*
 - Food Security Guidances – includes facility, people (employees), suppliers/raw materials, anti-tampering
- Develop a written plan of these hazards

FSMA : Section 301 - Foreign Supplier Verification Program (FSVP)

- Whether you are an importer or a manufacturer, retailer, wholesaler or distributor that falls under the definition of importer, it is critical that you understand and be prepared for the rollout of the FSVP rule

15% of the food in the US is imported!

FSMA : Section 301 - Foreign Supplier Verification Program (FSVP)

- Represents a dramatic change in the way food importers in the United States will continue to import foods from foreign suppliers

FSMA : Section 301 - Foreign Supplier Verification Program (FSVP)

- Food Importers: Required to establish, apply and maintain a FSVP
- Places the responsibility for safety of the food products squarely on the shoulders of the importers who are introducing food products into the US
- They will be held accountable for any food safety issues related to the imported food products and their suppliers

FSMA : Foreign Supplier Verification Program (FSVP)

- Importers must:
 - Carry out a HARPC assessment of each food product to be imported into the United States
 - Evaluate the current status of his foreign suppliers' food safety procedures, processes and practices, complaints history with FDA regulations (Import alerts, warning letters), food safety performance history, and other factors related to food safety (storage & transportation)

Acknowledgements:

- SSAFE: <http://www.ssafe-food.org/15/>
- GMA: <http://www.gmaonline.org/issues-policy/product-safety/food-and-product-safety/food-and-product-safe/fsvp-rule/>
- FDA: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>