

GMA

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



Food Safety Modernization Act: Risk Based Determination of Mechanisms to Verify Control of Hazards

*Collaborative Food Safety Forum: Foreign Supplier Verification
Program Workshop
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GMA

Who is the Grocery Manufacturers Association?

- GMA represents the world's leading food, beverage and consumer product companies
- GMA provides leadership to the industry in food safety through promotion of scientific excellence
 - ❖ State of art research and analytical laboratory
 - ❖ Training in regulatory and food safety issues
 - ❖ Collaboration with U.S. government on food issues
- GMA promotes sound public policy and champions initiatives for productivity and growth

GMA Members

General Members



Associate Members



*Represents a sample of GMA members

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Overview

- GMA members fully support establishment of supplier verification requirements through FSVP
 - One of the four pillars of food safety
 - FSVP should allow for implementation of state of the art practices that deliver safe food cost effectively
 - FSVP should be practical to implement, risk-based and flexible

Guiding Principles for FSVP

- Requirements in FSVP rule must add value:
 - Implementable and enforceable
 - Improve food safety
 - Have costs balanced with benefits
- Support innovation and continuous improvement
- Minimize burdensome bureaucratic activity
- Avoid barriers to trade
- Wherever possible, we support advancement of comparability assessments for foreign countries



Role of Audits

- Effective food safety management systems ensure delivery of safe food
- Auditing is an important tool but a sub-part of food safety management if conducted effectively
 - Provides independent real time assessment
 - Identifies problems and compliance issues
 - Drives continuous improvement
- Auditing alone is insufficient to deliver safe food

FSVP Option 1 vs. Option 2

- FDA co-proposed two alternative approaches to verification activities for hazards controlled by a foreign supplier
- Option 1 is prescriptive and not based on risk
- Option 2 is flexible and risk-based
- **GMA strongly supports Option 2**



Benefits of FSVP Option 2

- Option 2 represents state-of-the-art practice that consistently delivers safe food
- A risk-based approach allows efficient use of resources
 - Provides flexibility to determine the verification activities assessments of product risks and supplier risks
 - Allows resources to be directed at solving real problems
- Encourages critical thinking across the supply chain
- Considers issues broader than Class I hazards
- Encourages investment in supplier improvement programs

Issues with FSVP Option 1

- Option 1 represents a major step backwards versus state-of-the-art practice
- A single standard audit envisioned in Option 1 decreases rigor and removes motivation for continuous improvement
- Results in unnecessary operational burden without corresponding food safety and public health benefit
 - Audit overkill diverts resources to cover bureaucratic overhead
 - Limits resources available to improve food safety procedures
- Availability of trained auditors to conduct yearly audits is a significant issue
 - Capability
 - Cost

Economic Analysis

Annualized Costs of FSVP Option 1 and Option 2

	Option 1	Option 2	Variance
PRIA Annual Foreign Supplier Audits	47,679	43,364	4,315 or ~10% more audits for Option 1
PRIA FSVP Annualized Costs	\$473M	\$461M	\$12M added cost to audit 10% more foreign suppliers
GMA Member Data: % of Foreign Suppliers required for an annual audits as proposed in FSVP	30-50%	10%	3-5 fold increase for Option 1
Increased Annualized Costs to Implement FSVP Option 1 or 2	\$1.4 – 2.3B	\$460M	

Smaller less capable businesses will need support

- Small and very small foreign suppliers will need robust guidance on effective implementation
 - Elements of option 1 must be included in guidance framework
 - Available for use by businesses as needed
- Qualified Individuals
 - Will be essential supporters of smaller businesses
 - Will bring critical thinking and good decision-making into these operations
 - Build capability to operate flexible risk-based food management systems

Summary

- GMA strongly supports Option 2, a flexible and risk-based approach to supplier verification with a long history of successful use
- Option 1 represents a step backwards in food safety: implementation of a prescriptive codified approach will waste resources and stifle innovation
- The needs of smaller business can be met through
 - Development and implementation of robust guidance
 - Training of Qualified Individuals who will drive continuous improvement

Thank you for your interest!

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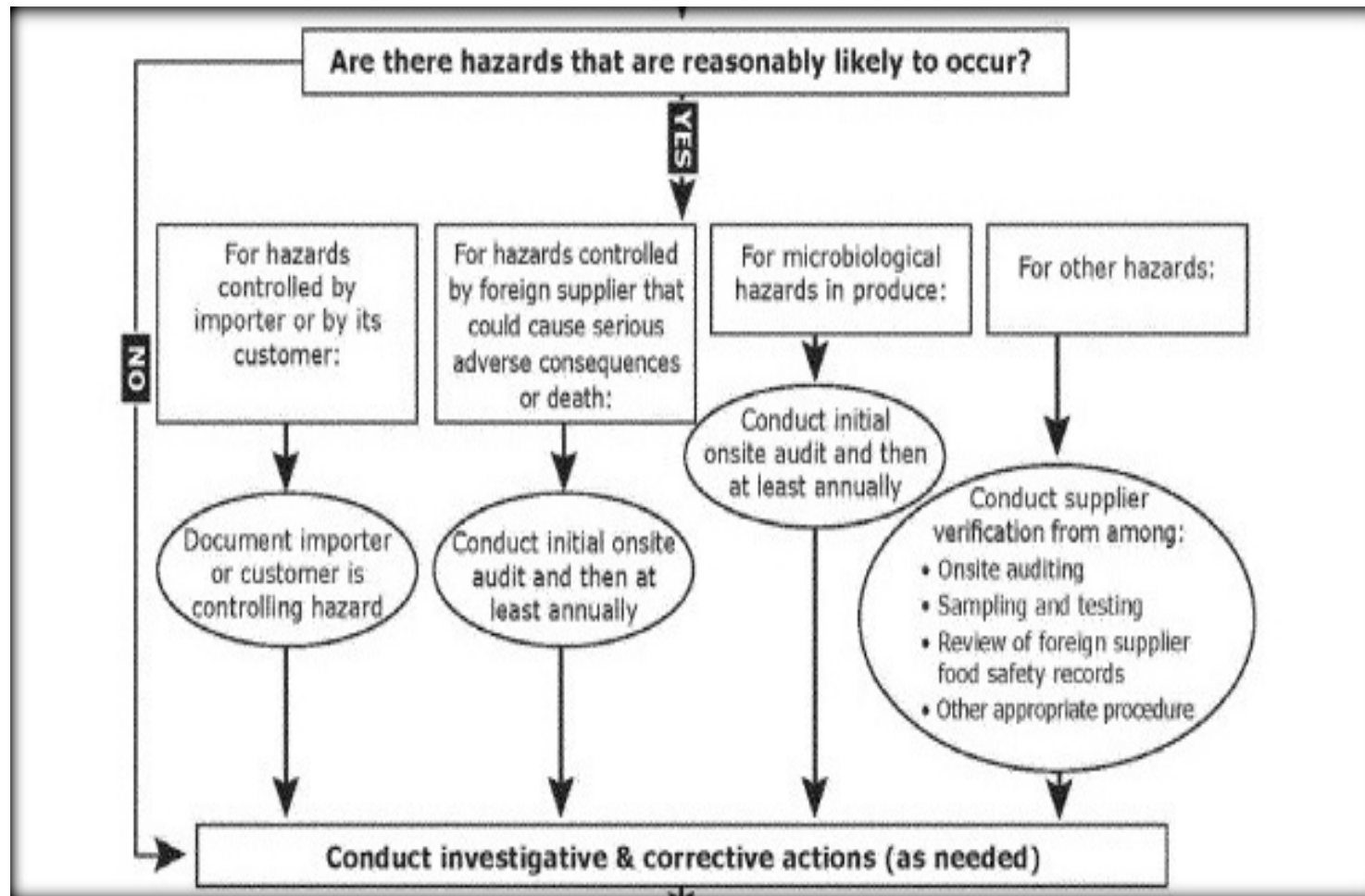
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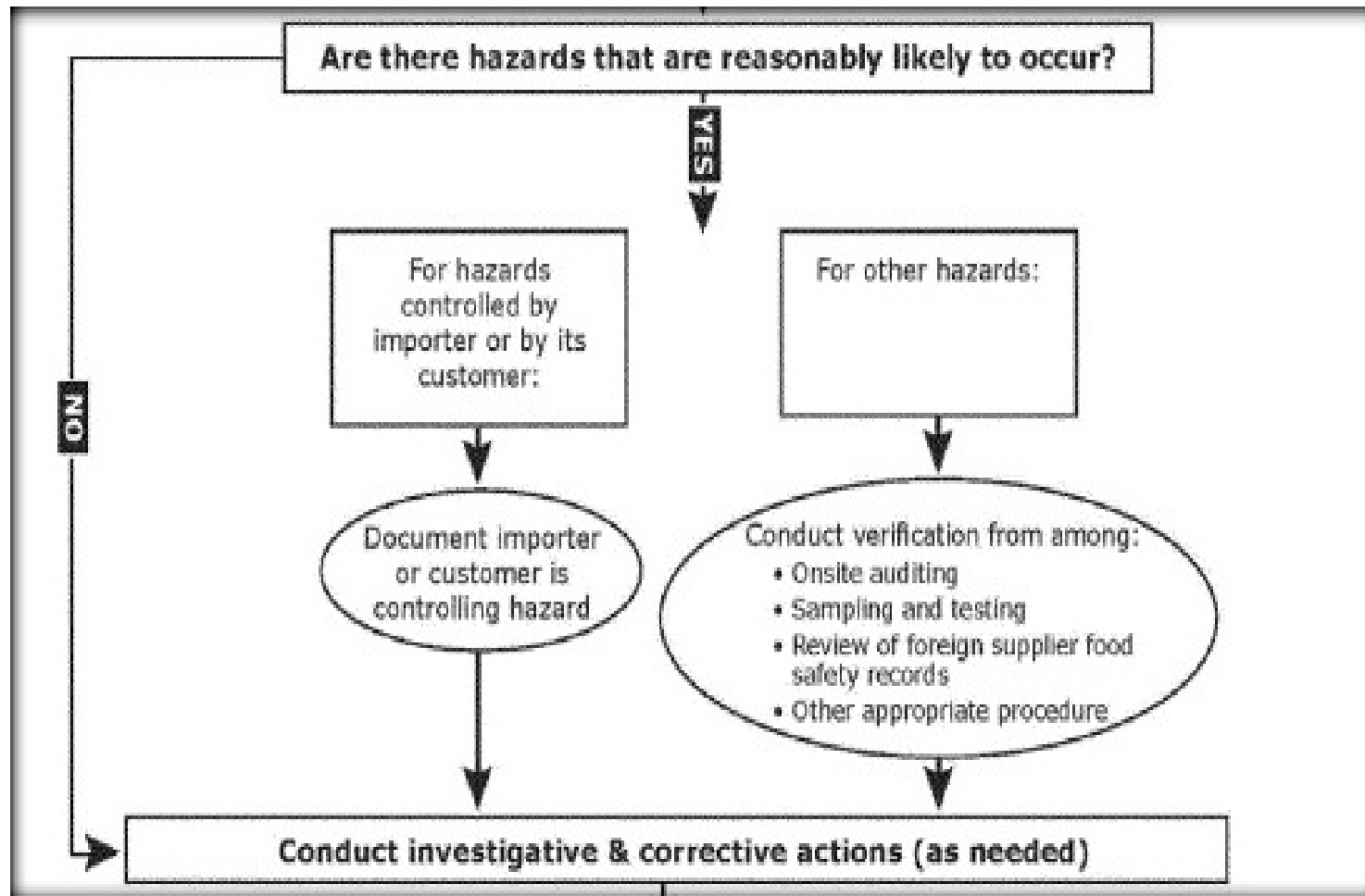
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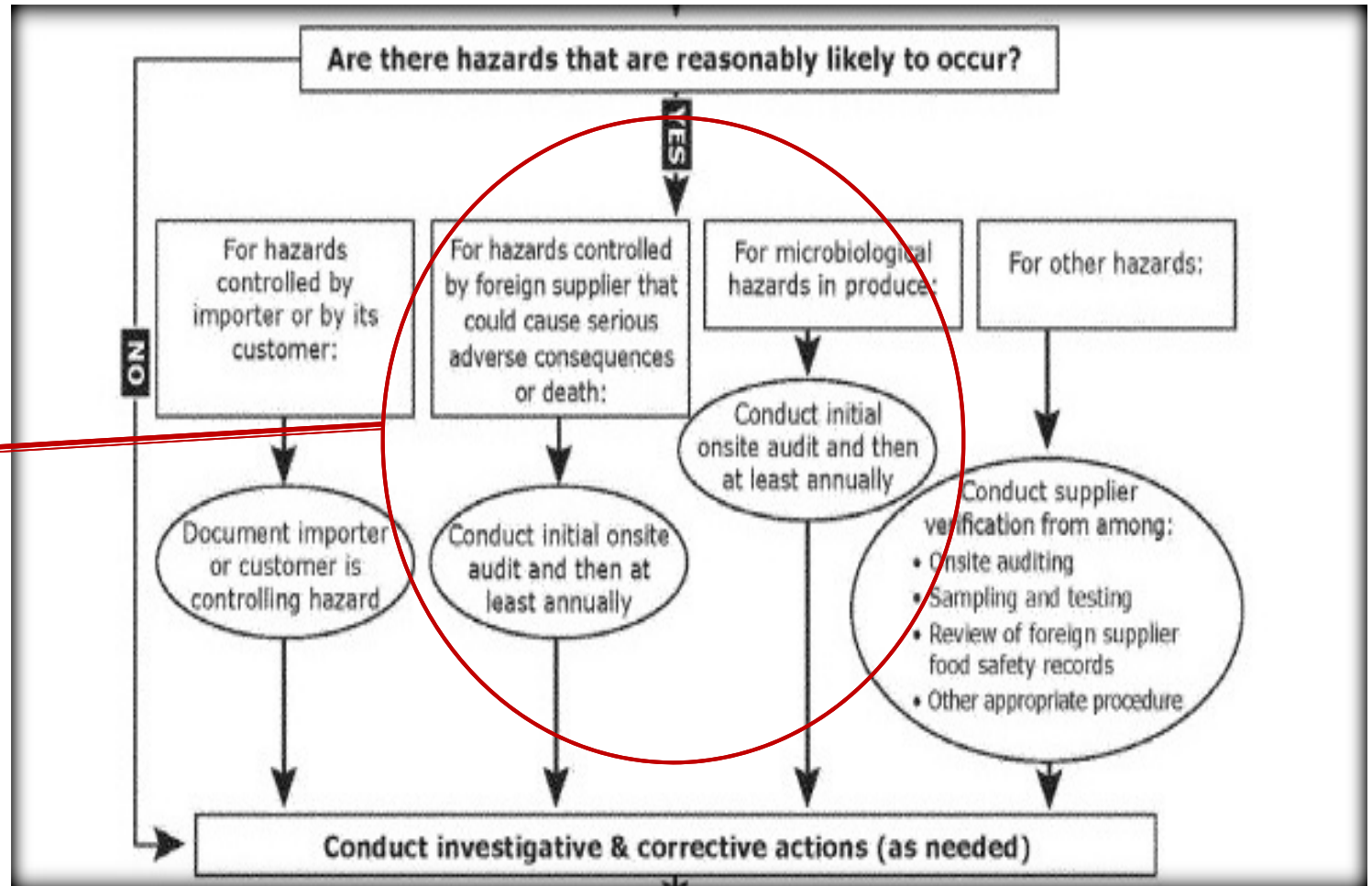
FSVP Option 1



FSVP Option 2



FSVP Recommended Approach for Supplier Verification



***Robust
Guidance***