

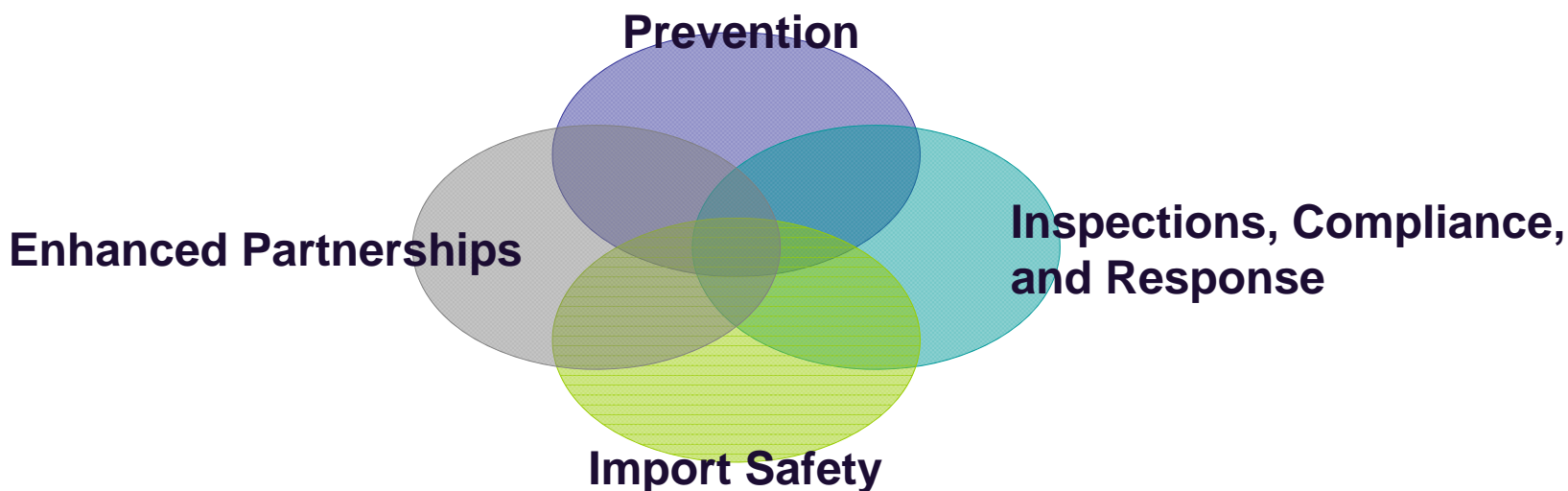


# **FSVP Proposed Rule: Small and Very Small Suppliers**

**Dr. Donna Garren**  
**Vice President, Regulatory and Technical Affairs**  
**American Frozen Food Institute**



# Main Themes of FSMA





## “Very Small” Importers

- ***Objective:*** Discuss how to determine who qualifies as a “very small” importer and what requirements are expected of them.



# Key Elements For Consideration: Foreign Supplier

- **FDA should revise the definition of “foreign supplier” so that supplier verification is only needed for the entity one step back in the supply chain.**
- As proposed, there are situations where an importer may need to verify the harvester of a commingled raw agricultural commodity that could be several steps back in the chain.
  - This requirement exceeds FDA’s legal authority for traceability.
  - Instead, each party in the supply chain should be required to verify one step back, to their immediate supplier.



# Key Elements For Consideration: Foreign Supplier

- Part of this supplier verification should include an assessment of whether this supplier has a program in place to verify its own suppliers, in order to ensure that verification activities continue back in the supply chain, as needed.



# Key Elements for Consideration: Very Small Businesses

- We disagree with the proposed modified requirements for very small foreign suppliers and very small importers.
- FSMA does not provide any business size-based exception from the FSVP requirements for very small importers.
  - This reflects Congressional intent to require supply chain oversight by all importers in the same way.
- Imposing less rigorous verification requirements on very small importers is not justified as a risk-based approach.
- HOWEVER, we recognize the challenges for very small importers to come into compliance with the FSVP.



# Key Elements for Consideration: Very Small Businesses

- We support providing these businesses with additional time (at least 3 years, as proposed) before enforcement begins.
- We also support education of these very small importers and capacity building in the countries where they are located.
- In contrast, the Tester amendment in the preventive controls section of FSMA contains an express recognition that modified requirements are appropriate for very small businesses, which would include very small foreign suppliers.



# Key Elements for Consideration: Very Small Businesses

- An importer's FSVP responsibilities over these very small foreign suppliers would relate to assuring these modified preventive controls requirements are complied with, that the food is not adulterated, and that the food does not contain any undeclared allergens.
- This is the same obligation whether the importer is a large, small, or very small importer.





# Thank you. Discussion?

Dr. Donna Garren

[dgarren@affi.com](mailto:dgarren@affi.com)

(703) 821-0770