

FSMA's Intentional Adulteration Rule What Does It Mean for Industry?

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GTMA

The Association of Food, Beverage and Consumer Product Companies

Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

About the Grocery Manufacturers Association

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. We pride ourselves in serving large, international brands and regional brands, as well as foodservice companies and industry service providers from consulting, technology, logistics and other sectors.



GMA Members

General Members



Associate Members



History of GMA with Food Defense

- ⦿ GMA formed a “food security” committee six months after 9-11



History of GMA with IA Rule-Making

- ⦿ First ever FSMA meeting between GMA and FDA was on Intentional Adulteration rule
 - Occurred soon after FSMA signed into law
- ⦿ Proposed rule
 - GMA submitted comments proposed IA rule and corresponding PRIA on June 30th 2014
 - Met with the agency to express GMA's feedback regarding proposed rule



History of GMA with IA Rule-Making

(continued)

Engagement on Proposed IA rule (continued)

- ◉ Provided comments at FDA's public meeting in spring of 2014 on "Focused Mitigation Strategies to Protect Food against Intentional Adulteration"
 - GMA stated publicly:
 - Fundamental Premise: Many food companies already have implemented food defense measures on a voluntary basis, and the importance of leveraging and reinforcing successful industry practices in Final IA rule.
 - IA rule, like other FSMA rules, needs to be implemented in a way that is transparent and even-handedly applied throughout industry.
 - FDA's inspection and enforcement program must be applied consistently throughout the country and in a way that truly advances the end goal – improved food defense.
 - FDA's implementation and enforcement of IA rule, as with other FSMA rules will require extensive training.

Final Rule versus Proposed Rule

What Changed, What was Added, What was Deleted?

⦿ Tag Line: Pay Close Attention!

From Proposed to Final IA Rule (not all encompassing):

- Key Activity Types (KATs) removed from the regulation. KATs will be specified in guidance
- Removed distinction between “broad” and “focused” mitigation strategies
- Adds requirement to consider the possibility of an inside attacker
- Additional requirements to provide written explanations of the reasoning behind certain conclusions
- Adds training requirements for employees conducting activities under the rule, including FSPCA-IA training
- Rule Specifies 3 elements that must be considered during vulnerability assessment
- Requires consideration of each point, step, or procedure in the food operation as part of the vulnerability assessment



Challenges for Industry on Food Defense

- Not many food defense experts
- Numerous universities offer specific degrees in food science. Not the case for food defense
- Most companies have a quality/regulatory manager at each facility whose job function is specifically food safety and regulatory compliance. Not common at facilities to have a food defense expert whose sole function and primary role is food defense.
 - Just because someone is a food safety professional does not necessarily translate to them being a food defense expert



Challenges for Industry on Food Defense

(continued)

- Food defense is *different* than food safety. Food defense does not equal food safety
 - **Food safety** addresses the accidental adulteration of food during processing or storage by biological, chemical or physical hazards
 - **Food defense** focuses on protecting the food supply from intentional contamination with a variety of chemicals, biological agents or other harmful substances
- Agents used in acts of IA could include materials that are **NOT** naturally-occurring or are **NOT** routinely tested for (unlike food safety events)
- Intentional acts are generally not reasonable and are hard to predict (not RLTO).

Challenges for Industry on IA Rule

(not complete list)



- FDA's IA rule is the **FIRST** rule of its kind in the world.
- Rule focuses on preventing food from acts of IA where there is intent to cause wide-scale public health harm
- US Industry has protected the public with current successful industry practices that have resulted in zero injuries/illness from acts of intentional adulteration at a US food manufacturing facility in the last 16+ years.
 - IA final rule has new requirements that are significantly different from current successful practices employed by food manufacturers to protect the consumer by acts of IA.
 - Current successful foundational food defense programs include programs such as background checks, visitor screening, awareness training, perimeter and building security, etc.
 - Challenge for industry in how these successful, existing programs fit within framework of IA rule

Challenges for Industry on IA Rule

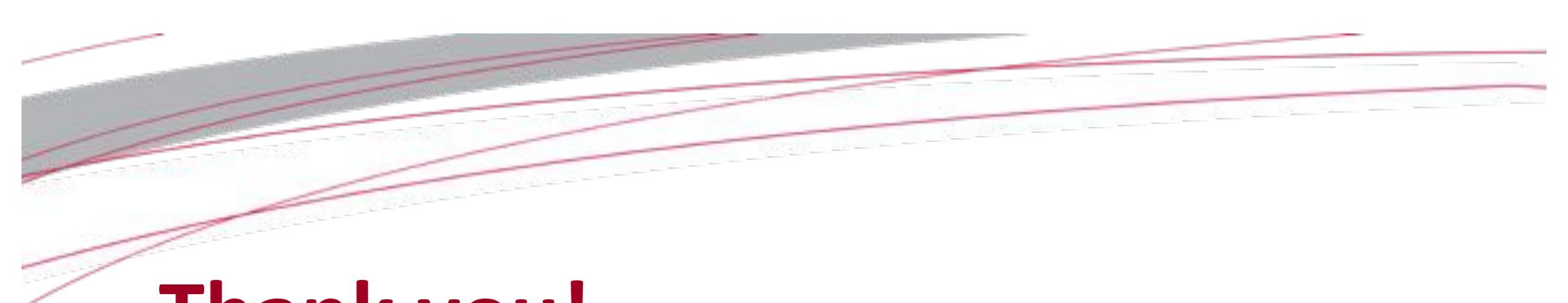
(not complete list)

- Participation with global food safety schemes and programs such as C-TPAT or CFATS **DOES NOT** substitute for compliance with IA rule.
 - While these programs decrease a facility's vulnerability to intentional adulteration and can work in concert with the requirements of the final rule, industry will still have to determine what additional steps are needed, beyond these voluntary programs, to achieve compliance with the IA rule.
- Compliance date is nearing: 7/26/19 (**about 1.5 years away**)
 - FDA still working on draft guidance and training for IA rule. Challenge for industry as compliance is nearing and many businesses already need to plan/forecast for 2019 capital.



How can Industry Prepare for IA Rule?

- ⦿ Thoroughly review IA final rule and preamble
- ⦿ Connect with trade associations, especially GMA, on your questions and challenges with the IA rule
 - Attend GMA's Science Forum. Breakout session devoted to methods available for performing vulnerability assessments
- ⦿ Trade associations can join the GMA FSMA Coalition where GMA keeps other associations updated on FSMA implementation and associated policy develops
- ⦿ Sign-up for webinar series offered by Food Safety Preventive Controls Alliance (FSPCA) in collaboration with the FDA on IA rule
 - View previous IA webinars:
<https://www.ifsh.iit.edu/fspca/courses/intentional-adulteration>
- ⦿ Join Food Defense Consortium (see me afterwards for more information)



Thank you!

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