FFI Report

Review: Final Rule for FSMA Intentional Adulteration (Food Defense) Regarding Food Fraud and EMA

By John Spink[1], Douglas C Moyer[1], Andrew Huff[2] & Bradley Evans[3]

[1]Michigan State University, Food Fraud Initiative, College of Veterinary Medicine
[2]Michigan State University, College of Veterinary Medicine
[3]University of Auckland (NZ), Business School – Department of Marketing

SUMMARY

The Food Safety Modernization Act (FSMA) Intentional Adulteration Rule (FSMA-IA) draft was published in December 2013, public meetings started in February 2014 and the final rule was published May 27, 2016. The effective date is in 60 days but "[FDA] are providing for a longer timeline for facilities to come into compliance" in at least three years or July 27, 2019.

Economically Motivated Adulteration (EMA) – and Food Fraud (FF) – is in the FSMA law due to the text "…intentional adulteration, including acts of terrorism." FDA announced their scope narrowed to "wide scale [human] public health harms" and removed from this rule the concepts of EMA, disgruntled employees, tampering, etc. The FSMA compliance requirements for FF&EMA are in the Preventive Controls Rule (FSMA-PC).

FSMA-IA also continually confirms many times that the Food, Drug & Cosmetics Act (FDCA) is still in effect, which includes all types of Food Fraud, even without a health hazard ("Adulterated Foods" and "Misbranded Foods").

CONCLUSION

Even though Food Fraud (FF) and Economically Motivated Adulteration (EMA) are ***not*** a compliance requirement for FSMA-IA, this final rule provides important insight into FSMA and assessments:

1. Addressing all types of Food Fraud is a requirement – and subject to a recall – under the Food, Drug & Cosmetics Act (FDCA).
2. FDA specifically reiterated the FDCA compliance requirement in sections on "Adulterated Foods" and "Misbranded Foods."
3. FSMA-IA stated that stolen goods (various types of theft) that lead to a public health hazard are clearly defined and expected to be covered under FSMA-PC.
4. There were no more clarifications of key terms such as reasonably foreseeable hazard, significant vulnerability, rare occurrence, credible threat, or the threshold of *acceptable* or *unacceptable*.

The compliance requirement for Food Fraud is addressed in FSMA-PC ***not*** in this FSMA-IA. Other FSMA final rules provide some insight on FDA's thinking regarding assessments, thresholds of acceptable/unacceptable, and the compliance priorities (see appendix of May 26, 2016 FDA public call).

Contact
Dr. John Spink
517-381-4491
FoodFraudPrevention.com

BACKGROUND

This is our Food Fraud Insight Report (FFI Report or FFIR) review of the Food Fraud[1] (FF) aspects – including the sub-category of Economically Motivated Adulteration (EMA) – of the recently published US Food Safety Modernization Act (FSMA) Intentional Adulteration Final Rule (Food Defense). The formal name of the final rule is **Mitigation Strategies to Protect Food against Intentional Adulteration** [FDA-2013-N-1425] (FSMA-IA).

This review includes a section-by-section review of the Food Fraud aspects of the Intentional Adulteration Final Rule (FSMA-IA).

We will continue to review other aspects of the FSMA Final Rules such as changes or clarifications in definitions of terms applied to Food Fraud and then specific review of concepts such as what is a "harm," "hazard," "reasonably foreseeable hazard," a "qualified person," and a "qualified auditor." We will also further research other sections of FSMA that do – or could – address other aspects of food fraud such as smuggled food, supply-chain practices, and third-party certifications.

We will continue to inform global stakeholders as to the relationship between Food Fraud and Economically Motivated Adulteration, Food Crime, Food Integrity, and Food Authenticity in order to encourage a global set of terms and definitions that are consistent.

During our internal review process, there was a question of whether the term Food Fraud should be used since FSMA only uses the term Economically Motivated Adulteration. Our consensus was that the overall and international focus is broadly on Food Fraud – with a sub-category that focuses only on adulterant-substances and only on acts that lead to a health hazard. So it was helpful to directly explain the application to all types of fraud, only to adulterant-substances, and applied to health hazards. Per our previous reports, we stated that the broader requirements for GFSI or securities compliance appear to also meet FSMA related compliance. It is most efficient to implement one system that meets multiple compliance requirements. Since there are many other government and industry activities already underway, it is most efficient to use the more widely used, and broader, Food Fraud term.

FSMA-IA acronyms and definitions are included here:

[1] The *acronym* FF&EMA will be used where the situation refers to both Food Fraud and adulterant-substances. The FSMA-IA text often refers to threats that are both *Food Fraud* (all types of fraud in foods) and the FDA published Federal Register notice definition of *Economically Motivated Adulteration* (EMA) (a substance for economic gain that causes a human health hazard).

Acronyms

- *EMA - Economically Motivated Adulteration*
- *EC - European Commission (includes the Director General groups that manage Food Fraud)*
- *FDA - US Food and Drug Administration*
- *FF - Food Fraud*
- *FF&EMA – where the reference applies to both Food Fraud and EMA*
- *FSMA - US Food Safety Modernization Act of 2011*
- *FSMA-IA - FSMA Intentional Adulteration Section*
- *FSMA-PC – FSMA Preventive Controls section which actually includes two final rules: Human Foods and Animal Foods.*
- *GFSI - Global Food Safety Initiative (www.myGFSI.com)*
- *UK - United Kingdom (includes the Food Standards Agency)*
- *USG – US Government*
- *GAO – US Government Accountability Office*
- *CRS – US Congressional Research Service*

Definitions

- *Food Defense (General) – the broader, generally adopted definition*
- *Food Defense (FDA, Pre-FSMA) – From an FDA presentation at the Food Safety Summit in 2013 "the efforts to prevent intentional contamination of food products (Human intervention as the source of contamination)"*
- *Food Defense (FSMA-IA) – Food Defense as defined by the IA rule*
    - *Note: this only includes "wide scale [human] health harm"*
- *Contaminant (FSMA-IA) – substances intentionally added to cause harm*
    - *[Note: it is undefined how contaminant (FSMA-IA) compares to adulterant (FDCA, FSMA-PC). Also, this is an intentional act to create harm whereas CODEX is unintentional act with no intent to harm.]*
    - *Contaminant (CODEX) – a substance used in usual food operations that is unintentionally included in a product in an unacceptable level*
- *CODEX – Codex Alimentarius,*
    - *The food safety standards and guidelines officially adopted by the World Health Organization and generally globally adopted.*
- *Economically Motivated Adulteration (FDA 2009 Federal Register) – a substance for economic gain with a health hazard. Note: in general this term is avoided in our publications since there is often confusion between the application in this FSMA-IA rule, the 2009 FDA definition in the Federal Register, the Food Drug & Cosmetics term of "adulteration" within the "Adulterated Foods" section, and the common usage of the terms using dictionary definition.*
- *Economically Motivated Adulteration (FSMA-IA) – this was not defined in the final rule and refers to the FSMA-PC rule.*
- *Economically Motivated Adulteration (FSMA-PC) – this is not defined in the FSMA-PC final rule but it was made clear by FDA that all "economically motivated" acts that lead to an agent that creates a health hazard are within the scope.*
- *Intentional Adulteration (FSMA-IA) – the phrase defined in FSMA-IA*
- *Intentional Adulteration (FDCA) – the words and phrase defined by the US Food, Drug& Cosmetics Act of 1938, specifically the Adulterated Foods section*

History of Food Defense for FDA and FSMA

The FDA originally defined "the intentional act to cause harm in food" as ***Food Security*** but this was later adjusted by the US Government (USG) to ***Food Defense***. This was due in part to "Food Security" already being widely adopted per the World Health Organization's (WHO) definition as the safe, continuous, nutritious, and economic supply of food. The distinctly different term *Food Defense* was very helpful in that multiple uses of the same words would have caused confusion in the US and abroad. Food Security and Food Defense were not defined in a law or regulation so the FDA and USG were not restricted to any previous definitions.

FDA created a Food Defense and Emergency Coordination Staff to address Food Defense (FD). FDA and USDA had taken the lead through the Government Coordinating Council as the Sector Specific Agencies, and private sector owner and operators are represented by the Sector (industry) Coordinating Council (GCC/SCC). The GCC/SCC supports the National Critical Infrastructure Protection Plan for ***all*** Agroterrorism (also referred to as bioterrorism). Their work has included the development of the free CARVER+SHOCK assessment software[2] which was retired and replaced in compliance requirements in the Food Defense Plan Builder.

The Food Safety Modernization Act of 2011 (FSMA) – the law written by the US Congress – included eleven mentions of "intentional adulteration" (IA) usually with the phrase "intentional adulteration, including acts of terrorism" (note the placement of the comma). As strict grammatical interpretation of the text would addresses all types of intentional adulteration and one type of intentional adulteration is terrorism. As such, it was assumed that EMA would be addressed as part of the FSMA-IA Final Rule. Of note, ***Economically Motivated Adulteration*** (EMA) or ***Food Fraud*** are not specifically mentioned, defined, or addressed in the original law written by Congress.

After the draft of the FSMA-IA rule was published December 24, 2013, FDA mentioned in several public meetings starting on February 20, 2014 their intent to shift EMA into the previously released FSMA Preventive Controls Rule (FSMA-PC). This was logical because FDA stated that the countermeasures for EMA are more akin to Food Safety preventive controls. The prevention of FF&EMA is more efficient and akin to a Food Safety preventive control than a physical location based or site security plan elements that are typical for a Food Defense or counter-terrorism strategy.

The FSMA-IA Final Rule focused on "catastrophic" events that are intended to cause "wide scale [human] health harms." Essentially, FSMA-IA narrows the focus to large scale incidents – such as terrorist attacks – from the FDA Food Defense and Emergency Coordination Staff's scope of any size of intentional act. Large scale incidents could have included those that might be performed by "insider threats." That said, within the previous FSMA-IA proposed rule "Insider threat" excluded disgruntled employees, malicious tampering, mischievous tampering, return fraud, or stolen goods including cargo theft.

Changes since the FDA FSMA-IA public meetings are reviewed below.

[2] As of May 28, 2016, the Carver+Shock free software download was not available on www.FDA.gov. Also, the Vulnerability Assessment homepage stated "Update - The [Carver+Shock] tool below no longer represents FDA's current thinking. In May 2016, the FDA released the Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration."

Summary of the Review

FSMA INTENTIONAL ADULTERATION (FOOD DEFENSE) FINAL RULE REVIEW

Keyword Search

The keyword search quickly conveys how much attention is given to FF&EMA in the FSMA-IA Final Rule. The final rule contains 216 pages of 62,992 words (compared to over 470,000 in FSMA-PC). EMA was addressed directly in Part III (G) (2) (b) that included 675 words. Listed below are keywords associated with FF&EMA including the number of times they are mentioned in the two documents.

- *Economically Motivated Adulteration: 25 mentions*
- *Economic Adulteration: 0 mentions*
- *Food Fraud: 0 mentions*

Section-by-Section Review

The following is a section-by-section review of the FSMA-IA Final Rule as it relates to *Food Fraud* and the narrower FDA-defined *Economically Motivated Adulteration*. This includes public comments from the initial rulemaking process and the FDA responses.

For reference purposes, coding has been added to each pertinent section. Codes have three components:

- The first character defines the source document as the Intentional Adulteration rule ('IA'). This designation is used since these comments are often combined in reviews of the other FSMA final rules.
- The next three digits (after the dash) refer to the source document page number
- The final digit (after the decimal) identifies a separate concept addressed on that page.
- "FF Comment" sections are included, numbered, and authored by our researchers.
- For example, 'IA-200.3' refers to the Intentional Adulteration rule on page 200 with a specific note of the 3rd concept on that page. (Note: Any in-text emphasis (e.g., underlining) is added by the authors.)

This is a review of the FSMA-IA ONLY as it relates to Food Fraud and Economically Motivated Adulteration

Mitigation Strategies to Protect Food against Intentional Adulteration [FDA-2013-N-1425]

- **FF INSIGHT 01:** While the title is "Mitigation Strategies to Protect Food against Intentional Adulteration" this addresses the FSMA section on "Intentional Adulteration" which has been narrowed to Food Defense (FD).
- **Note:** FSMA-IA states legal authority under "Section 103 of FSMA" and "Section 106 of FSMA." Food Defense was mentioned in FSMA but not in those sections. Food Defense is mentioned in the original FSMA law under Section 108 National Agriculture and Food Defense Strategy and Section 110 (g) Biennial Food Safety and Food Defense Research. FSMA-IA expanded out of Section 106 Protection against intentional adulteration. To note: Section 103 Hazard analysis and risk-based preventive controls.
- **FF INSIGHT 02:** This is referred to as the "Intentional Adulteration Rule" and FDA uses the term "Food Defense." For example, from FDA's homepage " FDA Issues Final Food Defense Regulation - Final Rule will help prevent wide-scale public health harm by requiring companies in the United States and abroad to take steps to prevent intentional adulteration of the food supply."
- **Note:** the original title was "Focused Mitigation Strategies…" and it was simplified to just "Mitigation Strategies…" The concepts of "Focused" or "broad" mitigation strategies were removed from the final rule.

The Rule: Executive Summary

IA-001.1: "SUMMARY: The Food and Drug Administration (FDA or we) is issuing this final rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act [or FDCA]) to address hazards that may be introduced with the intention to cause wide scale public health harm."

- **FF INSIGHT 03:** This rule applies to US and foreign facilities to legally import and sell product in the USA. Domestic and foreign companies will need a FD identification/assessment/control/monitoring and prevention plan.
- Note: the phrase health *harm* is used not health *hazard*.
- **FF INSIGHT 04:** Within the very first sentence of the FSMA final rule there is an emphasis on the FDCA. Specifically the concept that applies is "Adulterated Foods."
- **FF INSIGHT 05:** The scope of FSMA-IA – emphasized repeatedly – is "to cause wide scale [human] public health harm" (the only other derivation of this was only one mention of "causing widespread human casualties").

IA-001.2: These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is issuing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA)."

- **FF INSIGHT 06:** The FSMA-IA compliance foundation is the "vulnerability assessment." The current primary vulnerability assessment is the FDA Food Defense Plan Builder (***not*** the previous Carver+Shock).

DATES: "This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION"

- **FF INSIGHT 07:** The "effective date" is stated as "60 days after the date of publication" but later the document states at least a three (3) year delay. Compliance with FSMA-IA may technically be in 60 days but there will be no enforcement or inspections for several years.
- **FF INSIGHT 08:** For insight on the compliance requirements this review included insight from: (1) the open phone-call on May 28, 2016 and the public webinar on June 21, 2016, (2) review content from the yet to be developed industry qualified individual training, (3) review content from the yet to be developed agency inspector training (e.g., the FSMA-PC rule inspector training has not been completed or implemented), and (4) review the yet to be developed vulnerability assessment training.

IA-005.1: "Executive Summary - Purpose and Coverage of the Rule – This regulation implements three provisions of the FD&C Act, as amended by FSMA, that relate to the intentional adulteration of food. Section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (21 U.S.C. 350d). Section 419 of the FD&C Act (21 U.S.C. 350h) addresses intentional adulteration in the context of fruits and vegetables that are raw agricultural commodities. Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk. FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C Act in this rulemaking."

- **FF INSIGHT 09:** This section defines the scope of FSMA-IA but there is recurring emphasis on the FDCA.

IA-005.2: "The purpose of this rule is to protect food from intentional acts of adulteration where there is an intent to cause wide scale [human] public health harm. This rule applies to both domestic and foreign facilities that are required to register under section 415 of the FD&C Act."

- FF INSIGHT 10: This reiterates—using a slightly different phrase—the focus on wide scale human public health harm.

IA-007.1: "Summary of the Major Provisions of the Final Rule - This rule establishes various food defense measures that an owner, operator, or agent in charge of a facility is required to implement to protect against the intentional adulteration of food."

- **FF INSIGHT 11:** All of FSMA is facility-focused but it could be managed or coordinated centrally. A facility will be the point of focus for IA. The facility must be able to demonstrate compliance. (A review of the science-based role of the centrally coordinated plan can be found in ***Food Control*** journal May 2016: http://www.sciencedirect.com/science/article/pii/S0956713516301219)

IA-007.2: "Identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. For each mitigation strategy implemented at each actionable process step, include a written explanation of how the mitigation strategy sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step (§ 121.135)."

- **FF INSIGHT 12:** Different sections of FSMA-IA use different terms for the same concept. Here "adulterated" seems to mean an intentional act to add a substance for wide scale [human] public health harm. Later this definition is used for the term "contaminant."
- **FF INSIGHT 13:** It is unclear whether "adulterated" includes the FDCA section on "Adulterated Foods" or is more narrowed "for this rule." This an important question for FSMA-IA compliance due to variation in the threshold and nature of what is considered "adulterated" for FSMA-IA and FDCA.

IA-008.1: "The effective date is 60 days after this final rule is published. However, we are providing for a longer timeline for facilities to come into compliance. Facilities, other than small and very small businesses, have 3 years after the effective date to comply with part 121. Small businesses (i.e., those employing fewer than 500 full-time equivalent employees) have 4 years after the effective date to comply with part 121."

- **FF INSIGHT 14:** While the FSMA-IA final rule is effective in 60 days there will be no compliance requirement for at least three (3) additional years until August 2019.

IA-009.1: "We specified three elements that must be evaluated when conducting a vulnerability assessment: (1) The potential public health impact (e.g., severity and scale) if a contaminant were added; (2) the degree of physical access to the product; and (3) the ability of an attacker to successfully contaminate the product."

- **FF INSIGHT 15:** Several key terms remain undefined including "potential public health impact," "severity and scale," "degree of physical access," and "ability of an attacker."
- **FF INSIGHT 16:** FURTHER REVIEW – the use of the term contaminant versus adulterant.
- **FF INSIGHT 17:** FURTHER REVIEW – although FDA stated Carver+Shock was discontinued, FSMA-IA mentioned four times that FDA FD recently used the Carver+Shock methodology.

IA-009.2: "We specified that the vulnerability assessment must consider the possibility of an inside attacker."

- **FF INSIGHT 18:** The definition of an "inside attacker" is limited to someone being able to cause "wide scale [human] public health harms." In the 2015 public meetings FDA stated that a typical "disgruntled employee" did ***not*** fit into this category.

These were the insights on the Summary and Executive Summary that applied to all Food Defense not only specifically to Food Fraud and Economically Motivated Adulteration. The next section will review the specific Food Fraud content.

The Rule: Economically Motivated Adulteration (Food Fraud)

This part is a review of specific FSMA-IA content that directly addresses FF&EMA. An additional section will review concepts that indirectly apply to FF&EMA.

IA-066.1: "Part II (G) (2) b. economically motivated adulteration. ¶ In the proposed rule, we stated that the goal of the perpetrator of economically motivated adulteration is for the adulteration to go undetected so the perpetrator can continue to obtain the desired economic benefit. Unlike with intentional adulteration, where the intent is to cause wide scale public health harm through instances such as acts of terrorism focused on the food supply, occurrences of economically motivated adulteration are expected to be long term, and would not be appropriately viewed as a rare occurrence, but rather as reasonably likely to occur. Because of these reasons, we concluded that the approaches in the PCHF and PCAF final rules are better suited to address economically motivated adulteration."

- **FF INSIGHT 19:** Moving FF&EMA to FSMA-PC – and addressed by a preventive control – is consistent with scholarly research, industry practice, and global regulatory direction.
- FF INSIGHT 20: FURTHER REVIEW - Food Defense is defined as a "rare occurrence" and ***not*** a "reasonably foreseeable hazard." EMA is "reasonably foreseeable hazard" and ***not*** a "rare occurrence." The nuance is important since it seems that a "rare occurrence" is *mitigated* (reduce the impact of an event) while a "reasonably foreseeable hazard" is *prevented* (the event can be avoided).

IA-067.1: "We sought comment on our conclusions. ¶ We received numerous comments related to economically motivated adulteration, including comments suggesting economically motivated adulteration is best addressed in this rule, comments suggesting it is best addressed in the PCHF and PCAF [FSMA-PC] final rules, comments recommending different hazard identification methodologies, comments related to terminology and definitions, and comments requesting postponement of any economically motivated adulteration-associated requirements. ¶ We continue to believe that the approaches in the PCHF and PCAF final rules are better suited to address economically motivated adulteration, and have finalized this rule with no requirements related to economically motivated adulteration for facilities covered by those rules."

- **FF INSIGHT 21:** The bottom line is that the compliance requirements for FSMA-IA (Food Defense) or FSMA-PC (Food Safety and Food Fraud) – regardless of the definition of terms such as hazard, reasonably foreseeable, significant vulnerability, credible threat, adulterant, contaminant – is to be able to demonstrate and defend a (1) vulnerability assessment and (2) a mitigation/prevention plan.

This section reviewed the content that specifically and directly addressed FF&EMA. The next section reviews other content that provides additional or indirect insight.

The Rule: Content That Applies to FF&EMA

The FSMA-IA content has many points that provide additional or indirect insight for FF&EMA. Such insight provides clarity to or—expands on—other sections of FSMA. For example, the FSMA-IA rule includes an extensive discussion of those types of facilities whereas the FSMA-PC rule does not elaborate on them with respect to FF&EMA. Many of the discussion topics seem to be more appropriate in the Preventive Controls rule but they *may* be included to provide more overall clarity for FSMA as a whole.

IA-064.1: "Part II (G) 2. Other Types of Intentional Adulteration: Disgruntled Employees, Consumers, and Competitors; and Economically Motivated Adulteration. ¶ a. Disgruntled employees, consumers, and competitors. ¶ In the proposed rule, we explained that when we considered the spectrum of risk associated with intentional adulteration of food, attacks conducted with the intent of causing massive casualties and to a lesser extent, economic disruption, would be ranked as relatively high risk."

- **FF INSIGHT 22:** This section states that "disgruntled employees" posed a "relatively high risk" but the focus has narrowed to exclude them based on the new concept of "wide scale [human] public health harm".

IA-064.2: "Note that to further clarify the rule's focus we have removed the reference to economic disruption from the definition of "food defense."

- **FF INSIGHT 23:** This section states that "economic disruption" is a relatively high risk but later the focus is narrowed only to human health hazards (in the rule referred to as harm).

IA-064.3: "We further explained that attacks by disgruntled employees, consumers, or competitors would be consistently ranked as relatively low risk mainly because their public health and economic impact would be generally quite small."

- **FF INSIGHT 24:** This is an example of the narrowing of the scope (see FF INSIGHT 01, 02, and 05 above).

IA-067.1: "In the proposed rule, we also tentatively decided not to require produce farms subject to section 419 of the FD&C Act and farms that produce milk (also referred to in this document as "dairy farms") subject to section 420 of the FD&C Act to take measures to address economically motivated adulteration. With regard to produce farms, we tentatively concluded that there are not procedures, processes, or practices that are reasonably necessary to be implemented by these entities to prevent the introduction of known or reasonably foreseeable biological, chemical, or physical hazards that can cause serious adverse health consequences or death as a result of economically motivated adulteration. ¶ With regard to farms that produce milk, we tentatively concluded that there are not appropriate science-based strategies or measures intended to protect against economically motivated adulteration that can be applied at the farm."

- **FF INSIGHT 25:** Although it was already stated for all products, this section expanded that addressing Food Fraud is ***not*** a FSMA-IA compliance requirement for "produce" and "farms that produce milk" including "dairy farms." This extra statement may have been necessary since the major food fraud incident databases identify milk and dairy products as a top-10 in food fraud.
- **FF INSIGHT 26:** The document continues to emphasize "in the proposed rule" reiterating that the statements do ***not*** apply to other final rules, all FSMA, or all US food laws.
- **Note:** The term "science-based strategies"—or "science-based approach"—is undefined. A peer-reviewed, scholarly article that is published in a journal with an *impact factor*[3] meets the threshold.

IA-067.2: "Those tentative conclusions were based on our assessment that preventive controls are suitable to address economically motivated adulteration when it is perpetrated by the entity's supplier, but not when it is perpetrated by the entity itself, and supplier controls are not warranted in this context because of the lack of inputs into the growing, harvesting, packing, or holding of produce or milk (i.e., activities within our farm definition) that could be subject to economically motivated adulteration that could cause serious adverse health consequences or death under sections 419 and 420 of the FD&C Act."

- **FF INSIGHT 27:** FURTHER REVIEW – this is the FSMA-IA final rule but there is extensive discussion clarifying and confirming what does or does not apply to FF&EMA. Specifically this section refers to "preventive controls" which *may not* explicitly be a statement about FSMA-PC compliance.
- **FF INSIGHT 28:** The content defines that FDA is aware that fraud can occur by suppliers and even producers, themselves. It would be ineffective to require a fraudster to implement, manage, and qualify their own fraud prevention plan.

IA-067.3: "We received one comment suggesting we include requirements related to economically motivated adulteration on produce farms and stating that economically motivated adulteration (e.g., illegal use of dyes and ripening agents) has occurred on foreign produce farms.

- **FF INSIGHT 29:** The commenter's example is an *intentional* act but most likely *not* intended to cause wide-scale public health harm. The example is not within the scope of FSMA-IA and, depending on the hazard analysis, a preventive control may not be required under FSMA-PC rule.

IA-067.4: "We continue to believe that preventive controls are suitable to address economically motivated adulteration when it is perpetrated by an entity's supplier, but not by the entity itself."

- FF INSIGHT 30: FURTHER REVIEW - It is unclear how this text applies to FF&EMA in "preventive controls" covered in FSMA-PC. This does provide some insight on FSMA-PC "supply chain controls" concepts.

[3] **Impact Factor:** In regard to scholarly publications, an *impact factor* is a ranking based on the number of times their published articles are cited in other scholarly articles, and for how long over time. The more times a journal's articles are published, over time, is an indication that that article has made a significant "impact" on research and scholarship. Journals with a higher impact factors – relative to other journals in their field – are usually more competitive for publication, attract more experienced authors as well as reviewers, and thus, often publish the most intense research.

IA-067.5: "Preventive controls for economically motivated adulteration are not suitable to address the situation where the same farm that would be economically adulterating the food (which is already prohibited) would also be responsible for implementing preventive controls to prevent the adulteration."

- **FF INSIGHT 31:** FDA and FSMA-IA again state an understanding that producers may be conducting Food Fraud. FDA also reiterates that, regardless of FSMA-IA or any of FSMA – this is still an illegal act under laws such as FDCA. Thus, if the act is ***not*** included in FSMA-IA, the US food laws still define this as illegal.

IA-067.6: "After considering this comment, we have finalized this rule with no requirements related to economically motivated adulteration on produce and dairy farms."

- **FF INSIGHT 32:** The content reiterates, again, that FF&EMA is ***not*** a FSMA-IA compliance requirement. The content also reiterates FF&EMA does not apply to produce or dairy farms for FSMA-IA.

This section addressed content that was related to FF&EMA but did not directly apply under FSMA-IA. The next section reviews broader concepts that apply more generally to the identification of human health harms and for vulnerability assessments.

The Rule: Other Content Related to Assessments

This part will review other text that provides insight but does not directly address EMA.

IA-023.1: (Comment 1) Some comments state food defense and food safety require different approaches because they are different disciplines. The comments explain that the science is different, that food safety deals with known and identifiable risks whereas food defense deals with unknown, often unidentifiable, and ever changing threats and that food safety risks can be prevented or reduced to an acceptable level but food defense threats only can be mitigated. ¶ (Response 1) We disagree that food safety and food defense require entirely different approaches to ensure that food is not adulterated. We agree that there are important, specific differences between food safety and food defense, and these differences require different requirements for particular components of the approaches. However, we believe that food safety and food defense are more similar than they are different. For both food safety and food defense, the framework for preventing adulteration, whether it is intentional or unintentional, is the same: (1) An analysis is needed to identify the hazards for which measures should be taken to mitigate the hazard; (2) appropriate measures must be identified and implemented; and (3) management components are needed to ensure systematically that the measures are functioning as intended.

- **FF INSIGHT 33:** For regulatory compliance in this rule, FDA recommends the basic risk analysis structure of risk assessment, hazard identification, risk management, and risk communication. No unique or special assessment method is required in this rule. This would seem to apply to Food Fraud as well.

IA-024.2: "We agree that the nature of the hazards being analyzed for food safety and food defense purposes are different, but we disagree that this means they need a different analytical approach. As discussed more in the responses to Comment 71 and Comment 72, the vulnerabilities considered for food defense, while not as predictable as some food safety hazards, lend themselves to analytical assessment because they have commonalities that would make them attractive to an attacker, particularly an inside attacker. In this rule, we are focusing on preventing the actions of an inside attacker. … Given the potential for wide scale public health harm from intentional adulteration of the food supply, we believe that a comprehensive, systematic approach, such as a HACCP-type approach, is the most appropriate one and is not too rigorous."

- **FF INSIGHT 34:** For regulatory compliance in this rule, no additional or different analytic approach is required. This would seem to apply to Food Fraud as well.
- **Note:** If there is one "analytic approach" for all rules in FSMA then a Food Safety risk assessment would be the formula. If the Food Safety assessment is applied to Food Defense and Food Fraud incidents, the combined likelihood and consequence of a Food Defense or Food Fraud incident may not be defined as a hazard (or there may be a near infinite number of vulnerabilities).

IA026.1: "We agree that, while the regulatory approaches for food defense and food safety fundamentally should be similar, there need to be differences in how the approach is implemented for food defense. We do not agree that a HACCP-type approach is too prescriptive in general for food defense, but additional flexibility is needed in the application of the approach for food defense given the difference in the nature of the potential adulteration and the implementation of mitigation strategies that are not likely to be process-oriented or readily lend themselves to validation. We also agree that differences in terminology are appropriate. (See responses to Comment 2, Comment 45, and Comment 47.)"

- **FF INSIGHT 35:** The basic model is the same, the analytic approach is the same, but FDA recognizes a difference in the application for food defense.
- **FF INSIGHT 36**: The foundational "science-based" HACCP concepts of validation and verification do not apply to Food Defense and thus, presumably, not to Food Fraud.

IA-041.1: "(Comment 13) One comment states that the term "credible threat" is not adequately defined in the proposed rule, nor is the relationship between a "credible threat" and a "reasonably foreseeable hazard" adequately described. …. ¶ (Response 13) We disagree with this comment and decline the request to include a definition for credible threat. It is not possible to identify with precision what constitutes a credible threat. There are many factors to consider in regards to how, what, when, or why those who intend to cause harm may take action. As such, it is not possible to write a definition for credible threat that is so broad that it covers potentially any do not piece of intelligence, nor so narrow that it is unnecessarily limiting. FDA routinely works with other agencies to maintain situational awareness of potential threats to the food supply and will consider that information in determining whether intelligence rises to the level of a credible threat."

- **FF INSIGHT 37:** The FSMA-IA scope does *not* include a definition of "credible threat."
- **FF INIGHT 38:** FUTURE REVIEW – It will be important to review comments in public meetings, additional formal FDA clarification, vulnerability assessment training details, FDA Warning Letters, recalls that may provide more insight on what is an unacceptable "credible threat."

- **Note:** This may be an irrelevant debate since there are no current known credible threats. It is undefined how credible threats would be communicated to the risk assessors. On page 24 it was stated "Though FDA is not aware of any information that points to an imminent, credible threat to the food supply, achieving public health harm through an attack via food remains an advocated option for terrorist groups." Further, if there is no credible threat there would seem to be no trigger for reanalysis of the FD plan considering this quote from page 35 "Specifically, § 121.157(b) (4) requires reanalysis of a food defense plan (which could lead to the identification of additional needed mitigation strategies) whenever FDA requires it to respond to new vulnerabilities or credible threats to the food supply."

IA-062.1: "These steps together will then work to significantly reduce the significant vulnerabilities associated with the transport of food. With respect to the prevalence of theft of food during transport, such theft is economically motivated; the scope of this rule is limited to acts of intentional adulteration where the intent is to cause wide scale public health harm."

- **FF INSIGHT 39:** FDA recognized and defined stolen goods including cargo theft ("theft of food during transport") as 'economically motivated.' While this is *not* a FSMA-IA requirement, it would be a FSMA-PC requirement.

IA-065.1: "The final rule is focused on protecting food against intentional adulteration where the intent of the adulteration is to cause wide scale public health harm. In the circumstance described by the comment where a disgruntled employee is recruited by a terrorist organization, the motivation of the employee has changed from harming the reputation of the company to that of the terrorist organization intending to cause wide-scale public health harm."

- **FF INSIGHT 40:** FSMA-IA seems to use terms "contaminant" and "adulterant" interchangeably.
- **FF INSIGHT 41:** The scope of "disgruntled employee" – or "insider threat" – is clearly defined only to be included when there is intent for "wide scale [human] public health harm

IA-081.1: "(Comment 43) One comment states that references to "terrorism" in the preamble to the proposed rule were unnecessarily limiting and confusing and recommends that instead of attempting to narrow the scope of intentional adulteration to "terrorism," FDA should use the definition of "food defense" to explain and further clarify the focus of activities covered by the rule. ¶ (Response 43) We agree with this comment and have modified the definition of "food defense" in the final rule as follows: "Food defense means, for purposes of this part [FSMA-IA], the effort to protect food from intentional acts of adulteration where there is intent to cause wide scale public health harm."

- **FF INSIGHT 42:** This new definition of Food Defense in FSMA-IA. It was not stated whether this definition would be adopted for all of FDA or just for compliance with FSMA-IA. It also was not stated which agency would be accountable for other types of terrorist attacks using food such as economic harm or psychological terror.
- **FF INSIGHT 43:** Adulteration is not clearly defined and it is assumed it is a substance intentionally added not the broader FDCA definition of "Adulterated Foods."
- **FF INSIGHT 44:** FUTURE REVIEW – The other US food law or bioterrorism regulations should be reviewed considering the compliance requirements separate from FSMA-IA. As with Food Fraud, a company could be FSMA-PC compliant but not FDA compliant due to the FDCA sections on "Adulterated Foods."

IA-081.2: "The purpose of this rule is to protect the food supply against individuals or organizations with the intent to cause wide scale [human] public health harm. Further, although economic disruption is likely to occur in any such instance of wide scale public health harm, because the focus of the rule is not the protection against economic disruption we have removed that language from the definition of "food defense" for purposes of this rule. In addition, as discussed in section III.G.2, economically motivated adulteration is not addressed in this final rule."

- **FF INSIGHT 45:** Again, it is clearly stated that Food Fraud not included in FSMA-IA – "economically motivated adulteration is ***not*** addressed in this final rule."
- **FF INSIGHT 46:** It is important to define the compliance requirements for FSMA-IA, FSMA-PC, all of FSMA, FDCA, any US Food Law, or any US law. Regardless of which exact type of compliance is being sought, Food Fraud is illegal, unfit for commerce, and companies face losses due to a recall under the FDCA sections on "Adulterated Food" or "Misbranded Food." A product can be compliant with FSMA-IA – or even of all FSMA – and still be illegal. It is most efficient to address all compliance requirements within one strategy.

IA-084.1: "7. Significant Vulnerability [Definition] - We proposed to define the term "significant vulnerability" to mean a vulnerability for which a prudent person knowledgeable about food defense would employ food defense measures because of the potential for serious adverse health consequences or death and the degree of accessibility to that point in the food process."

- **FF INSIGHT 47:** FSMA-IA mentioned future training that should define a "prudent person" (FSMA-PC has training for a "qualified individual").

IA-084.2: "Although we did not receive comments on the proposed definition for significant vulnerability, we have revised the definition to improve understanding of the regulatory requirements in § 121.130 (Vulnerability assessment to identify significant vulnerabilities and actionable process steps). In this final rule, significant vulnerability is defined to mean a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment, conducted by a qualified individual, that includes consideration of the following: (1) potential public health impact (e.g., severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker. For further discussion of the related changes made to the requirement in § 121.130 for a vulnerability assessment to identify significant vulnerabilities and actionable process steps, see section V.B."

- **FF INSIGHT 48:** A "significant vulnerability" is the result of a vulnerability assessment where the vulnerability is defined by a prudent person or qualified individual as "unacceptable" ("unacceptable" is not defined).

IA-095.1: "(Comment 44) One comment states that the proposed rule defines "food defense" within the scope of the rule and requests that FDA establish a generalized definition of "food defense" that can be adopted for the purposes of all FDA activities and subsequently the scope of this rule can then be further elaborated. The comment proposes the following definition of food defense: "Actions and activities related to prevention, protection, mitigation, response, and recovery of the food system from intentional acts of adulteration. This includes intentional adulteration from both terrorism and criminal

activities. Criminal activities include economically motivated adulteration, as well as acts by disgruntled employees, consumers, or competitors intending to cause public health harm or business disruption." ¶ (Response 44) We decline this request."

- **FF INSIGHT 49:** FSMA-IA is clear that the scope only includes "intentional… wide scale [human] public health harm." Addressing general criminal acts are ***not*** a FSMA-IA compliance requirement.
- **FF INSIGHT 50:** FUTURE RESEARCH – Review and confirm if the FDA Food Defense and Emergency Coordination Staff's focuses has also shifted. Originally their scope did include a broad definition of intentional acts including counterfeiting, FF&EMA, and others. For example, FDA requirements to address and enforce other related laws.

IA-096.1: "12. Vulnerability [definition] - We proposed to define the term "vulnerability" to mean the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration. ¶ We did not receive comments on the proposed definition of vulnerability and we are finalizing the definition as proposed."

- **FF INSIGHT 51:** The term "vulnerably" is consistent with scholarly research, international standards, and current initiatives such as the Global Food Safety Initiative (GFSI).
- **FF INIGHT 52:** FUTURE RESEARCH - FSMA-IA did not define acceptable or unacceptable level of vulnerability. The current tools, and future FDA examples or incidents, will be reviewed.

IA-096.2: "3. Reasonably Foreseeable [definition] - (Comment 59) Some comments state FDA should clearly define what constitutes a "reasonably foreseeable" threat as it relates to the risk of intentional adulteration. ¶ (Response 59) We decline this request. The term "reasonably foreseeable" is not used in the regulatory text of this rule."

- **FF INSIGHT 53:** FSMA-IA does not use the term "reasonably foreseeable hazard" and this content did not provide any additional guidance. This term is the foundation for FSMA-PC.

IA-105.1: "(Response 66) We disagree with these comments and continue to believe that animal food is not at high risk for intentional adulteration within the context of this rule. While we agree that some animal feed could be intentionally contaminated, our analysis shows only minimal potential for human morbidity and mortality as a result of an attack during, or associated with, animal food production. We analyzed both human and animal food using CARVER+Shock methodology."

- **FF INSIGHT 54:** There are no FSMA-IA compliance requirements for animal food.
- **FF INSIGHT 55:** FUTURE REVIEW – Carver+Shock was identified as the tool that led to the FDA conclusion for the exclusion of animal foods. A search of www.fda.gov on June 1, 2016 found no links to the Carver+Shock free software downloads. It is unclear when the software was last updated and the webpage note compatibility with old operation systems of Windows 98, Window 2000, and Window XP.[4]]

[4] The personal computer operating system has evolved to Windows 7 in 2009, Windows 8/ 8.1 in 2012, and now Windows 10 in 2015.

IA-105.2: "The event in 2007 involving contamination of wheat flour and wheat gluten with melamine that resulted in pet illnesses and deaths did not affect human health and was motivated by economic gain. That form of intentional adulteration (i.e., economically motivated adulteration) is addressed by the PCHF (FSMA Preventive Controls Rule for Human Food) and PCAF (FSMA Preventive Controls Rule for Animal Food) final rules."

- **FF INSIGHT 56:** FDA clearly defined that melamine in pet food is addressed in FSMA-PC.
- **NOTE:** FDA does not mention here that outside the USA melamine did cause a human health hazard in infant formula and skim milk powder – that said, this was an intentional act with ***no*** intent to harm.

IA-172.1: "(Comment 109) One comment suggests that FDA should mandate training on a "code of ethics" to prevent economically motivated adulteration. ¶ (Response 109) Acts of intentional adulteration for the purpose of economic gain, i.e., economically motivated adulteration, are outside the scope of the rule and are addressed in the preventive controls for human food rule (80 FR 55907 at 56028-56029) and the preventive controls for animal food final rule (80 FR 56170 at 56244-56246)."

- **FF INSIGHT 57:** This request is not a good fit for FSMA-IA, FSMA, or even a US food law. The comment essentially proposed that criminals pledge they will not commit crime. While this may seem like an illogical request there is value is a commercial agreement including a statement that the supplier will provide *authentic* or *legitimate* product. This type of statement clarifies the exact expectation and specifically defines non-compliance.

CONCLUSION

It will be important to review ongoing FDA public meetings or clarifications on the Food Safety Modernization Act as it applies to Food Fraud and EMA. It does appear that companies are already in the process of complying with the FSMA-IA rule as it applies to Food Fraud and EMA by virtue of compliance with international regulations and standards such as by the European Commission or emerging industry standards such as by the Global Food Safety Initiative.

The key concepts related to FOOD FRAUD/ ECONOMICALLY MOTIVATED ADULTERATION include:

1. FF&EMA is *not* a FSMA-IA compliance requirement though all types of Food Fraud are still requirements under the Food, Drug & Cosmetics Act (FDCA).
2. FDA specifically reiterated the FDCA sections on "Adulterated Foods" and "Misbranded Foods."
3. Stolen goods and cargo theft that lead to a public health hazard are clearly defined and expected to be covered under FSMA-PC.
4. There were no more clarifications of key terms such as reasonably foreseeable hazard, significant vulnerability, rare occurrence, credible threat, or the threshold of acceptable or unacceptable.

The key concepts related to FOOD DEFENSE:

1. While the FSMA-IA Final Rule is "enacted" in 60 days (July 25, 2016) it will ***not*** be a compliance requirement for at least three (3) years (July 25, 2019).
2. The coming months and years should provide clarity on the compliance requirements including from public meetings, additional reports, or statements, FDA Qualified Individual training for industry, and the training for agency inspectors.
3. FSMA-IA – and possibly all FDA Food Defense – only covers "wide scale [human] public health harm" and *not* economic harm or psychological terror. FDA originally managed these Bioterrorism Act requirements.
4. Other intentional acts that are now out scope include disgruntled employees, Food Fraud/ economically motivated adulteration, malicious tampering, and others

FUTURE RESEARCH: We will continue to review other aspects of these Final Rules such as changes in definitions of terms and then specific review of concepts such as what is a "harm," "hazard," "reasonably foreseeable hazard," "critical threat," "qualified person," "prudent person," and a "qualified auditor." We will also further research other sections of FSMA that do – or could – address other aspects of food fraud such as smuggled food, supply-chain practices, and third-party certifications.

Appendix

TITLE: FDA Public Conference Call on May 26, 2016 for the Same Day Release of the FSMA Intentional Adulteration Final Rule (FSMA-IA)

SUMMARY: This is a review of the May 26, 2016 FDA public conference call introducing the Food Safety Modernization Act (FSMA) Intentional Adulteration Rule. The final draft was posted in the Federal Register this day and the rule was officially published the following day. FDA announced this call to "Undisclosed Recipients" at 9:23AM for a Noon call.

The call was scheduled for 60 minutes but ended when there were no more questions at 36 minutes (which is not surprising since the 200+ page final rule was released 2.5 hours before this call). The lead on writing the FSMA-IA rule was Dr. Ryan Newkirk of FDA's Food Defense Coordination Staff. The first 12 minutes were introductions and a message from Dr. Steven Ostroff the new FDA Director of Foods. He spent much of his time commenting on the creation of the overall FSMA law by his predecessor. Dr. Ostroff stated, "Michael Taylor, more so than anyone else, is one person most closely identified with FSMA. and he has been a continuous presence… while [the final rules] were being developed and writing and implementing the regulations."

Several key insights from the call

- Dr. Ostroff made an especially important comment about FSMA-IA and all of FSMA stating, "Don't think of the foundational FSMA rules as seven stand-alone regulations since they work together from farm to table." Thus, for any subject including Food Fraud, there should be a view across all the rules not only the central Preventive Controls final rule (FSMA-PC).
- FDA reiterated that FSMA "fundamentally changes the food safety paradigm" from compliance to prevention. The agency will try to shift their focus and resources to this mission.
- Specifically addressing prevention, the FSMA-IA rule is significant because a food defense mitigation plan is a compliance requirement and not just recommended or voluntary.
- FDA reiterated that the most significant risk is from an "insider attacker" who has intent for wide scale human public health harm and not just a *disgruntled employee* who is probably just trying to harm the company (If *disgruntled employees* are not covered in FSMA-IA, it is not clear if they are covered in any food law.). Dr. Newkirk referred to this focus stating "… and the statue directs us to do so." (Note: to review the statute, the FSMA law text states "intentional adulteration, including acts of terrorism.")
- Source: FDA, US Food and Drug Administration, (2016). FSMA Public Call: Final Rule on Mitigation Strategies To Protect Food Against Intentional Adulteration, FDA Food Defense Coordination Staff, Presented by Dr. Steve Ostroff and Dr. Ryan Newkirk, Thursday, May 26 21, 2016, 12:00 to 1pm ET, URL: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm

TITLE: Review of the Food Fraud aspects or application of the FDA Public Webinar on June 21, 2016 for the FSMA Intentional Adulteration Final Rule (FSMA-IA)

AUTHOR: John Spink

DATE: June 21, 2016

SUMMARY: This is a review of the June 21, 2016 FDA public webinar introducing the Food Safety Modernization Act (FSMA) Intentional Adulteration Rule. The webinar was scheduled for 11 to Noon. There were no major clarifications or insights. For this review, there was a focus on Food Defense concepts, insights, or logic that would seem to apply to Food Fraud rather generally the more detailed Food Safety requirements.

Several key insights from the call:

- **General Concepts**
- There was more discussion about the written requirements. The Food Defense (FD) plans include a requirement for a "written explanation" of how the *mitigation step* will mitigate or eliminate the vulnerability. This is supports the requirement to shift from a prescriptive approach ("we put up a fence" to "we put up a fence to control an outside attacker from covertly accessing the bulk liquid storage tanks").
- The speaker emphasized a HACCP-type approach but was very clear to emphasize the final rule did ***not*** require ***all*** the formality or specifications of a preventive controls HACCP program.
- There lengthy discussion about preventative controls versus mitigation strategies. For example, preventive controls are more like process controls whereas mitigation strategies reduce access or availability. It was emphasized that the mitigation strategies were not subject to 'scientific validation' as is a core tenant of HACCP and preventive controls. The mitigation steps can be verified ("we locked the door and check it once a year") not validated ("by heating the product to 170F we have at least a 5-log kill reduction in C. Botulinum spores").
- The speaker made clear the final ruled did ***not*** apply to these facilities:
    - Dairy
    - Produce
    - Farms
    - Retail/ stores
    - Locations that only store or hold product other than bulk holding tanks
    - The speaker confirmed that dietary supplement production ***is*** included required
- **Training**
- International Compliance Requirements – since a "qualified individual" is required to conduct the food defense assessment and no international "qualified individual" training is available, then there will be challenges to completing the requirements. An option for the international supplier is to

send someone to the USA for the training or hire a consultant who has completed the Qualified Individual training.
    - This brought up and interesting discussion about the challenge or opportunity for internationally based companies to have access to a Qualified Individual required to conduct the FD plan. This would seem to restrain the ability for international companies to comply with FSMA – or necessitate hiring a consultant who has had the training in the USA.
    - This was specifically mentioned as a concern from an audience question regarding the Preventive Controls rule. Note: the FMSA-PC rule was effective in September 2015, PC Qualified Individual training is ongoing, and the Inspector Training has not been conducted, and compliance will be required for large companies in one year or on September 2016.
    - No online or web-based training has been offered.
- It was stated that the training would be "coming out in the next couple years." The rule will not be a compliance requirement for at least three years.
- **FSMA-Wide Semantics**
- Although *contaminant, contamination*, and *intentional contamination* is used in the Final Rule (originally the Food Defense staff used the term *intentional contamination)* the speaker only used the term *intentional adulteration*.
- To explain why FDA set a certain direction – or narrowed the scope -- the speaker used phrases such as "as the statute directed FDA," "the law required us," or "Congress did direct us," etc.
- The speaker emphasized that a less prescriptive approach – or fewer explicit requirements – increased the flexibility for industry. While there is increased flexibility that may also create more accountability as occurred in the tamper-evident requirements and apparently applied to Food Fraud/ Economically Motivated Adulteration. There are fewer required actions but if there is an incident it is also less clear as to what countermeasures are acceptable or unacceptable. Without a clear definition of what is acceptable or unacceptable there is more leeway for an FDA inspection or investigation to determine non-compliance.
    - Note: The threshold for what is "wide scale [human] public health harm" is still undefined. The lowest Carver+Shock category was 100 deaths.
- Source: FDA, US Food and Drug Administration, (2016). FSMA Webinar: Final Rule on Mitigation Strategies To Protect Food Against Intentional Adulteration, FDA Food Defense Coordination Staff, Presented by Dr. Ryan Newkirk, Tuesday, June 21, 2016, 11:00 a.m. – 12:00 p.m. ET, URL: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm502791.htm

Contact Information:
www.FoodFraudPrevention.com, spinkj@msu.edu. (517) 381-4491