To: Food and Drug Administration, Department of Health and Human Services

Re: Proposed Rule – Focused Mitigation Strategies to Protect Food against Intentional Adulteration; Document Citation: 78 FR 78013, Page: 78013 -78061, Docket No. FDA-2013-N-1425

Date: June 20, 2014

This response is to the request for public comments regarding the proposed rule regarding the Focused Mitigation Strategies to Protect Food against Intentional Adulteration by the Food and Drug Administration.

To note, our research is specifically focused on Food Fraud – including Economically Motivated Adulteration of food. This research includes an interdisciplinary approach including Food Safety, Food Science, Criminology, Public Health, Agricultural Economics, Supply Chain Management, Food Law, Consumer Behavior, Social Anthropology, Political Science, and others. Our previous research was cited in the original Federal Register notice for the Intentional Adulteration Section (see Everstine, Spink & Kennedy, 2012 and Spink & Moyer, 2011).

Our Comments – General Principles:

“Food fraud is a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product, for economic gain” (Spink & Moyer, 2011). A subset of Food Fraud includes adulteration commonly referred to as economically motivated adulteration (EMA). It is important to emphasize that while the motivation is economic, for every incident there always an economic threat and always a real and significant public health vulnerability. The following comments to the proposed rule addresses specific text from the Federal Register – which do not necessarily accompany a request for comment – and requests for input that pertain to Food Fraud and EMA.

Our Comments – Summary:

To summarize three main comments:

- **Focus on Food Fraud and Address Economically Motivated Adulteration.** To holistically embrace prevention, it is recommended to support a broader scope covering all Food Fraud and then defining a more specific focus on adulterants and adulteration. This is consistent with current FDA drug initiatives which are focusing on security rather than a detail such as counterfeiting.

- **Food Fraud and Economically Motivated Adulteration should be addressed separately from Food Safety or Food Defense.** This is consistent with FDA comments as well as current activity by other governments, non-governmental organizations, and industry. Many of those activities were mentioned in the Draft Rulemaking or previous US Government Accountability (GAO) of US Congressional Research Service (CRS) report.

- **Expand Definitions and Harmonize Terminology.** There are important terms that are not currently defined in a law or by FDA. Also, there are terms used by various stakeholders that often overlap the descriptions of the same incidents. It is efficient to harmonize terminology both within the US government and with outside stakeholders. In some cases the harmonization may lead to a changing the basic terms. There are examples of the US Government and FDA adapting to new terminology. For example, the US previously adjusted from the term Food Security to Food Defense. The term Food Security was already in use with a different and confusing definition.

The Food Safety Modernization Act is the most significant food law since the Food, Drug & Cosmetics Act of 1938. A major shift to prevention will be complex. FDA has been very proactive in public meetings and in publishing extensive draft rulemaking. There has been an excellent opportunity to participate.

The shift to prevention will not be easy but our food industry can learn from previous efforts. The healthcare field has a major focus on prevention through the focus on public health. The law enforcement field has balanced prosecution with crime prevention. More directly applicable to Food Fraud, the food industry can learn from the last 20 years of anti-counterfeiting efforts in the pharmaceutical segment.

At Michigan State University and within the Food Fraud Initiative, we are pleased to participate in the process and to contribute to the research. We look forward to continuing to be a part of the process of protecting the food supply chain.

This represents the opinion and insight of the individual authors and not of the overall Programs, Schools, Colleges, or University.
Sincerely,

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Executive Summary, Cost and Benefit Estimates – Benefits: The nature of product fraud – and citing broad previous research in Intellectual Property Rights – is that statistical, quantitative estimates of the economic impact are “unknown and probably unknowable” (Spink & Fejes, 2011). The fraud opportunity is unique to a specific fraudster, and thus, macroeconomic trends such as globally fluctuating commodity prices may be of no consideration to the specific fraudster. Those commodity price differentials would influence the local fraud opportunity – making fraud more lucrative, but only if the fraudster can individually benefit. Also, many of the fraudsters are opportunistic and may commit a fraud act at only one point in time (Spink, Moyer, Park & Heinonen, 2013). What is known is that the cost of a fraud act can be immense in terms of economics and public health. Thus, the benefits should be viewed more in terms of reducing vulnerabilities that may be financially intangible. Conclusion: The benefits of preventing fraud are defined very differently than for Food Safety and Food Defense estimates and mirror the efforts in Intellectual Property Rights. Also, estimating the cost of an intentional adulteration incident and the benefit of prevention will be extremely complex to quantify and potentially erroneous.

II. Background – Types of Intentional adulteration: From the proposed rule, “Acts of intentional adulteration may take several forms, including acts of terrorism; acts of Disgruntled Employees, consumers, or competitors; and economically motivated adulteration. Acts of terrorism are associated with intent to cause massive public health harm and, to a lesser extent, economic disruption (Ref. 5, Ref. 2, Ref. 3, Ref. 6).” Also, “The primary purpose of economically motivated adulteration is to obtain economic gain, and not to impact public health (Ref. 7, Ref. 8, Ref. 9), although public health harm may occur (Ref. 10, Ref. 11).” Conclusion: These three types of “Intentional Adulteration” have very different motivations. The criminology-based key to prevention is understanding the motivation of specific fraudsters. The motivation for a terrorist is wide-spread harm and panic, a disgruntled employee is to harm their employer in some way, and for economically motivated adulteration the goal is economic gain. To implement the most efficient and effective countermeasures, they should all be dealt with separately.

II. Background – Definitions, EMA: For a focus on prevention there should be a broader assessment of Food Fraud and not only adulteration. In many instances – or for specific products – a focus on adulteration is often more efficient. For food ingredients, generally adulteration acts have the highest potential to cause harm. Also, the capabilities or scope of many organizations’ are attuned to detecting adulteration. That said, for many packaged foods, product counterfeiting is often the major concern. This is also the case for other

1 Note: “Ref 7” is Everstine, Spink, and Kennedy, 2012; “Ref 9” is Spink and Moyer, 2011.
FDA regulated products such as medicines, medical devices, cosmetics, and others. This broader focus is efficient since the “bad guys” are focused on economic gain through deception not just through the act of adulteration. FDA Drug regulations appeared to have recognized this since the focus shifted from counterfeit medicines (Counterfeit Drug Task Force Report, 2003) to supply chain security (Secure Supply Chain Pilot Program to enhance the security of imported drugs, 2013). Additionally, Food Fraud is the over-arching concept used by the Global Food Safety Initiative (GFSI) which was mentioned in the Draft Rulemaking as an industry standard, the European Commission Resolution on Food Fraud, the UK Elliott Review of Food Fraud / Food Crime, ongoing UK Food Standards Agency activities in Food Fraud, the International Standards Organization in all product fraud, and others. Each of these groups defines adulteration as a critical component of Food Fraud. Conclusion: For harmonization with industry and international efforts, as well as the theoretical framework for crime prevention, it is recommended to define and focus on Food Fraud. It is also important to define Economically Motivated Adulteration in the regulations.

II. Background, C. Resources for the Food Sector: To note, the listed FDA resources are consistent with the traditional focus on Food Defense that is based on Homeland Security Presidential Directive-7 and -9. Conclusion. FDA Intentional Adulteration activities have focused on Food Defense.

II. Background, E. Industry Standards: The draft rulemaking stated: “Guidelines accompanying industry standards in the United States have addressed intentional adulteration of food. For example, the Global Food Safety Initiative's (GFSI) Guidance Document Sixth Edition (Ref. 33) addresses food defense. Some organizations that own and manage industry standards have worked or are working to incorporate food defense requirements into their standards to meet this GFSI guideline.” Since the publication of this Draft Rulemaking, GFSI has defined their focus on Food Fraud – including adulteration as one of the characteristics – with specifically separate approaches for Food Safety (HACCP), Food Defense (TACCP, threat assessment), and Food Fraud (VACCP, vulnerability assessment). GFSI adopted the TACCP concept from Publically Available Standard 96 (PAS 96) – PAS 96 was mentioned in the Draft Rulemaking. Conclusion: For efficiency and to leverage industry and global resources, FDA should consider aligning with current and pending industry and standards organization activities such as Food Fraud and VACCP.

2 For a summary see http://foodfraud.msu.edu/2014/05/08/gfsi-direction-on-food-fraud-and-vulnerability-assessment-vaccp/.
IV. Regulatory Approach, 1. Scope of Intentional Adulteration Covered by this Rule: FDA has stated the intent to only focus on terrorist and large scale attacks. Conclusion: It is agreed that the primary intent of Congress was probably to focus this section on counter-terrorism. But, FSMA has a broad scope of preventing all food safety incidents, and Food Fraud is also clearly within the scope of the overall FSMA. From subsequent GAO and CRS reports – as well as considering Congressional and Presidential direction to agencies in regard to Intellectual Property Rights – there is a clear expectation for FDA and USDA to combat Food Fraud and EMA.

IV. Regulatory Approach, 3. Requirement for a HACCP-Type System of Controls: The HACCP type approach is already familiar – and clearly accepted to be successful and efficient – to industry and agencies. It is consistent to use similar concepts for Food Defense and Food Fraud. As noted in the Draft Rulemaking, PAS 96 already uses “TACCP” for Food Defense, and now GFSI has stated intent to adopt TACCP for Food Defense and VACCP for Food Fraud. Conclusion: A HACCP-type approach is efficient. But, it is important to emphasize that current HACCP programs is not sufficient to address Food Defense or Food Fraud.

Additional Details: Our comments will focus on the application to Food Fraud/EMA and specifically that the vast majority of incidents do not include a public health threat.

- “From which entities would implementation of measures to protect against intentional adulteration derive the greatest benefit to public health protection? How could this proposed regulation be modified to better target such entities?” Consumers hold the entire food supply chain, industry, and governments responsible for providing safe food. The 2013 European horsemeat scandal may not score high as a public health risk or vulnerability, but if it were to happen again, there would be consumer outrage as to why this known type of fraud recurred. It has been clear through GAO and CRS reports that Congress expects the FDA and USDA to focus on prevention of Food Fraud and EMA. Conclusion: Consumers expect the food to be protected. Through GAO and CRS reports the US Government has established the expectation for the FDA and USDA to focus on preventing food safety incidents including Food Fraud and EMA.

- “Would it be feasible to require measures to protect against intentional adulteration only in the event of a credible threat? If so, would such an approach be consistent with the intentional adulteration provisions of FSMA? How would such requirements be communicated to industry in a timely and actionable manner?” Defining a credible threat or a reasonably foreseeable hazard is arguably the greatest challenge and the
key to implementing this section of FSMA. To emphasis this point, without clear definitions of these limits, the threshold of regulation could be very low. Implementation – e.g. companies taking action for compliance with the regulation – could be indefinitely delayed if these expectations are not clearly defined. Fortunately, this is a question that can be addressed through public-private collaboration. Basic terminology and concepts need to be defined as they apply to Food Safety, Food Fraud, and Food Defense. There is sound scholarly research and publications that are applicable such as the Criminology concepts of Situational Crime Prevention, Rational Choice Theory, and Routine Activity Theory. For example, Criminology prevention theory focuses on fraud opportunities regardless of whether an incident has actually occurred. **Conclusion:** The base concepts of “credible threat” and “reasonably foreseeable hazard” should be clearly defined before setting direction for enforcement and prevention. Preventing potential fraud opportunities, regardless of actual incidents, should be the focus. This may not be an easy shift but it is the best way to protect the consumers. Industry has shifted to prevention by implementing quality programs. Similarly Law Enforcement agencies have implemented crime prevention programs. Also, the Public Health field has established success in focusing on prevention activities for immediate risks (e.g., hand washing), near-term hazards (e.g., smoking secession, breast cancer awareness, etc.), and chronic issues (e.g., hypertension, exercise, etc.). Reducing the public health threat of Food Fraud requires a focus on prevention. We will not test our way to safety. We will not arrest our way to safety.

- “What is an appropriate level of public health protection with respect to intentional adulteration, considering the intentional adulteration provisions of FSMA?” FSMA is a challenging law to implement since it further shifts both government and industry from a prescriptive approach to a preventative approach. The prescriptive approach of shifting to prevention was previously implemented by FDA for tamper-evidence/tamper-resistance packaging laws. Comparable European regulations do not have the challenge of acting only after a public health threat due to a long-standing focus on “food integrity” rather than just “public health.” Although there are benefits and drawbacks both approaches, many groups such as GFSI are defining “food safety management” to include all root causes including Food Fraud. **Conclusion:** As previously stated, the base concepts need to be addressed and defined before setting the direction for enforcement and prevention.

- “Are there other ways to further focus the scope of the rule (see also section IV.1 of this document)?” There seems to be a fundamental question regarding intervention and prevention when addressing food
laws. The recent Food Fraud incident of ground beef having been adulterated with horsemeat illustrates this. While intervention should include testing for the presence of horsemeat, prevention must address the root cause of the fraud opportunity. In this example, the root cause relates to the valuable ingredient of protein. This exemplifies the efficiency of a separate VACCP-style approach for preventing Food Fraud. Crime prevention theory can help efficiently and effectively implement countermeasures. **Conclusion:** As with other submitted comments, scholarly articles, and industry activities, there is efficiency in adjusting to prevention in order to reduce the fraud opportunity. Although shifting to prevention will require a fundamentally different way of thinking for agencies and their metrics, there are successful examples from industry, government Law Enforcement, and Public Health agencies. Industry successfully shifted to a systems-approach for managing quality processes. Whether new systems are labeled Kaizen, Deming, Crosby, Six Sigma or others, industry now benefits from the new approach. Improved results including incident reduction are still the ultimate measure, there is now a focus on root causes and vulnerabilities throughout the supply chain. It is much more efficient to remove manufacturing vulnerabilities than to re-work off-specification product. These lessons on shifting from intervention to prevention are applicable to governmental management of Food Fraud opportunities.

- **IV. Regulatory Approach, E. Acts of Disgruntled Employees, Consumers, or Competitors:** These acts have a different motivation than for a terrorist or a Food Fraud/EMA perpetrator. The act of a Disgruntled Employee is still an intentional act with intent to harm (which could include economic harm), and thus is defined as a Food Defense act. Prevention countermeasures would be more similar to other Food Defense activities and distinctly different than combating Food Safety or Food Fraud acts. **Conclusion:** Preventing acts by a Disgruntled Employee is most efficiently addressed in similar Food Defense programs as physical facility security and terrorist acts.³

- **IV. Regulatory Approach, F. Economically Motivated Adulteration**

  - **A different approach than for Food Safety:** It is important that FDA reiterated “Efforts to protect against intentional adulteration require a shift in perspective from that applied to traditional food safety” and “...likely will require different kinds of controls, and would be best addressed in a separate rulemaking (this proposed rule).” This shift and requirement for different approaches has been stated by FDA over time.

³ The food related Disgruntled Employee is the subject of a soon to be published report that will be available at www.FoodFraud.msu.edu.
such the GAO report on EMA. **Conclusion:** Combating Food Fraud is fundamentally different than combating Food Safety or Food Defense.

- **Food Fraud and EMA should be addressed in the Preventative Controls Rule:** The FDA has noted stated that EMA is different from Food Safety and that it would not to be addressed in traditional Food Defense countermeasures. Food Fraud prevention theory is more aligned with the preventative-controls section and – as the FDA has stated – it is fundamentally different from addressing Food Safety. **Conclusion:** The preventative controls approach is logical only if that includes a system for Food Fraud that is separate from Food Safety and Food Defense. This is consistent with many other FDA statements as well as conclusions of many other organizations.

- **Vulnerability assessments:** Vulnerability assessments and countermeasures are unique to each specific supply chain, food product, and food integrity program. The evaluation of an acceptable assessment and countermeasure should consider specific fraud opportunities because virtually identical products in a virtually identical supply chain could have vastly different fraud opportunities. While macroeconomic forces such as dynamic commodity pricing obviously have an impact, the final decision to commit fraud is based on microeconomic factors. For example, if a fraudster deals in production and local delivery of bread then the fraud opportunity would not be in alcoholic beverage counterfeiting. **Conclusion.** Vulnerability assessments should be required but allow for the selection of countermeasures that are unique to each individual fraud opportunity. Justifying a performance-based program is much more difficult for a company than simply meeting a prescriptive directive (e.g., “include two of the following tamper evident features”) but it does provide more flexibility. Ultimately this flexibility achieves the goal for government and industry of protecting supply chains.

- **“Hazard assessment” or “vulnerability assessment” approach:** This is an example of confusing terminology and a need for harmonization. FDA refers to “vulnerability approach” aligned with Food Defense incidents whereas PAS 96 uses the term “threat” in TACCP. Also, GFSI uses the term “vulnerability assessment” with respect to Food Fraud. These are familiar credible sources since both PAS 96 and GFSI were referenced in the Draft Rulemaking. The EU has adopted the term Food Fraud while the UK is using Food Fraud and Food Crime. **Conclusion.** It would be most efficient if there was harmonized terminology.

- **“CARVER+Shock are not currently configured to assess the risk of EMA”:** This is true and also applies to Disgruntled Employees and Malicious Tampering. For example, the Tylenol tampering in the mid-
The 1980’s was essentially the single event that led to tamper-resistant packaging legislation and industry adoption. Because only six people died from this malicious tampering, a proactive CARVER+Shock risk assessment would have only suggested a potential “1” or “2” value in the Shock category. Considering Food Safety risk assessments, the horsemeat scandal would not have been prioritized since there was no – or a very low – public health threat. Applying CARVER+Shock or a Food Safety public health threat assessment to the horsemeat adulteration incident or the Tylenol tampering incident would have assessed both events as being low priority. Nevertheless consumers and Congress expect to be protected against such incidences – whether novel or not. **Conclusion.** Food Defense assessment tools are not appropriate to apply directly to Food Fraud.

- **Note – Additional Concept of Product Tampering:** Our previous comments above on product tampering raises a good point of where “malicious tampering” would be addressed in FSMA. **Conclusion:** Define where – or if – product tampering is addressed in FSMA

- **IV. Regulatory Approach. E. Economically Motivate Adulteration – request for comments:**

  - **Specific Food Fraud factors** – “Specifically, we [FDA] are interested in information on the specific factors that are most relevant for determining whether economically motivated adulteration is reasonably likely to occur, particularly in instances where the specific product or supplier has not been previously associated with such adulteration. In addition, we [FDA] seek comment on whether and how these relevant factors may be used to develop appropriate predictive tools or establish a standard for when preventive controls are necessary.” These are the right questions to ask. There are many initiatives underway to address them. GFSI has been mentioned above but there are also activities by the US Pharmacopeia/ Food Chemicals Codex, Grocery Manufacturers Association, and others. Many of these activities have been challenged since the most basic question is still undefined. That being, “What is needed to meet regulatory compliance?” It is not clear where – or if – Food Fraud will be addressed in FSMA Actually, the terms Food Fraud and EMA are not mentioned in FSMA. While it seems illogical given the GAO and CRS reports, the question remains of whether Food Fraud and EMA will be holistically addressed by FDA let alone in FSMA. Nevertheless, the development of Food Fraud prevention standards is underway in industry, other governments, and other organizations. **Conclusion.** These are the right questions to be asking but they can really only be answered after it has been assured that Food Fraud/ EMA will be directly addressed within FSMA. The FDA via FSMA is still in the
position to leverage ongoing activity in industry and globally.

- **Inclusion in other HACCP regulations (i.e. juice, seafood, etc.):** Again, a definition for Food Fraud and EMA is required before it can be addressed in FSMA (or any law and regulation). **Conclusion:** Food Fraud/EMA should first be defined in FSMA before considering expanding to other laws or regulations.

- **Expand to Dietary Supplements:** “…, FDA would consider proposing to amend 21 CFR part 111, the Dietary Supplements current good manufacturing practice (CGMP) rule, to include economically motivated adulteration.” FDA should take a holistic approach and address Product Fraud/EMA across all FDA regulated products. That scope would include dietary supplements but also medicines, medical devices, cosmetics, and tobacco. There are many “bad guys” who focus on “all products” not just food. A holistic prevention approach would cover all types of fraud and all products. **Conclusion.** Food Fraud/EMA must first be defined for food in FSMA. After that, consider how Product Fraud would apply across all FDA regulated products.

- **V. The Proposal, A. Definitions:** The entire definition section of FSMA – and the FDA’s website, should be reviewed and harmonized. Even the most basic terms that are used throughout FSMA and all of FDA should be in a glossary (e.g., review the FDA-wide use of the term “contaminant”). Many seemingly common terms have very different definitions by different stakeholders let alone across industries, in global laws, and in different cultures. Thorough terminology harmonizing research activities are being conducted by groups such as the International Standards Organization. Additionally to further examine establishing definitions from the Draft Rulemaking, “**FDA is proposing to define the term “contaminant” as any biological, chemical, physical or radiological agent that may be intentionally added to food and that may cause illness, injury or death.**”: How does this differ from adulterant? Can there be adulterated foods without an adulterant such in the case of spoilage or filth? Also, does the EMA term apply only to food or does it apply to medicines and all FDA-regulated products? **Conclusion.** Define and harmonize terms including the review of common definitions and definitions already in use. There should be strong consideration and evaluation of both the common definition of terms and those currently being use by other organizations. This would include contaminant, adulterant, economically motivated adulteration, significant vulnerability, science-based approach, vulnerability assessment, actionable process step, focused mitigation strategies, significantly minimize, prudent person, credible threat, reasonably likely to occur (and if there are differences for Food Safety, Food Fraud, and Food Defense), verification, and vulnerability.
References Cited: