Food Fraud Initiative

Master of Science in Food Safety Program

College of Veterinary Medicine

John Spink, PhD
Director & Assistant Professor
517-381-4491
SpinkJ@msu.edu
www.FoodFraud.msu.edu

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

Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Proposed rule; supplemental notice of proposed rulemaking. USA Department of Health and Human Services, 21 CFR Parts 1, 16, and 117, [Docket No. FDA–2011–N–0920]

http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920

Date: December 15, 2014

This is a response to the request for comments from the public for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Proposed rule; supplemental notice of proposed rulemaking by the Food and Drug Administration. This submission specifically addresses the FDA request for additional comments regarding Economically Motivated Adulteration.

To note, our research specifically focuses on Food Fraud – including the sub-category of food related Economically Motivated Adulteration. Our research includes an interdisciplinary approach including Food Safety, Food Science, Business Managerial Accounting / Enterprise Risk Management, Criminology, Public Health, Agricultural Economics, Supply Chain Management, Food Law, Consumer Behavior, Social Anthropology, Political Science, Public Policy, and others. Our previous research was cited in the original Federal Register notice for the “Intentional Adulteration” Section (see Spink & Moyer, 2011 and Everstine, Spink & Kennedy, 2012).

To begin, there have been a series of excellent and thorough responses to previous request for public comment solicitations. We encourage FDA to consider those previous comments in addition to the formal comments currently being submitted.

Before getting to our new comments, we will provide our previously submitted summary:

Comments – Summary:

- **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 by FDA or in a law. Also, there are terms used by various stakeholders that often overlap the descriptions of the same type of 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 globally with a different and confusing definition.

Since the previous public comment submissions and open meetings there are new specific insights on FDA addressing Economically Motivated Adulteration and Food Fraud. We will specifically expand on our first comment from above:

Focus on Food Fraud and Address Economically Motivated Adulteration.

- FDA is not restricted to the concept of Economically Motivated Adulteration: EMA was defined in the Federal Register Notice meeting invitation not in a law, regulation, or rulemaking document. EMA is not mentioned in FSMA. The FSMA focus was on “Intentional Adulteration” – and even the IA term was adjusted by FDA to only cover Food Defense.
- It is Logical to Review EMA during this shift from the FSMA Section on “Intentional Adulteration” to “Preventative Controls”: The shift of EMA from the FSMA IA section to the FSMA PC section is a logical opportunity for FDA to review the scope of the concept. An overall review of terms and terminology is warranted and this is consistent with the review of the IA term, itself, was adjusted by FDA to only cover Food Defense rather than all types of IA.
- Food Fraud is a Broader, More Holistic, and Efficient Concept to Address Prevention: Addressing all types of Food Fraud – or all crimes – is consistent with the leading theories and scholarship for Criminology and crime prevention. The preventative countermeasures and initiatives are most efficient when aligned with the way that criminals or fraudsters are conducting their activities. This is sometimes not aligned with the statutory boundaries of specific agencies or individual laws. This holistic approach has been adopted across the US Government in a wide range of crime fighting task forces including intellectual property rights, organized crime, human trafficking, and illegal drugs.
- Food Fraud is the Industry and Globally Harmonized Term: Considering industry and global harmonization – as well as the preventative approach to be holistic and all-encompassing – it would be most efficient to address Food Fraud not just Economically Motivated Adulteration. See below for more details.

Next we will expand on our second comment:

Food Fraud and Economically Motivated Adulteration should be addressed separately from Food Safety or Food Defense.

- Address Food Fraud in “Preventative Controls” but not in the Food Safety (HACCP) Activities: Comments by other submitters mirror this statement that Food Fraud is most efficient to be addressed under the FSMA “Preventative Controls” concept but that there should be a separate assessment for Food Fraud than for Food Safety (specifically see public submissions by USP and GMA). The current Food Safety
HACCP regulations and programs are very efficient, effective, and successful. We recommend the Food Safety HACCP programs are not changed or modified to add Food Fraud. This does not mean that there will be tremendous public or private resources needed to implement a new Food Fraud preventative controls program.

- **Coordination of Countermeasures:** There is a continuum of controls for Food Safety, Food Fraud, and Food Defense. Many of the countermeasures, inspections, audits, tests or monitoring already conducted for Food Safety or Food Defense naturally provide intelligence for Food Fraud prevention. While the overall vulnerability assessment or preventative control programs should be separate, many of the testing, audit, and monitoring functions can be integrated into Food Safety and Food Defense standard operating procedures. To effectively manage or assess Food Fraud prevention countermeasures, a laboratory manager or auditor does not need to be an expert in Food Fraud prevention.

- From our previously submitted comments:

  - 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.

- **Food Fraud Vulnerability Assessment Activities – Leverage Collaboration and Momentum:** There is current successful and effective public-private collaboration on Food Fraud (rather than just adulterants and EMA) and uniquely addressing Food Fraud prevention (separately from Food Safety and Food Defense). The public activities include the European Commission resolution on Food Fraud and the United Kingdom Elliott Review. Also, the EU Food Integrity Project and the UK Food Standards Agency have projects holistically addressing Food Fraud and prevention. The private activities include the Global Food Safety Initiate Position Paper on Food Fraud, the SSAFE Food Fraud Mitigation Guide Workshops that are supporting the GFSI Food Fraud initiative, the Grocery Manufacturers Association draft Workgroup on Economic Adulteration activities which define the difference between Food Fraud and EMA, and the US Pharmacopeia draft General Chapter on Food Fraud Vulnerability Assessment which specifically defines addressing adulterants versus all product food fraud. In general, EMA is a term only used in the US and only when referring to the FDA activities.

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

Sincerely,

John Spink, PhD  
**Director & Assistant Professor**  
Food Fraud Initiative (FFI)  
Master of Science in Food Safety Program  
College of Veterinary Medicine  
Michigan State University
Attachments

- MSU FFI FRN PC Rule Attachment One Review of Final PC Rule
- MSU FFI FRN PC Rule Attachment Two Seafood Fraud Submission
- MSU FFI FRN PC Rule Attachment Three PC EMA Submission
- MSU FFI FRN PC Rule Attachment Four Review of USP Submission
Several additional specific points are included or reiterated:

**FDA: Costs and Benefits. Review later.**
- AGREED. We agree the assessment of the costs and benefits should be addressed in the future after there is more clarity on the Food Fraud or EMA rulemaking.

**FDA: We requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons.**

**FDA:** When we [FDA] developed the 2013 proposed intentional contamination rule, we tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and for animal food (including hazard analysis, preventive controls, monitoring, corrective action, verification, and recordkeeping) rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism (see the 2013 proposed intentional adulteration rule, 78 FR 78014 at 7802).
- AGREED. Considering that Food Fraud/EMA must be addressed by the US Government, it would be most efficient for FDA to address Food Fraud/EMA to address it in FSMA, and in the PC section.

**FDA: Under the definitions that would be established in the rule, a hazard would be an agent that is reasonably likely to cause illness or injury in the absence of its control.**
- AGREED. Terms should be clearly defined including hazard, agent, adulterant, adulteration, adulterated foods (confirm the application to EMA), substance, prudent person, reasonably likely to occur, foreseeable hazard, and others.
- RECOMMENDATION: FDA should clarify and formally define the term “agent” if FDA intended the term “agent” to be synonymous with the term “substance” then the text should be changed to “substance.” There are international definitions adopted – or soon to be adopted – such as by the International Standards Organization Technical Committee 247. There are other ISO activities in relate Security Management, Anti-Counterfeiting, and Risk Management.
- Note: The term “agent” is confusing and should be changed or an FDA or CFR referenced definition should be provided. This term could be especially confusing when translating to a foreign language. For example the first definition in the Merriam-Webster Dictionary is “one that acts” and then “a person acting or doing business for another.” It appears FDA intended the term “agent” to be synonymous with “substance” as is used in the published Federal Register definition of EMA. Also, the next sentence in the proposed rulemaking shifts to the term “adulterant.”
- Note: There is confusion with the use of the terms adulterant, adulteration, and “Adulterated Foods”. Using the Food Fraud term – and an “Adulterant” as one type of Food Fraud – is less confusing. Food Fraud and “Adulterant” are also terms harmonized with industry and global initiatives. The term “Adulteration” should not be used due to confusion with “Adulterant” and the Food Drug and Cosmetics Act definition of “Adulterated Foods.” These terms and concepts are confusing especially when translating to a foreign language. We recently published a journal article simultaneously in English, Korean, Chinese, and Russian. During the development of the article we had many discussions about “Adulterated Foods” that did NOT include an “Adulterant.” Also, the term “Economically Motivated Adulteration” includes the term “Adulteration” which would insinuate an
“Adulterant” but would also insinuate the “Adulterated Foods” definition from the Food, Drug, and Cosmetics Act.

FDA: Thus, the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public health harm.

- AGREE and DISAGREE.
- AGREE. We agree that most of the intervention and response should be on “adulterants” and fraud opportunities that have the potential to create the greatest public health threats.
- DISAGREE. We disagree that this is the most efficient and effective preventative control. The fraudsters shift their focus based on a shift in the fraud opportunity. Prevention should focus holistically on entire supply chain prevention.
- RECOMMENDATION: “Economically Motivated Adulterants” should be defined separately from “Economically Motivated Adulteration.”
- Note: It is interesting to consider the use of the term “Economically Motivated Adulterants.” We are not aware of that term being used industry or governments. This term is clearer than “Economically Motivated Adulteration” since it clearly includes only products with an “adulterant.”

FDA: We also requested comment on when an economically motivated adulterant can be considered reasonably likely to occur.

FDA: We believe that it is practicable to determine whether economically motivated adulteration is reasonably foreseeable.

- RECOMMENDATION. This should be addressed after where – or if – Food Fraud/EMA is addressed by FDA in FSMA and “Preventive Controls.” In a previous blog post we noted that the current text of the rulemaking allowed a question of if Food Fraud or EMA would actually be addressed by FDA or in FSMA.
- RECOMMENDATION. We already noted the terms “reasonably likely to occur” and “foreseeable hazard” should be defined.
- In a previous blog post reviewing previous US Pharmacopeia comments, we included:
  - Reasonably Likely to Occur
    - USP brought up a key point – maybe THE key point when considering a legal challenge of the application of this regulation – with the use of the term ‘reasonably likely to occur.’

- Also, we previously stated:
  - Our previous comments pointed out the challenge of the concepts of “reasonably likely to occur” as well as the “credible threat.” In our previously submitted public comments on the IA rule we stated “Defining a credible threat or a reasonably foreseeable hazard is arguably the greatest challenge and the key to implementing this [IA] section of FSMA. To emphasize 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.”
Part C was: “Potential Requirements to Address Economically Motivated Adulteration.” FDA stated that they were requesting comments on “a potential requirement for the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain.” They add, “… with respect to our previous request for comment on whether to include potential hazards that may be intentionally introduced for economic reasons.” This insinuates that EMA may not be a requirement in FSMA.

To emphasize the critical insight: “This [FDA statement] insinuates that EMA may not be a [covered] by FSMA.”

FDA: In light of this [melamine adulteration] incident, a prudent person would include in its hazard analysis the potential for melamine to be an economically motivated adulterant in a facility’s food products when using milk products from a country where melamine adulteration had occurred and, based on the outcome of that hazard analysis, determine whether melamine is a hazard that must be addressed in the food safety plan.

- RECOMMENDATION: Due to the emerging regulatory, science, and industry practices, the definition of a “prudent person” and related countermeasures, are very difficult to define or assess. As noted above, the term “prudent person” should be defined further specifically as it relates to Food Fraud prevention, assessment of “reasonably likely to occur” and “foreseeable hazards.”