

MICHIGAN STATE UNIVERSITY

To: National Oceanic and Atmospheric Administration, Department of Commerce

Re: Request for Comments – *Presidential Task Force on Combating Illegal, Unreported and Unregulated Fishing and Seafood Fraud*; Document Citation RIN 0648-XD401, Docket No. NOAA-NMFS-0214-0090, Page: 44404-44405

[Note: These are our *preliminary comments* for discussion at the Public Meetings starting which start August 13, 2014 in advance of the due date of final written comments on September 2, 2014.]

Date: August 18, 2014

This response is to the request for comments regarding the *Presidential Task Force on Combating Illegal, Unreported and Unregulated Fishing and Seafood Fraud* by the National Oceanic and Atmospheric Administration, Department of Commerce.

To note, our research is specifically focused on Food Fraud – including economically motivated adulteration (EMA) of food. This research includes an interdisciplinary approach including based on Criminology crime prevention theory, as well as international business and public policy systems. This is supported by a multi-disciplinary approach with disciplines of Food Safety, Food Science, Public Health, Agricultural Economics, Supply Chain Management, Food Law, Consumer Behavior, Social Anthropology, Political Science, Fisheries and Wildlife, and others. A Food Fraud Reference Sheet is available at:

<http://foodfraud.msu.edu/food-fraud-reference-sheet/>

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).



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Our Comments – Summary:

We recommend a focus on prevention not just detection or deterrence – *suppress not solve*. Prevention is important since combating product fraud is more like managing diabetes than fixing a broken leg. For a Seafood Fraud Prevention plan to be holistic and all-encompassing a “comprehensive framework” must be global and consider all types of fraud. Of course this Task Force will explicitly focus on Seafood Fraud aspects of Food Fraud.

- **Focus on Prevention rather than just Detection:** The most efficient and effective focus is on prevention rather than just detection (finding the fraudulent product) or even deterrence (thwarting a specific perpetrator attacking in a specific way). There are applicable prevention strategies based on Criminology and crime prevention theory. There is an established academic foundation in Food Fraud that utilizes Situational Crime Prevention to understand the *fraud opportunity*. The process to analyze the risk includes identifying the incidents, assess why there was a *fraud opportunity*, conduct cluster analysis to define common characteristics, consider supply chain-wide countermeasures, and continue market monitoring for incidents. Constant monitoring is important since we should expect the bad guys to evolve their methods to continue conducting fraud. This is not easy as there are a near infinite number of potential fraudsters and types of fraud. We propose the “task force approach” adopt the process steps above in order to formalize a review of the *fraud opportunity* and understand how a broad range of countermeasures interact. This shifts the focus to prevention.
- **Focus on Over-Arching Supply Chain Integrity:** As noted in our response (see attached) to the Food Safety Modernization Act request for comments on the Intentional Adulteration section - specifically on EMA, there is efficiency in focusing on broader supply chain integrity issues. This is also applicable to Seafood Fraud prevention. When the supply chain is tightened there is a reduced *fraud opportunity*. Note: Similar Seafood Fraud specific *Food Integrity* concepts were addressed at the UK FERA Symposium of Food Integrity in February 2014 (this coincided with a meeting of the of the UK Food Integrity Project).
- **Review Other Related Food Fraud Prevention Activities:** The goals of this Task Force are similar to – if not conceptually identical to – ongoing global agency and industry activities in Food Fraud prevention. Specific actions include: the Global Food Safety Initiative's (GFSI) Food Fraud Position Paper; the European Commission's adopted referendum creating a definition of Food Fraud (and defining a focus on prevention); the United Kingdom's Elliott Review of Food Fraud (scheduled publication September 4). In the US, there are parallels to review the FDA drug supply chain integrity activity for perspective

on broad concepts that have very focused results. Some non-traditional food or Seafood Fraud enforcement actions could be to apply other laws such as treasury (tax avoidance), customs (smuggling), or food (a food product with our pedigree or traceability could be determined to be “unfit for commerce” under the “adulterated foods” section of the Food, Drug & Cosmetics Act). The goal is to reduce the *fraud opportunity* not just to trace product.

- **Focus on Broad Countermeasures – Transparency vs. Traceability:**

Increasing supply chain integrity and transparency is achieved by applying an integrated set of countermeasures including: traceability, authenticity testing, supply chain integrity systems, supplier management, laws and regulation, and investigation and prosecution. The importance of law enforcement and judicial system priority-setting cannot be underestimated. Seafood Fraud or Food Fraud often would be a low priority on a list dominated by *drugs, guns, and violence*. Also, the vast majority of Food Fraud – and Seafood Fraud – incidents do *not* have an obvious public health threat, so they often would be a low priority on public health threat priority lists. Nevertheless, there is *always* a public health vulnerability since there is low confidence in how suspect product was handled.

Our Next Steps

- Develop Our Final Comments: After the public meetings we will submit our final comments.
- Further Activity: We would be interested in supporting the Task Force in any way deemed valuable.

Conclusions

There are many food laws – or other laws we can use such as treasury, importation, or transportation – already enacted that can creatively be applied to prosecute food fraudsters and fundamentally shift to prevention. The Food Safety Modernization Act is the most significant food law since the Food, Drug & Cosmetics Act of 1938. The mandated shift to prevention will be complex.

The shift to prevention will not be easy for the food industry either. But they can learn from previous examples. The healthcare field shifted to prevention through its focus on public health. The law enforcement field now balances 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 industry.

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 as 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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Attachment: Seafood Fraud Questions

Comments to Specific Questions:

We will address these specification questions in our final submission.

“II. Topics for Comment and Discussion”

“Comment is particularly sought in response to the following questions:”

- ‘1. How can the government better coordinate its efforts across the full suite of activities related to the seafood supply chain?
- ‘2. What existing authorities and tools should be enhanced to combat IUU fishing and seafood fraud?
- ‘3. What are the key opportunities at the international level to address these issues through the regional fishery management organizations and bilateral efforts, such as technical assistance and capacity building?
- ‘4. What existing authorities should be better coordinated or streamlined to strengthen and harmonize enforcement provisions of U.S. statutes for implementing international fisheries agreements?
- ‘5. What existing authorities should be better coordinated or streamlined to strengthen and harmonize efforts between agencies, including Federal, State and local?
- ‘6. What opportunities are there, whether existing or new, to work with industry and other partners, including foreign partners, to develop and implement measures such as traceability programs to combat IUU fishing and seafood fraud?
- ‘7. How prevalent are mislabeling and species substitution within the domestic and foreign seafood supply in general?
- Where in the seafood supply chain is species substitution most likely to occur, and what role or actions can the federal government provide or enhance to address it?
- ‘8. To what extent is the comingling of seafood products from different origins an issue? Where along the supply chain does it occur?
- ‘9. What specific actions need to be taken to improve the transparency and traceability of seafood in the supply chain?
- ‘10. What are the actions and issues the Task Force should prioritize in developing its recommendations for addressing IUU fishing? What about seafood fraud?
- ‘11. What other topics related to IUU fishing and seafood fraud should the

Attachment: Previous Public Comments from our Submission for the FDA Food Safety Modernization Act section on “Intentional Adulteration”

These are selected comments from our previously submitted comments to the public record regarding the US Food Safety Modernization Act section on “Intentional Adulteration”. Our comments specifically focused on the Economically Motivated Adulteration concepts.

- **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.
- **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 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.

- **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.¹
- **Additional Details:**
- *“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.
- *“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 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. 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

¹ For a summary see <http://foodfraud.msu.edu/2014/05/08/gfsi-direction-on-food-fraud-and-vulnerability-assessment-vaccp/>.

regardless of whether an incident has actually occurred. **Conclusion:** *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 cessation, 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.

- **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.*

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