

MICHIGAN STATE UNIVERSITY

To: Office of the Deputy Under Secretary for Food Safety, USDA, Barbara.McNiff@fsis.usda.gov

Re: Meeting of the Codex Alimentarius Commission, Notice of public meeting and request for comments, [Docket No. FSIS-2016-0013]

Detail: Request for Comments Specifically on Agenda for the 39th Session of the CAC item "Food integrity/authenticity"

Date: June 9, 2016, Updated

This is a response for request for comments by USDA specifically of the CAC item "Food integrity/authenticity" (Food Fraud including Economically Motivated Adulteration).

Part I – For Codex in general

- (1) *A critical need is for Codex to develop a position paper including definition of adulterant, adulteration, Food Integrity, Food Authenticity, and Food Fraud.*
- (2) *There is a need for Codex leadership to define and provide risk assessment, vulnerability assessment, risk management and risk communication standards to address Food Fraud.*

Recommendation 1: A formal Codex statement on Food Fraud is recommended. By beginning with a statement the concept can be reviewed and assessed for possible next steps. MSU has interest, expertise and has been expanding its resources in this area and is prepared to support the US Delegation.



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Part II – For the USA within Codex

- (1) *Various aspects of the Agriculture sector -- collectively and individually as well as, in the public and private sector -- are addressing Food Fraud. For many public health and economic reasons it is important for the USA to establish a global leadership role.*
- (2) *Codex leadership addressing in Food Fraud and adulterants could support the evolving US food laws that would specifically provide insight for the Economically Motivated Adulteration aspects of the Food Safety Modernization Act recently published the Preventive Controls Final Rule.*

Recommendation 2: It is recommended that the US Delegation propose to host and be secretariat of an *Electronic Working Group* which may lead to an *ad hoc Inter-governmental Task Force* to examine both the potential public health impacts and the trade economic aspects of Food Fraud. MSU has interest and expertise to support inputs from the US Delegation.

More details are included below in the Background.

Sincerely,

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BACKGROUND

This is a response for the *Codex Alimentarius Commission: Meeting of the Codex Alimentarius Commission, Notice of public meeting and request for comments* by the Office of the Deputy Under Secretary for Food Safety, USDA. This submission specifically addresses the FDA request for additional comments regarding *Agenda for the 39th Session of the CAC item “Food integrity/authenticity” (Food Fraud including Economically Motivated Adulteration)* on June 27, 2016 in Rome.

To begin, we applaud the Office of the Deputy Under Secretary for Food Safety, USDA for seeking public comment on the agenda items. We are pleased to have the opportunity to respond to this Request for Comments.

A few definitions are included here:

- **Food Fraud** is illegal deception for economic gain using food. This is the general definition is adopted by the Global Food Safety Initiative, European Commission, the UK in The Elliott Review, UK by the Food Standard Agency, and recent Chinese government publications. The types of Food Fraud include adulterant-substances, tampering including misleading statements, theft, unauthorized production, diversion and smuggling, simulations, and intellectual property rights infringement of product counterfeiting. Note: Food Fraud including the sub-category of economically motivated adulteration.
- **Food Integrity** is defined by the EU as “the state of being whole, entire, or undiminished or in perfect condition. Providing assurance to consumers and other stakeholders about the safety, authentic, and quality of European food is of prime importance in adding value to the European Agri-food economy.”
- **Food Authenticity** is defined by the UK as “about ensuring that food offered for sale or sold is of the nature, substance and quality expected by the purchaser. Specifically this is from the UK Elliott Review citing “Section 14 Food Safety Act 1990).
- **Economically Motivated Adulteration**, per the 2009 FDA Federal Register Notice, is a “substance” for “economic gain” that causes a “hazard.” The Food Safety Modernization Act scope addresses “economic acts” that could lead to a human health hazard – which would cover all types of Food Fraud explicitly including stolen goods. To note, this term is not widely used outside the USA. Note: other terms that have been previously used in the USA include *willful adulteration*, *intentional contamination* and *economic adulteration*. Note: in this context, the *contamination* term is used counter to the Codex definition.
- **Food Crime** has several definitions based on criminal acts which would include intentional fraud, *un-intentional* fraud such as accidental mislabeling, and intentional acts to harm including Food Defense, disgruntled employee and malicious tampering. For example the UK Elliott Review states “Food Fraud becomes food crime when it no longer involved a few random acts by ‘rogues’ within the food industry but becomes an organized activity perpetrated by groups who knowingly set out to deceive and or injure those purchasing a food product.

Once the focus broadens to all types of Food Fraud, it may seem to be a low priority for Codex or the USA but there is a significant negative impact on public health and trade (e.g. melamine in skim milk powder, horsemeat in beef, and counterfeit infant formula). There is a timely opportunity for a coordinated effort to greatly increase the global efficiency and effectiveness of reducing the public health and economic impact of Food Fraud. By creating early and clear direction there could be globally harmonized terms and countermeasures dealing with both the public health and the trade issues. This harmonization would create great efficiencies that support economic growth, protect the public, and also support food security efforts to feed an increasing world population.

We received comments that “Codex Alimentarius is in a better position to set up a common platform from which we can [develop a common Food Fraud prevention strategy].” Also, comments included that there are many separate Food Fraud – or some sub-component -- activities and efforts around the world led by regulators, enforcement, global food companies, academia and trade associations that “will lead to higher levels of complexity that will require painful convergence and harmonization in the near future.” Also, regarding this type of risk, “Food Fraud is probably the best place [for Codex] to start at this point.” Other related areas are unapproved food additives, environmental contaminants, etc.

MSU FFI RESEARCH SCOPE

Our MSU Food Fraud Initiative (MSU FFI) research specifically focuses on Food Fraud – including the often misused term associated with the sub-category of food related Economically Motivated Adulteration. Our research includes a multidisciplinary 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 research, teaching, and outreach activities provide unique insight on Codex and specifically “Food integrity/authenticity” (addressing Food Fraud which includes the act of Economically Motivated Adulteration):

Publications:

- We have published over 30 peer-reviewed, scholarly journal articles or chapters on Product Fraud, Food Fraud or product counterfeiting.
 - An especially important publication related to international affairs and Codex includes Codex Committee chair Dr. Yongning WU from the Chinese National Center for Food Safety Risk Assessment (CFSA): Spink, John; Moyer, Douglas C; Forsht, Victor; Park, Hyeohn Ho, & Wu, Yongning. (2015), Introducing Food Fraud including Translation and Interpretation to Russian, Korean, and Chinese Languages, *Food Chemistry*, Volume 0, Number 0, pp. 00-00 (ISI 3.259; SJR 1.559)
- We have been frequent contributor to Request for Comments from FDA and others regarding food safety related topics in the USA.

Teaching:

- The MSU FFI has developed and taught online, distance education graduate courses on product fraud, including Food Fraud, since 2003 for over 500 graduate students from over 25 countries.
- Food Fraud MOOC (Massive Open Online Course): We developed and teach this free, open program to educate. The 7th and 8th versions are planned for July and November 2016. The 6th version was co-hosted by the Chinese National Center for Food Safety Risk Assessment (CFSA) and includes their translation in the sub-titles. To date there have been over 3,000 participants from over 50 countries.
- The MSU Institute for Food Laws and Regulations has taught a distance learning course entitled *Codex Alimentarius* twice per academic year since 1998. Included are modules written by a retired Secretary of Codex Alimentarius, and high ranking officials in WHO, WTO, World Bank, a government official in a developing country and a representative of the food industry --- all are/or/were frequent attendees at Codex meetings.

Outreach Activities by FFI Director or Faculty where noted:

- Instructor, for the *Food Fraud* as well as *Prerequisite Programs* sections of the *Qualified Individual Training* for the Preventive Controls for Human Foods (PCHF) final rule for the Food Safety Modernization Act (FSMA).
- Chair, US Delegation to ISO Technical Committee 247 on (Product) Fraud Countermeasures and Controls.
 - The TC has created standards including 12931:2012, *Performance criteria for authentication tools for anti-counterfeiting in the field of material goods* and 16678:2014, *Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade*.
- Advisor to the Chinese National Center for Food Safety Risk Assessment (CFSA) to focus on Food Fraud prevention in 2015.
 - My host was Dr. Yongning WU who is leading the food integrity/ authenticity/ fraud research in China. He is also an active member and chair of Codex committees. This work has led to Dr. Wu co-authored articles and chapters including translations into Chinese. The key work is a co-authored chapter on Food Fraud in Food Safety in China: Past, Present and Future (edited by Dr. Junshi CHEN and Dr. Joseph JEN).
- Advisory Board, European Commission, Food Integrity Project, 2015+.
 - This is the coordinating project for EC food integrity research which is funded to 12 million Euros.
- Visiting Scholar, Queen's University Belfast.
 - My sponsor is Professor Christopher Elliott, lead researcher and author of the UK Elliott Review of the Food Crime and Food Fraud. This is the UK guide for Food Fraud prevention.
- Member, Food Fraud Think Tank, Global Food Safety Initiative (GFSI).
 - This Think Tank was created by the GFSI Board of Directors to provide a review and recommendation for addressing Food Fraud. GFSI has adopted the recommendations and the GFSI Compliance will now require addressing Food Fraud in vulnerability assessment and prevention plan.
- Advisor, Economic Adulteration/ Food Fraud Working Group, Grocery Manufacturer's Association (GMA), 2012+

- Member, Food Defense Committee, Grocery Manufacturers Association (GMA), 2012+
- Founding Member, Expert Panel, Dietary Supplement Adulteration with Drugs, U.S. Pharmacopeia/ Food Chemicals Codex (USP), 2013+
- Advisor, Brand Protection Working Group, Grocery Manufacturer's Association (GMA) & Food Marketing Institute (FMI), 2013+
- Founding Member, Expert Panel, Food Ingredient Intentional Adulteration, USP/Food Chemicals Codex (USP), 8/2010+
- Steering Committee, Member, State of Michigan's Food and Agriculture Protection and Defense Team, 2004+
- In addition, we have averaged over 40 external presentations per year for the last five years with an emphasis on global trends and international presentations.

PREVIOUS MSU FFI COMMENTS to the USG

Before providing comments for the Codex meeting, we restate our previous Food Safety Modernization Act Preventive Control Rule comments submitted on November 16, 2013:

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.

MSU FFI COMMENTS for CODEX

Regarding Codex, we have been reviewing the current activity and have several comments for (1) Codex in general and (2) for the USA within Codex:

Part I – Codex in general

(1) *A critical need is for Codex to develop a position paper including definition of adulterant, adulteration, Food Integrity, Food Authenticity, and Food Fraud.*

- a. This is similar to GFSI creating a Food Fraud Think Tank to review the concept and application within the scope of the standard.
- b. This is also similar to the ISO TC 247 activities developing standards for product fraud.
- c. Note: Codex has a definition of *contaminant* but not of *adulterant*. Contaminants have defined acceptable levels and are common substances used in legitimate food operations. Codex should review the need for a definition of *adulterant* to be able to clearly define in relation of Food Fraud, Food Integrity, and Food Authenticity to the Codex *contaminant* standards.

(2) *There is a need for Codex leadership to define and provide risk assessment, vulnerability assessment, risk management and risk communication standards to address Food Fraud.*

- a. Food Fraud – including Economically Motivated Adulteration, Food Integrity, Food Authenticity, and Food Crime – is an urgent issue that is a concern for countries and companies. Without Codex guidance, or at least a statement or definition, is potential for tremendous confusion and inefficiency in the selection and implementation of countermeasures or control systems.
- b. Confusion arising from the lack of a Codex harmonized term or risk analysis system results in “guardian and hurdle gaps” that undermine the global food supply chain and the Codex mission (from the Codex Procedural Manual, 24th Edition, Statutes of Codex, Article 1, page 4):
 - “(1) protect the health of consumers and ensure fair practices in the food trade;”
 - a. = Food Fraud is a health vulnerability or hazard
 - b. = Fraudulent practices undermine the economic viability of producer and consumer marketing
 - “(2) promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations;”
 - a. = Codex standards and definitions would provide a common global set of terms and prevention strategies.
 - “(3) determines priorities and initiates and guides the preparation of draft standards through and with the aid of appropriate organizations;”
 - a. = At least a statement or framing document would provide clarity on the optimal role of Codex in Food Fraud prevention.

- “(4) finalizes standards elaborated and publishes them in a Codex Alimentarius (food code) either as regional or worldwide standards,”
 - a. = Companies and countries are making policy and strategy decisions and a Codex statement would increase the efficiency of all the activities.
- “(5) together with international standards already finalized by other bodies, wherever this is practicable;”
 - a. = See #4 above.
- “(5) and amends published standards, as appropriate, in the light of new developments.”
 - a. = See #4 above.

Recommendation 1: A formal Codex statement on Food Fraud is recommended. By beginning with a statement the concept can be reviewed and assessed for possible next steps. MSU has interest, expertise and has been expanding its resources in this area and is prepared to support the US Delegation.

Part II - The USA within Codex

(1) The world collectively and individually, in the public and private sector, is addressing Food Fraud. For many reasons it is important for the USA to establish a leadership role.

- a. Food Fraud is a subject that is becoming the focus of laws, regulations, certifications, and standards. Beyond novel food safety vulnerabilities there are financial concerns for the global economy, international regulations that will apply to US exports, as well as for imported foods and commerce within the USA. All countries and regions that must address Food Fraud or risk major economic losses (e.g., European Member States due to counterfeiting and Protected Designation of Origin [PDO]), export trade barriers (e.g., Australian and New Zealand dairy products to China), general loss of consumer confidence (e.g., the horsemeat incident had a major negative impact on the overall UK economy not just the food industry), and general trust of governments or social harmony.

(1) Codex leadership addressing in Food Fraud and adulterants could support the evolving US food laws that would specifically provide insight for the Economically Motivated Adulteration aspects of the Food Safety Modernization Act recently published the Preventive Controls Final Rule.

- a. USA activity in Codex could -- as it has for contaminants -- be a leading resource for the world to address the issue as one body. There is great efficiency in a harmonized set of terminology and standard practices for countermeasures and control systems.

Recommendation 2: It is recommended that the US Delegation propose to host and be secretariat of an *Electronic Working Group* which may lead to an *ad hoc Inter-governmental Task Force* to examine both the potential public health impacts and the trade economic aspects of Food Fraud. MSU has interest and expertise to support inputs from the US Delegation.

We have demonstrated our interest and ability for engaging international harmonization efforts. We welcome the opportunity to support the USDA or Codex in any of these efforts and in any capacity.

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

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