FFI Report

Review: Final Rule for FSMA Preventative Controls Regarding Food Fraud and EMA

By Spink & Moyer

Video overview (11-minutes): https://youtu.be/JoVRi73AUEg

SUMMARY (150-word-brief): This is the our review of the Food Safety Modernization Act Preventive Controls (FSMA-PC) Final Rule for Human Food and for Animal Food that was published yesterday. The Final Rule confirms that FF/EMA must be addressed. FF/EMA is addressed under Preventative Controls (Food Safety) and not Intentional Adulteration (Food Defense). This Final Rule does ***NOT*** address ***ALL*** US Government or even all FDA Food Fraud related requirements (e.g. another FSMA Section 309 covers Smuggled Food). Though a new FDA rule, it appears FSMA-PC compliance is achieved by meeting the most basic GFSI Food Fraud requirements. It would be logical – or forced if the US faces a horsemeat fraud type crisis – that the US Government will eventually more holistically addressed Food Fraud prevention. The rest of the world (e.g., EU, UK, China, and industry through groups such as GFSI) has holistically addressed the broader Food Fraud and prevention concept.

CONCLUSION: The key FF/EMA related findings are included here:

1. The Final Rule has defined that specifically addressing the Food Fraud/EMA incidents that could led to a public health hazard is a compliance requirement. The rule did not differentiate the source of the fraud act between adulterant-substances or any economically motivated act.
2. The FSMA-PC Final Rule only defines compliance to this rule and not necessarily the Food Fraud aspects of other parts of FSMA (e.g. Section 309 Smuggled Foods), other Food Laws (e.g. Food Drug & Cosmetics Act sections on Adulterated Foods) or other US Government laws (e.g. tax avoidance smuggling, intellectual property rights, stolen goods, etc.).
3. It appears that current broad Food Fraud Vulnerability Assessment and Food Fraud Prevention Plan activities will lead to compliance with FSMA-PC.

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BACKROUND

Introduction

This is the our review of Food Fraud (FF) aspects – including the sub-category of Economically Motivated Adulteration (EMA) – of the recently published US Food Safety Modernization Act (FSMA) Preventive Controls Final Rule. This review covers the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for* ***Human Food*** [FDA-2011-N-0920] (FSMA-PC) and accompanying rule for ***Animal Food*** [FDA-2011-N-0922].

This includes an overview as well as a section-by-section review of the Preventive Controls Final Rules.

Our research team will continue to review other aspects of these Final Rules such changes in definitions of terms and then specific review of concepts such as what is a "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.

Acronyms

- EMA - Economically Motivated Adulteration
- EU - European Commission (includes the Director General groups that manage Food Fraud)
- FDA - US Food and Drug Administration
- FF - Food Fraud
- FF/EMA - Food Fraud and EMA
- FSMA - US Food Safety Modernization Act of 2011
- FSMA-IA - FSMA Intentional Adulteration Section. (i.e. Food Defense, catastrophic events, etc.). This includes the accompanying Draft and Final Rule.
- FSMA-PC – FSMA Preventative Controls section. This includes the Final Rules for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food [FDA-2011-N-0920] and the accompanying version for Animal Food [FDA-2011-N-0922]
- GFSI - Global Food Safety Initiative (See www.myGFSI.com)
- UK - United Kingdom (includes the Food Standards Agency for the UK and also for the country of Ireland)
- USG – US Government
- GAO – Government Accountability Office
- CRS – US Congressional Research Service

History of FDA Regulations Regarding Food Fraud/ EMA

The use by FDA of the term Economically Motivated Adulteration (EMA) has not been officially mentioned or defined in a law or regulation. EMA was only defined by FDA in a public meeting invitation. Here is a summary of some US EMA related events:

2009

- In the FDA's invitation to the 2009 Public Meeting on EMA, EMA was defined as a "substance" for "economic gain" with an emphasis on incidents with a "health risk." EMA has not been defined by the US anywhere else. Since FDA started with that definition, and then was restricted by the rulemaking process during FSMA implementation, the EMA or Food Fraud terms have not been more holistically addressed. Fortunately, the US and FDA can benefit from extensive global agency and industry activity and research in the Food Fraud area.
- Note: From the Federal Register: "For purposes of this public meeting, FDA proposes a working definition of EMA as the fraudulent, intentional substitution or addition of a substance in a product … for economic gain. EMA includes... to the extent that such dilution poses a known or possible health risk to consumers,… ."

2011

- In January 2011 the US passed the Food Safety Modernization Act. Most rules were due to published between 6 and 24 months.
- The term "Economically Motivated Adulteration" is *not* mentioned in the 2011 Food Safety Modernization Act law. Thus the FDA had to choose where – *or if* – it would be addressed in FSMA.

2013

- In 2013 the FDA released the Draft Rule for Preventative Controls (FSMA-PC) to address traditional Food Safety health hazards.
- The comment period for the FSMA-PC closed without mention of FF/EMA. It was suggested at the time that FF/EMA would be addressed within the impending Draft Rule on Intentional Adulteration. This was logical as FF/EMA is an intentional act.
- In 2013 the FDA released the FSMA Intentional Adulteration (FSMA-IA) Draft Rule that included the phrase "intentional adulteration, including acts of terrorism" (note the placement of the comma).
- The comment period for the FSMA-IA rule closed without a conclusion on FF/EMA. The FDA stated they interpreted Congress's intent for this section to address "catastrophic events" such as "acts of terrorism." (Essentially they perceived the comma as providing clarification to limit the types of intentional adulteration for an intentional "catastrophic event.")
- In that FSMA-IA document FDA stated that FF/EMA was better addressed within the FSMA-PC rule.

2015

- FSMA-PC Final Rule was published on September 17, 2015 which included the conclusions for how EMA would be addressed. There would be no usual comment time periods.
- Rather than the typical sequence of publishing a revised Draft Rule, gathering public comment, and publishing a Final Rule, the FDA inserted its interpretation of FF/EMA directly into a revised FSMA-PC Final Rule.
- There is no formal comment period or process for the FSMA-PC Final Rule. "This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]."

The FDA conclusions and direction for Food Fraud/ EMA were published in the FSMA-PC Final Rule. Usually new regulatory guidance on topics are typically vetted via Draft Rules that enable public comments before a Final Rule is released.

FDA Options for Addressing and Defining FF/EMA Were Limited

The options for the FDA to more thoroughly define FF/EMA were very limited given the sequence of events described above. Those options included the following:

- (1) Create a separate Rule for EMA or more broadly for Food Fraud. FSMA is a comprehensive regulation that was created to broadly address "food safety" with a focus on "prevention." This

new landscape presented an opportunity to holistically cover Food Fraud and prevention. In reality, FDA did not have the capacity to expand the scope. FDA could comply with the law and follow the current narrow statutory boundaries of definition and scope.

- (2) Delay the FSMA-PC rule to gather public input on FF/EMA definitions and regulations. This was not likely due to legal deadlines (i.e. the FDA had been sued for previous delays in the publication of the final rules).
- (3) Publish EMA requirements in the FSMA-PC Final Rule without public comment. The FDA chose this option.

These options were specific for FDA to meet the publication requirements for the Preventative Controls section. There are other sections of FSMA that directly (e.g. Section 309 Smuggled foods) or indirectly (e.g. Section 307 Accreditation of Third Party Auditors).

Complying with the FSMA-PC rule ***does not*** equate to compliance with ***all*** of FSMA or ***all*** of the USG Food Fraud related regulations. Food Fraud could be – and is – mentioned or addressed in other FSMA sections (e.g. Section 309 Smuggled Foods), FDA regulations (e.g., Food Drug & Cosmetics Act), and by other agencies such as economic crimes under the Department of Justice and Department of Commerce.

The following review ***only*** applies to compliance with respect to Food Fraud and the FSMA-PC Final Rule. It begins with a keyword search followed by a section-by-section review including comments.

FSMA PREVENTATIVE COTNROLS FINAL RULE REVIEW

Keyword Search

The keyword search quickly conveys how much attention is given to FF/EMA in the FSMA-PC Final Rule. The Human Foods document contains 906 pages and the Animal Foods document has an additional 666 pages. Overall there at over 470,000 words in the two Final Rule documents. Listed below are keywords associated with FF/EMA including the number of times they are mentioned in the two documents.

- *Reasonably Likely to Occur*: 21 mentions
- *Reasonably Foreseeable Hazard*: 123 mentions
- *Fraud* or *Fraudulent*: 12 mentions (Food Fraud: 0 mentions)
- *Economically Motivated Adulteration*: 40 mentions ("EMA": 0 mentions)
- *Adulteration*: 140 mentions
- *Adulterated*: 202 mentions
- *Adulterant*: 0 mentions

It is interesting that even though the FDA working definition of "Economically Motivated Adulteration" specifies a "substance," the term "adulterant" did not appear once in the over 1600 pages of rulemaking. Adulteration and adulterated were widely used. Also, although widely used in practice, the abbreviation "EMA" was never used. In part avoiding "EMA" could be due to several related confusing acronyms such as the European Medicines Agency. Even after the FDA public meeting on EMA – that covered all FDA regulated products – the term "EMA" was really only used for foods. The FDA – with the exception of organizations directly working to address FDA activities – is the only country or organization that still uses the term *Economically Motivated Adulteration*.

The keyword search indicates that FF/EMA is very small part of the FSMA-PC Final Rule.

Section-by-Section Review

The following is a section-by-section review of the FSMA-PC Final Rule as it relates to FF/EMA. 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 either the Human ('H') or animal ('A') rulemaking
- The next three digits (after the dash) refer to the source document page number
- The final digit (after the decimal) identifies a separate concept.
- "FF Comment" sections are included, numbered, and authored by our researchers.
- For example, 'H-200.3' refers to the Human Foods rule on page 200 with a specific note of the 3rd concept. (Note: Any in-text emphasis (e.g., underlining) is added by the authors.)

Preventative Controls Rulemaking for Human Food (FDA-2011-0920)

H-001.1: "SUMMARY: The Food and Drug Administration (FDA or we) is amending our regulation for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food in two fundamental ways. First, we are modernizing the long-standing current good manufacturing practice requirements. Second, we are adding requirements for domestic and foreign facilities that are subject to our regulation for Registration of Food Facilities to establish and implement hazard analysis and risk-based preventive controls for human food. We also are revising certain definitions in our regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided for "farms" and, in so doing, to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and risk-based preventive controls for human food. We are taking this action as part of our announced initiative to revisit the current good manufacturing practice requirements since they were last revised in 1986 and to implement new statutory provisions in the FDA Food Safety Modernization Act.¶ The rule is intended to build a food safety system for the future that makes modern, science- and risk-based preventive controls the norm across all sectors of the food system."

- FF Comment 1: Economically Motivated Adulteration is not mentioned in the summary section of the FSMA-PC final rule. EMA is a concept that was not explicitly mentioned in the original FSMA law so there is no specific requirement to address it directly. Addressing all Food Fraud was implied in the original text due to the emphasis on prevention and "intentional adulteration, including acts of terrorism" (note the comma) before that was interpreted to mean "intentional adulteration acts of terrorism" (no comma).
- Note: Per International Standards Organization (ISO), criminology theory and other resources, "prevention" is reducing the likelihood an even will occur and "mitigation" is reducing the impact if the event does occur (among others, see ISO TC292 Security Management).

H-015.1: "A facility subject to the rule must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are any hazards requiring preventive controls. The first step of a hazard analysis is hazard identification, which must consider known or reasonably foreseeable hazards, including biological, chemical, and physical hazards. The hazard analysis must consider hazards that may be present in the food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain."

- FF Comment 2: A hazard analysis (not explicitly a Hazard Analysis and Critical Control Plan or HACCP) is specifically required when "known or reasonably foreseeable hazards" exist and the motivation is for "economic gain." The hazard analysis will determine if there are hazards and which are "requiring preventive controls." To be consistent with the European Commission, the United Kingdom, and others such as the Global Food Safety Initiative (GFSI) this would be a "vulnerability assessment." There is some confusion because FDA refers to a Food Defense risk analysis as a "vulnerably assessment."
- FF Comment 3: Previous FDA Food Safety regulations and HACCP-type activities – e.g. Food Safety and separately, Food Defense – are focused on processes within a manufacturing "facility." This concept of overseeing and auditing a "facility" is naturally used throughout FSMA and the rulemaking. In the case of Food Fraud, the vulnerability and root cause usually occur outside the facility. Thus, "a facility subject to the rule" could have a Food Fraud Vulnerability Assessment implemented and managed by a central, enterprise-wide group. Often an entire company is subject to the same type of fraud (e.g. species swapping in meat), managed by a central function (e.g. corporate purchasing), across all facilities (e.g. their facilities use the same vendor), and the preventative controls would most efficient if implemented by and across the entire enterprise. (By definition, a preventative control that is implemented outside the physical facility would be a "pre-requisite program" and not explicitly in a facility-level HACCP plan [Reference the GMA, Grocery Manufacture's Association (2015). HACCP - A Systematic Approach to Food Safety: A Comprehensive Manual for Developing and Implementing a Hazard Analysis and Critical Control Point Plan, 5th Edition].)
- FF Comment 4: Food Fraud and EMA are new regulatory concepts so there are few examples to quantitatively or analytically define what FDA would consider a "known" hazard or what a "reasonably foreseeable hazard."

H-015.2: "We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past.

- FF Comment 5: It is interesting that the FDA states these conclusions even though there are few statements or documents were previously released addressing EMA.
- FF Comment 6: This is an example of some rulemaking statements that enable broad interpretation. Arguably this sentence could be used as a defense for a company to feel they did ***not*** need to implement EMA preventative controls. Wording such as "rare" and "a pattern" are currently not quantitatively or analytically defined.
- FF Comment 7: Due to current language it is unclear if the threshold of regulatory compliance will be high - or more likely – will be very low.

- FF Comment 8: Due to current industry initiatives and activities, the new FF/EMA FSMA-PC rule compliance requirements will likely ***not*** be a concern for industry. Addressing the FSMA-PC compliance will most likely not be an entirely new activity since preventative controls were already in development. During the crafting of the rulemaking, FDA may have been aware of this efficiency as Food Fraud Vulnerability Assessments and prevention plans are already being implemented due to global industry requirements (e.g., GFSI, etc.). Additionally, assessing and preventing FF/EMA vulnerabilities makes good business sense when producers consider Enterprise Risk Management. GFSI certification has become essentially a requirement for conducting food business.

H-015.3: "Economically motivated adulteration that affects product integrity or quality, for example, but not food safety, is out of the scope of this rule."

- FF Comment 9: It is important to emphasize the text is defining the compliance for "this rule" – the FSMA-PC rule only. FSMA, and specifically the PC rule, addresses health hazards and a traditional Food Safety scope. FSMA in general focuses on "Food Safety" with a priority on addressing hazards that are defined by illnesses or deaths. The conclusions and direction of the rulemaking is aligned with the FSMA focus on Food Safety.
- FF Comment 10: While FSMA – specifically the FSMA-PC rule – is focused on Food Safety, the GAO report on EMA as well as the CRS report on Food Fraud, clearly states an expectation that USG food agencies (including the FDA) will address the entire food supply chain and focus on prevention. It will be interesting how those overseers (e.g. Congress through the GAO and CRS), the broader industry initiatives, and the impact of Food Fraud incidents shape the future regulatory landscape.
- FF Comment 11: Globally, other regulatory agencies are focusing broadly to prevent all types of Food Fraud incidents including the European Union, United Kingdom, and China, as well as industry through the GFSI. A key concept is that, regardless of the results of the current incident (e.g. horsemeat fraudulently added to beef which did not have a current health hazard) where there is a vulnerability there is a root cause for a health hazard.

H-422.1: "(Comment 401) Some comments assert that predictable intentional hazards should be in the food safety plan but unexpected intentional hazards should be part of a food defense plan."

H-422.2: "(Response 401) This rule only requires a facility to consider intentionally introduced hazards when such hazards are introduced for purposes of economic gain. Hazards that may be intentionally introduced by acts of terrorism are the subject of the 2013 proposed intentional adulteration rule (78 FR 78014, December 24, 2013)."

- FF Comment 12: The comment author suggested splitting some of the FF/EMA incidents into Food Safety preventative controls and a Food Defense prevention plan. The FDA response does not directly address the question but does clarify that the Food Defense/ Intentional Adulteration section of FSMA only addresses catastrophic events such as acts of terrorism.
- FF Comment 13: The goal is to reduce the "fraud opportunity" by reducing the Food Fraud vulnerability. This is rooted in the criminology theories of Situational Crime Prevention, Routine Activities Theory, and Rational Choice Theory (there are hundreds of scholarly articles on the successful application of these theories). If FDA – or the comment author – accepted this comment then they would mandating the split of a widely accepted concept into two new parts that does not appear to add additional value. There is efficiency to reducing all fraud opportunities in one program, regardless of the historical results of a health threat tor only an economic threat. Also,

ongoing global activities (e.g. GFSI, US Pharmacopeia, European Commission's Food Integrity Project, UK Food Fraud Network, etc.) are already holistically addressing all Food Fraud vulnerabilities in one plan. Those systems prevent Food Fraud regardless of the actual human health threat. Prevention activities for all food-related risk countermeasures realistically are implemented in one over-arching system and are a continuum between Food Quality, Food Safety, Food Fraud, and Food Defense.

H-422.3: "(Comment 402) Some comments disagree that the human preventive controls rule should address hazards that are intentionally introduced for purposes of economic gain (economically motivated adulteration). Some of these comments assert that economically motivated adulteration is not a good fit for the hazard analysis and preventive controls framework because it is, in all but the rarest of circumstances, an issue of product integrity and quality, whereas food safety systems are designed and built to prevent or mitigate food safety hazards."

- FF Comment 14: This is a valid point but in the absence of a separate rule for EMA and the limited scope of FSMA-IA, the "Preventative Controls" section is the best fit.
- FF Comment 15: Of note, in the FDA's initial request for comments, they asked ***if*** EMA should be covered in FSMA ***at all***. The most important finding in this review is that addressing FF/EMA is a requirement for FSMA-PC compliance.
- FF Comment 16: The FDA seemed to originally entertain the idea there could be separate rulemaking for EMA but it is clear from the FSMA-PC Final Rule that EMA is only addressed here. Thus, if EMA will be addressed, it is most efficient to address it in the "Preventative Controls" section than the "Intentional Adulteration/ terrorist attack" section.

H-422.4: "Some comments state that traditional food safety hazards are primarily both identified and addressed at the facility level, but economically motivated adulteration is typically handled by the corporate parent company, where supply chain management programs are typically located. These comments also assert that food safety-related economically motivated adulteration is extremely rare and that predicting economically motivated adulteration to prevent it is extremely difficult."

- FF Comment 17: For companies with multiple locations, it is inefficient – if not impossible, for Food Fraud to be addressed exclusively at the facility level. This is a key point as it is much easier to build on or supplement current plant facility HACCP plans to address FF/EMA vulnerabilities. By definition HACCP food safety controls focus on significant health threats within operations that can be mitigated through facility actions. But Food Fraud prevention is also required outside production facilities. For example, species testing - even if conducted in the manufacturing plant's laboratory – is outside production operations. Thus, the comment is technically correct with respect to EMA as an entire supply chain concern.

H-422.5: "Some comments assert there will be no measurable benefit to food safety by imposing requirements to consider economically motivated adulteration as part of a food safety plan and that doing so will consume limited resources without a corresponding increase in consumer protection.

- FF Comment 18: There is global recognition that Food Fraud must be addressed because it is a food safety issue. Food Fraud incidents – regardless of the actual human health hazard –is a root cause for Food Safety incidents.

H-422.6: "Other comments assert that there is no need to require a facility to identify hazards intentionally introduced for purposes of economic gain because the misbranding and adulteration provisions of the FD&C Act already sufficiently provide safeguards against economic gain."

- FF Comment 19: There are two important points within this comment. The first point addresses facilities to implement a plan. See FF Comment 17 above regarding facilities and supply chain. The second point addresses existing regulations. FSMA is an important extension of the FD&C and the great value is in expanding prevention requirements and guidance.

H-422.7: "(Response 402) We agree with the comments stating that the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past.

- FF Comment 20: See FF Comment 8 above regarding subjects and vague terms.

H-422.8: "In addition, we define hazards to only include those agents that have the potential to cause illness or injury. Economically motivated adulteration that affects product integrity or quality, for example, but not food safety, is out of the scope of this rule."

- FF Comment 21: The key statement is "out of the scope of this rule" – the FSMA-PC rule. From the GAO and CRS reports it is clear the USG – and FDA – is expected to be addressing all types of Food Fraud but not explicitly in this rule. Fortunately the US has not experienced a significant Food Fraud incident such as the horsemeat fraud in beef or melamine in infant formula that sparked Food Fraud regulations in Europe and China (respectively).

H-422.9: "We continue to believe that there is benefit in taking this preventive approach to economically motivated adulteration, and not solely on enforcing the preexisting misbranding and adulteration provisions of the FD&C Act after a violation occurs."

- FF Comment 22: The powers granted in FSMA allow for additional activities by FDA to protect the food supply chain. These new powers add a prevention approach that is consistent with HACCP and the focus on process control. The FD&C really just defines what is illegal for a "product" and does not address the "process" control and prevention.

H-422.10: "As discussed in sections XLII through XLIX, we are finalizing supply-chain program provisions. It is consistent with the framework of this rule for a facility to address hazards requiring a preventive control that may be intentionally introduced for purposes of economic gain through the facility's supply-chain program."

- FF Comment 23: It appears the FDA intended that facilities address "hazards requiring a preventative control" as part of an enterprise-wide program and not simply the operations facility. This requires the corporation to coordinate such activities and assign prevention tasks to individual operations facilities.

H-425.1: "(Comment 403) Some comments express concern about identifying hazards that may be intentionally introduced for purposes of economic gain because there are potentially an unlimited number of unknown or yet-to-be-identified hazards that could be intentionally introduced for purposes

of economic gain by an unscrupulous supplier. These comments disagree with our attempt to narrow the field of potential scenarios for economically motivated adulteration to circumstances where there has been a pattern of such adulteration in the past."

- FF Comments 24: Identifying and addressing specific types of deterrence is consistent with crime science theory and crime prevention. Once specific adulterant-substances are known then it is important to share that information. Detection countermeasures can then be more universally applied (such as added to a "negative list" [see the Chinese National Center for Food Safety Risk Assessment] or products added to a traditional food contaminant testing list). Crime science theory also emphasizes continuous monitoring for evolving innovative crimes. Both are key aspects to prevention.
- FF Comments 25: Detection and deterrence must be part of prevention and, while there are many types of fraud that repeatedly occur, fraudsters will continue to innovate. The realization that detection and deterrence will not significantly protect consumers and prevent Food Fraud was the foundational theory that led to the vulnerably assessment and preventative approach adopted by the EU, UK, China, GFSI, and others.

H-425.2: "Some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time. These comments assert that our attempt is too broad, because we expect facilities to consider patterns of adulteration from the past 'even though the past occurrences may not be associated with the specific supplier or the specific food product' and a requirement to consider every potential product and potential supplier makes the task open ended. These comments further assert that our attempt is too narrow, because a focus on patterns of adulteration in the past is unlikely to reveal potential future instances of economically motivated adulteration and because those intending to defraud purchasers for economic gain are trying to avoid detection. According to these comments, once a food safety-related instance of economically motivated adulteration is uncovered, perpetrators quickly move to carry out their fraudulent activities in a different way."

- FF Comment 26: The Final Rule is appropriate for the scope of FSMA-PC. This is not a rule not for ***all*** of the USG or even ***all*** of FDA. The regulatory requirements to meet the FSMA-PC rule and for preventing FD&C "adulterated foods" are two different concepts. The comment author is asking questions that would be addressed in a more holistic and all-encompassing, USG-wide Food Fraud prevention plan. This Final Rule is defines FF/EMA countermeasure compliance just with this regulation.

H-425.3:"Some comments assert that there are alternative ways to control hazards that may be intentionally introduced for purposes of economic gain without specific regulatory requirements, such as by having an effective supplier approval program with appropriate qualification and verification activities; through business-to-business relations, expectations, and contracts; and through a vulnerability assessment and control plan tailored specifically to economically motivated adulteration."

- FF Comments 27: These "alternate ways to control hazards" are just additional systems our countermeasures in addition to food authenticity detection testing. When the focus on more than just adulterant-substance testing then these other programs are key countermeasures in reducing the fraud opportunity.

H-426.1: "(Response 403) We disagree that the requirement is too broad. A facility must conduct a hazard analysis for each type of food manufactured, processed, packed, or held at the facility. There is no requirement to consider every potential product or potential supplier. We also disagree that the requirement is too narrow. Some individuals intending to defraud purchasers for economic gain will develop entirely novel ways of adulterating food to suit their purposes. We agree that these circumstances may not lend themselves to the preventive approach required here."

- FF Comment 28: Overall, FSMA and the FDA are focused on auditing facilities. Any facility could implement a Food Fraud Prevention Plan but it should be determined and coordinated at an enterprise-wide level. Each facility can then refer to that enterprise-wide plan.

H-426.2: "We encourage, but do not mandate, that facilities adopt other measures they deem appropriate to mitigate the risks of economically motivated adulteration that this rulemaking does not address. Still, the repeated economically motivated adulteration of spices with toxic colorants demonstrates that patterns of economically motivated adulteration can emerge and should be considered as part of a food safety plan (see the examples in the 2014 supplemental human preventive controls notice, 79 FR 58524 at 58550-58551)."

- FF Comment 29: The "encourage, but do not mandate" statement is odd but it seems to be included to add support of systems or countermeasures that are broader than the compliance requirements of FSMA-PC. The FDA does ***not*** require an over-arching Food Fraud Vulnerably Assessment or Food Fraud Prevention Plan ***unless*** a health hazard is known or reasonably foreseeable. This is clearly the case for spice producers and consumers. The "encourage" statement seems to suggest that producers can and should pursue risk prevention beyond the minimal requirements for FSMA-PC compliance (e.g. address all types of FF, non-health-related risks, etc.).
- FF Comment 30: Here the FDA is simply reiterating the scope of FSMA-PC regulatory compliance requirements. Preventing known or reasonably foreseeable Food Fraud public health hazards is most efficient and proactive when implementing broad enterprise-wide activities that reduce the fraud opportunity. This is being mandated by GFSI. The FDA, being aware of this, may realize that the full Food Fraud Prevention Plans are being implemented without the need, oversight, or use of additional FDA resources.

H-427.1: "(Comment 404) Some comments ask us to limit the requirement to identify hazards that may be introduced for purposes of economic gain to only those hazards that pose a risk to public health for which there has been a pattern in the past. Some comments assert that in those few instances where a hazard was intentionally introduced the underlying intention was to defraud rather than to cause harm, and the food safety hazard was an unintended consequence. "

- FF Comment 31: FDA has clearly stated that the scope of FSMA-PC compliance is limited to public health risks.

H-427.2: "Some comments ask us to focus the hazard identification solely on inbound products, because it is obvious that hazards introduced by the facility itself will not be prevented through a hazard analysis."

- FF Comment 32: The opposite is actually true. HACCP monitors activities ***within*** the operations facility so including FF vulnerabilities in a HACCP-style assessment is readily possible and addresses specific facility risks.

- FF Comment 33: This highlights an important point - and gap – regarding Food Fraud that occurs in the supply chain ***after*** the operations facility and ***before*** the consumer. FDA and FSMA-PC consider health hazards in the marketplace regardless of where the fraud occurred. The Final Rule may appear to be operations or facility-centric because that is the main focus of other food safety FDA compliance activities. But any FF/EMA incident in the marketplace that is a health risk is a violation of the Preventive Controls regulation and of other laws such as the Food Drug & Costmetics Act section on Adulterated Foods.

H-427.3: "Some comments ask us to narrow the scope of the requirement by specifying that facilities focus on three situations: 1) Situations in which there has been a pattern of similar adulteration in the past; 2) foods or ingredients for which quality assurance methods may not sufficiently characterize the food or ingredient to assure its identity, and; 3) foods or ingredients for which there are substitutes that are likely to be harmful that would be considered obvious to one skilled in food science."

- FF Comment 33: This is more detail than usually included in rulemaking, but it adds clarity to three situations that *are* in the scope of the requirement. (See below.)

H-427.4: "(Response 404) We decline to make the changes suggested in these comments, because they are unnecessary. Because of our definition of hazard, the requirement is already limited to economically motivated adulteration that has the potential to cause illness or injury. Under the final rule, a facility does not need to identify a hazard related to economically motivated adulteration when there is no risk to public health or when the economically motivated adulteration is not known or reasonably foreseeable."

- FF Comment 34: This is some of the clearest wording regarding the scope of FF/EMA in the Final Rule.

H-427.5: "We agree that the three circumstances suggested by the comments are an appropriate focus for facilities who seek guidance on how to approach the requirements, but decline the request to specify these limitations of the scope in the regulatory text. As already noted, some comments assert that our attempt to narrow the field of potential scenarios for economically motivated adulteration is both too broad and too narrow at the same time (see Comment 403)."

- FF Comment 35: Agreed as previously noted above.

H-427.6: "Although we continue to believe that the instances in which a facility will identify a hazard intentionally introduced for economic gain will be rare, we also consider that limiting the scope of the requirement in the regulatory text would be both pre-judging the future and inconsistent with the public health objectives of this rule."

- FF Comment 36: Agreed as previously noted above. This demonstrates the FDA's foresight for as-yet unknown or novel situations with respect to rulemaking.

H-428.1: "(Comment 405) Some comments ask us to allow implementation of the major provisions in FSMA before establishing requirements to address economically motivated adulteration. These comments assert that economically motivated adulteration requires a completely different paradigm than unintentional adulteration."

H-428.2: "In addition, because economically motivated adulteration is typically addressed through product specifications, supplier relationships, and good business practices, implementation of these other provisions of the human preventive controls rule are likely to have a positive effect on preventing economically motivated adulteration."

H-428.3: "(Response 405) We disagree that economically motivated adulteration requires a completely different paradigm than unintentional adulteration. Hazards intentionally introduced for economic gain are addressed here with the same preventive framework as every other hazard. As such, we do not see a compelling reason to delay implementation of the requirements to address economically motivated adulteration."

- FF Comments 37: Unless there was a separate FF/EMA rule, this is an efficient conclusion for quickly implementing the FSMA-PC Final Rule. This is within the scope of the FSMA-PC rule (i.e. throughout this has been emphasized by "for this rule"). This is also consistent with the previous Economically Motivated Adulteration definition from the public meeting notice of a "substance" for "economic gain" with a "health risk."
- FF Comments 38: The paradigm of defining a human health hazard is the same for Food Safety and Food Fraud, but the preventative controls for unintentional pathogens is fundamentally different than intentional acts. For a pathogen the logical prevention science is microbiology and biology; for a human actor or perpetrator the logical prevention science is criminology and social science.
- FF Comments 39: Food Fraud has a completely different motivation and vulnerability than Food Safety. The concept of addressing Food Fraud prevention with a different methodology is widely accepted and already being implemented internationally. Maybe there is a nuance in the definition of 'paradigm'. (Merriam-Webster's dictionary defines it as a "model," "pattern," or "a theory or a group of ideas about how something should be done, made, or thought about."). The core principles of widely practiced Quality Management systems are the same for Food Fraud prevention, HACCP, and methodologies such as Six Sigma.

The Human Foods section as reviewed above. The next section reviews the Animal Food section. Many of the concepts are similar so it is logical that much of the concepts and text is very similar if not identical. This is noted in the review below.

Preventative Controls Rulemaking for Animal Food (FDA-2011-N-0922)

Since the preventive controls scope and concepts for human and animal food are virtually the same, the majority of this document virtually identical to the Human Foods document (FDA-2011-N-0922). Only text containing novel concepts is addressed here.

A-001.1: "SUMMARY: The Food and Drug Administration (FDA or we) is adding regulations for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Base Preventive Controls for Food for Animals. These regulations will, for the first time, establish requirements for the current good manufacturing practice (CGMP) for food for animals. In addition, we are adding requirements for certain domestic and foreign animal food facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. We are taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the FDA Food Safety Modernization Act (FSMA). The rule is intended to build an

animal food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system."

- FF Comment 40: This is an excellent expansion for the protection of the animal food supply chain to include animal food safety hazards.

A-021.1: "The hazard analysis must consider hazards that may be present in the animal food because they occur naturally, are unintentionally introduced, or are intentionally introduced for purposes of economic gain.

A-021.2: "We continue to believe that hazards that may be intentionally introduced for economic gain will need preventive controls in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past."

A-021.3: "Economically motivated adulteration that affects product integrity or quality, for example, but not animal food safety, is out of the scope of this rule."

A-567.1: "The regulations further require facilities to establish and implement verification procedures for product testing and environmental monitoring, and require that the hazard analysis and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration of animal food. Facilities that manufacture, process, pack, or hold food for animals and foods for human consumption and are subject to part 117 (as finalized elsewhere in this issue of the Federal Register) may choose to comply with part 117 with respect to the animal food, provided the food safety plan addresses the hazards specific to animal food where applicable."

- FF Comment 41: Examples of Food Fraud in animal production and of animal food are "known" and thus "reasonably foreseeable". Expanding the Food Fraud Vulnerably Assessment and Food Fraud Prevention Plan to animals is logical and efficient for the food supply chain.

There were extensive comments and responses included that were virtually – if not exactly, identical to the human food section. For the sake of brevity they are not contained here.

CONCLUSION

It will be interesting 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-PC rule as it applies to Food Fraud and EMA by virtue of compliance with international regulations or emerging industry standards.

Several key concepts are included here:

1. The Final Rule has defined that specifically addressing Food Fraud/EMA incidents that could lead to a public health hazard is a compliance requirement. The rule did not differentiate the source of the fraud act between adulterant-substances or any other economically motivated act.
2. The FSMA-PC Final Rule only defines compliance to this rule and not necessarily the Food Fraud aspects of other parts of FSMA (e.g. Section 309 Smuggled Foods), other Food Laws (e.g. Food Drug & Cosmetics Act sections on Adulterate Foods) or other US Government laws (e.g. tax avoidance smuggling, intellectual property rights, stolen goods, etc.).

3. It appears that current broad Food Fraud Vulnerability Assessment and Food Fraud Prevention Plan activities will lead to compliance with FSMA-PC.

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 "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.

Note: Our team conducts a wide range of teaching, research and outreach projects. The Food Fraud Insight Report series ("FFI Report" or FFIR) series was created to review specific emerging topics or recent laws, regulations, certifications, standards, or best practices. The summary and insight is not legal advice and is not intended to replace the counsel of a food law expert.

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References

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- FDA, US Food and Drug Administration (2015). Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based *Preventive Controls* for Food for Animals, Department of Health and Human Services (DHHS); 21 CFR Parts 11, 16, 117, 500, 507, and 579; Docket No. FDA-2011-N-0922, RIN 0910-AG10, ACTION: Final rule, Accessed: September 12, 2015, URL: http://federalregister.gov/a/2015-21921

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