

# FFI Report

## Review: Final Rule for FSMA Accredited Foreign Supplier Verification Program for Importers Regarding Food Fraud and EMA

By Spink & Moyer  
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### SUMMARY

This is a review of the US Food Safety Modernization Act **Foreign Supplier Verification Program for Importers of Food for Humans and Animals** Final Rule (FSMA-FSVP) [FDA-2011-N-0143] as it applies to Food Fraud (FF) and the sub-category of Economically Motivated Adulteration (EMA). This rule did directly address EMA in several sections. The FSMA-FSVP was officially published on November 27, 2015 and is effective January 26, 2016.

The FFI Report series reviews the minimum FSMA compliance requirements. An enterprise—a company or country—should consider broader enterprise risk management (ERM) processes to confirm their own *comfort level* or *acceptable risk threshold* E.g. addressing the European horsemeat food fraud scandal would not be required under FSMA since there was no health threat.).

### CONCLUSION

The key FF/EMA related findings include:

1. The Final Rule repeatedly emphasizes the preventative controls requirement applies to only health hazards.
2. Food Drug & Cosmetics Act (FD&C) sections on “Adulterated Foods” and “Misbranded Foods” are mentioned throughout the Final Rule. But *misbranded product* is usually clarified to refer only to allergen labeling.
3. For FF/EMA this rule frequently refers back to the FSMA Preventative Controls rule.
4. FSMA-FSVP specifically mentions the US Pharmacopeia’s (USP) Food Fraud database and the National Center for Food Protection and Defense’s (NCFPD) EMA database as resource for “known or reasonably foreseeable hazard.”
5. It appears implementing GFSI will comply with FSMA-FSVP and the other FSMA rules.



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## BACKGROUND

### Introduction

This is the MSU Food Fraud Initiative 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) **Foreign Supplier Verification Program for Importers of Food for Humans and Animals** Final Rule (FSMA-FSVP) [FDA-2011-N -0143].

This review builds on the FFI previous report on the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* [FDA-2011-N-0920] (FSMA-PC), the accompanying rule for *Animal Food* [FDA-2011-N-0922], and the *Produce Safety Rule* [FDA-2011-0921]. (See [www.FoodFraud.msu.edu/blog/](http://www.FoodFraud.msu.edu/blog/).)

This includes an overview as well as a section-by-section review of the FSVP Final Rule.

## FSMA ACCREDITED FOREIGN SUPPLIER VERIFICATION PROGRAM FOR IMPORTERS OF FOOD FOR HUMANS AND ANIMALS FINAL RULE REVIEW

### Keyword Search

The keyword search quickly conveys how much attention is given to FF/EMA in the FSMA-FSVP Final Rule. The document has 504 pages and contains over 101,000 words. There are several sections that directly address FF or EMA with approximately 1000 words.

- Economically Motivated Adulteration = 4 mentions (1 in references)
- EMA = 43 (2 in references)
- Economic gain = 9
- Food fraud = 2 (in references only)
- Adulterant = 4 (all in the comments and not directly used by FDA)
- Substance = 25
- Adulterated = 44
- Adulterated Food = 2

### Section-by-Section Review

The following is a section-by-section review of the FSMA-FSVP Final Rule as it relates to FF/EMA. This includes public comments from the initial rulemaking process and FDA responses.

For reference purposes, coding has been added to each pertinent section. Codes have three components:

- The first four characters define the source document as Foreign Supplier Verification Program (i.e. “FSVP”).
- The next three digits (after the dash) refer to the source document page number.
- The final digit (after the decimal) identifies a separate concept.

- “FFI Comment” sections are included, numbered, and authored by MSU Food Fraud Initiative researchers.
- For example, ‘H-200.3’ refers to the Human Foods rule on page 200 with a specific note of the 3<sup>rd</sup> concept. (Note: Any in-text emphasis (e.g., underlining) is added by the authors.)

### **Accredited Foreign Supplier Verification Program for Importers of Food for Humans and Animals Final Rule (FSMA-FSVP) [FDA-2011-N-0143].**

This review begins with the summary provided in the Final Rule. (*Emphasis provided by authors.*)

**FSVP-001.1:** SUMMARY: “The Food and Drug Administration (FDA) is adopting a regulation on foreign supplier verification programs (FSVPs) *for importers of food for humans and animals*. The regulation requires importers to verify that food they import into the United States is *produced in compliance with the hazard analysis and risk-based preventive controls* and standards for produce safety provisions of the *Federal Food, Drug, and Cosmetic Act* (the FD&C Act), is not adulterated, and is not misbranded with respect to food allergen labeling. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA). The regulation will help ensure the safety of imported food.”

- **FFI Comment 1:** The Food Drug and Cosmetics Act is mentioned and emphasized right up front in the “Summary.” It does clearly mention FD&C requirement for food to be “not adulterated” (the FD&C definition). For the scope of “Misbranded Foods” in FSMA-FSVP there will need to be more review of the statement of “not misbranded with respect to food allergen labeling.”
- **FFI Comment 2:** FSMA-FSVP applies to human and animal food.

**FSVP-001.2:** “This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. For the applicable compliance dates, see “Effective and Compliance Dates” in the Supplementary Information section of this document.”

- **FFI Comment 3:** The Final Rule is effective January 26, 2015.

**FSVP-005.1:** “Executive Summary - Purpose and Coverage of the Rule: ... This rule adopts provisions concerning FSVPs that importers must create and follow *to help ensure the safety of imported food*. ... Congress required importers to perform risk-based foreign supplier verification activities and directed FDA to promulgate regulations on the content of FSVPs in section 301 of FSMA, codified in section 805 of the FD&C Act. *The rule requires importers to implement FSVPs to provide adequate assurances that the importer’s foreign suppliers produce food in compliance with processes and procedures, including risk-based preventive controls, that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and preventive controls) or 419 (concerning produce safety) of the FD&C Act, as appropriate, and in compliance with sections 402 (concerning adulteration) and 403(w) (concerning misbranding regarding allergen labeling) of the FD&C Act.*”

- **FFI Comment 4:** The Executive Summary explicitly mentions the FD&C section on “Adulterated Foods” and “Misbranded Foods.” The FD&C previously implicitly covered all Food Fraud that could lead to a health hazard. Most of the mentions of “misbranded” specifically state allergen labeling or accompany the phrase “where applicable” presumably with respect to allergen labeling.

- **FFI Comment 5:** This rule clearly refers back to the requirements from the FSMA Preventive Controls rule. Refer to FSMA-PC for more direction.

**FSVP-007.1:** “FSVP regulation, importers are responsible for:

1. Determining the hazards reasonably likely to cause illness or injury with each food.
2. Evaluating the risk posed by a food, using the results of the hazard analysis, and evaluating the foreign supplier’s performance. This evaluation informs the approval of foreign suppliers and the determination of appropriate supplier verification activities. An importer may rely on another entity to conduct this evaluation and to determine the appropriate supplier verification activities...”
3. Conducting supplier verification activities. In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved.
4. Performing appropriate activities in other circumstances.
5. Conducting corrective actions. An importer must take appropriate corrective actions promptly if it determines that a foreign supplier of a food it imports does not produce the food in *compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act*, if either is applicable, or produces food that is *adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act*.
6. Retaining records of FSVP activities.”

Also,

**FSVP-012.1:** “Third, the rule excludes from most of the standard FSVP requirements (including hazard analysis and verification that identified hazards are significantly minimized or prevented) certain types of food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that The food is within the scope of the relevant official recognition or *equivalency determination*”;

- **FFI Comment 6:** The concept of “equivalency” will be interesting in practice. For example, GFSI recently recognized “equivalency” of GFSI FSMS to the Chinese government led “China HACCP.”

**FSVP-046.1:** “10. Hazard - We proposed to *define “hazard”* as any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control. On our own initiative, we have deleted “in the absence of its control” from the definition, consistent with a corresponding change to the definition of hazard in the preventive controls regulations, because the aspect of control of a hazard is addressed under the definition of “hazard requiring a control.”

- **FFI Comment 7:** The key for FSMA compliance will be the definition of “hazard” as defined in each specific final rule. That said, there is repeated emphasis on requirement for compliance with FD&C. FD&C has broader sections covering “Adulterated Foods” and “Misbranded Foods.” Also, other sections of FSMA address other Food Fraud types such as “Smuggled Foods” (Section 309).

**FSVP-047.1:** “11. *Hazard Requiring a Control* - In the Supplemental Notice, we proposed to adopt the term “significant hazard” and to define it as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.”

**FSVP-066.1:** “14. *Known or Reasonably foreseeable Hazard* - In the Supplemental Notice, we deleted the proposed term “hazard reasonably likely to occur” and replaced it with the term “known or reasonably foreseeable hazard.” We proposed to define “known or reasonably foreseeable hazard” as a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

- **FFI Comment 8:** These concepts are also addressed – and will presumably continue to be defined in practice – in other parts of FSMA including FSMA-PC.

**FSVP-066.1:** “(Comment 37) One comment suggests that we use the term “**reasonably anticipated contaminants**” as a phrase that clearly defines all hazards, whether deliberate or accidental, that can cause adulteration in the food supply. / (Response 37) We decline to make this change because “hazard” is a widely understood term in food safety and the word “contaminant” might suggest a substance that comes into contact with or is added to a food, but not all hazards arise from such contaminants. As discussed in section III.E.3.b of this document, importers are required to consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced for economic gain.”

- **FFI Comment 9:** This response to not use the “Contaminant” term is consistent with CODEX and others.
- **FFI Comment 10:** This is the first mention of “hazards” that may be “intentionally introduced for economic gain.” More details are covered below.

**FSVP-138.1:** “(Comment 104) One comment suggests that the requirement to have an FSVP be limited to problems that “cause a risk to the public health,” which the comment maintains would be consistent with the statement in the preamble to the proposed rule that the regulation should focus on foreseeable food safety risks identified through hazard assessment rather than all risks covered by the adulteration provisions. The comment contends that not all adulterants cause a food safety risk and many forms of adulteration are not amenable to discovery by the importer. // (Response 104) We do not believe that the proposed change is necessary. The importance of the existence of a risk to public health is incorporated in the definition of “hazard,” meaning any biological, chemical, or physical agent that is reasonably likely to cause illness or injury. ... However, under § 1.504(f), if an importer determines there are no hazards requiring a control in a food, the importer would not be required to conduct an evaluation of the risk posed by the food and the foreign supplier’s performance and would not be required to conduct supplier verification activities. E.g. U.S. international obligations.”

- **FFI Comment 11:** A “biological” hazard could occur by mishandling stolen genuine food.

- **FFI Comment 12:** FSMA in general implies that if an assessment finds no “hazard” then preventative controls are not needed. This is consistent with the text of the FSMA law since it is the *Food Safety Modernization Act* and is focused on preventing hazards that could cause adverse health effects. Also, the application and intent of the term “agent” or “physical agent” should be explored further. This is possibly not explicitly an adulterant-substance included for economic gain though a Food Fraud act could lead to the hazard. For example, mishandled stolen genuine goods could result in the growth of a pathogen that causes a hazard. The intentional act for economic gain is introducing stolen goods into commerce but the “agent” that caused the harm was unintentional.

**FSVP-163:** “E. *Hazard Analysis* (§ 1.504) - In the Supplemental Notice, we made several changes to the proposed requirements concerning importers’ analysis of the hazards in the foods they import in response to several comments and to align the FSVP requirements with the proposed supply-chain program provisions in the preventive controls regulations. These revisions primarily involved changing the requirement to analyze hazards that are reasonably likely to occur to a requirement to analyze known or reasonably foreseeable hazards (to determine if these hazards are significant), *as well as the addition of a proposed requirement that importers consider hazards intentionally introduced for purposes of economic gain.*”

Also,

**FSVP-170.1:** “b. *Reasons for presence of a hazard.* - We proposed to require, in § 1.504(b)(2), that an importer’s analysis of hazards include hazards that may be present in a food for any of the following reasons:

- The hazard occurs naturally;
  - The hazard may be unintentionally introduced; or
  - *The hazard may be intentionally introduced for purposes of economic gain.*”
- **FFI Comment 13:** Again, this states that “hazards” (not specifically defined here as a contaminant-substance or adulterant-substance) “introduced for purposes of economic gain” are a compliance requirement of FSMA-FSVP.

(The following comment and response is split to address each part of the question.)

**FSVP-170.2:** “(Comment 122) *Several comments object to the proposed requirement to consider hazards that might be intentionally introduced for purposes of economic gain.* Some comments assert that because *economically motivated adulteration (EMA)* is nearly always an issue of product quality and integrity rather than food safety, requiring importers to consider *EMA* hazards would provide little benefit to food safety. // (Response 122) *We decline to delete this requirement. EMA can and has resulted in safety concerns, including, as in the case of melamine in infant formula and pet food, the deaths of humans and animals.*”

- **FFI Comment 14:** “Response 122” is consistent with research and other public and private FF/EMA related activities. Also, the FSMA focus is continually defined as applicable to “hazards” defined as adverse health effects.

**FSVP-170.3:** “(Comment cont.) *Some comments suggest that it would not be appropriate to require consideration of EMA hazards because such hazards often are addressed by a corporate parent company rather than at the facility level.* // (Response) The fact that a plan for addressing EMA might be developed at the corporate level is irrelevant to whether an importer can determine whether EMA in a particular food is known or reasonably foreseeable.”

- **FFI Comment 15:** GFSI Food Fraud related discussions and presentations have addressed this where it is stated a “Food Fraud Vulnerability Assessment” and “Food Fraud Prevention Plan” may be led and managed by a central coordinator but the implementation would be at the facility level.

**FSVP-170.4:** “(Comment cont.) Some comments maintain that addressing EMA requires a completely different approach than that used for unintentional adulteration and that it would be better to address EMA in an importer’s food defense plan. *Some comments therefore request that we consider proposing regulations on EMA in a future rulemaking rather than in the FSVP regulation.* // (Response) Further, we disagree that *economically motivated adulteration* requires a completely different approach than unintentional adulteration.

- **FFI Comment 16:** The FFI will continue to review this concept as part of ongoing Food Fraud prevention research.
  - **Note:** Addressing EMA/FF in separate rulemaking is not required by FMSA law. Actually, Economically Motivated Adulterant or Food Fraud is not even specifically mentioned in the FSMA text of the law. Technically, EMA could just be covered more generally under “Intentional Adulteration” if the FSMA-IA rule was not previously narrowed by FDA to only catastrophic events (i.e. terrorism).
  - **Note:** Food Fraud is an intentional “human” act for economic gain with the intent to NOT be caught. This motivation is fundamentally different than Food Safety which is an unintentional act – actually if pathogens are considered the perpetrator; it is an intentional “microbe” act for procreation. To note, Food Defense is an intentional “human” act that is intended to create health hazards, economic loss, or terror. Food Defense attackers intend their acts to be found. Regarding prevention and the motivation, a fundamentally different approach is required. The fraud opportunity is fundamentally different and the assessment must be unique. For example the Tylenol malicious tampering in the Chicago area in the mid-1980’s would not be a priority for a Food Safety or Food Defense assessment (e.g. less than 100 deaths and less than \$1 billion in cost – 8 death and nearly a billion but in lost opportunity cost). Another example is the horsemeat illegally added to beef which would not be a priority in a Food Safety hazard assessment (e.g. since there was no immediate harm). Technically FSMA would not require mitigation plans for fraudulent species swapping as long as there was no health hazard.
  - **Note:** This also brings up the concern of small-scale “disgruntled employees” or “malicious tampering” acts as addressed (or not) in FSMA. As with the entire FSMA scope, these are addressed—at least in some way— in FD&C.

**FSVP-171.1:** “Although we acknowledge that many firms currently might not include *EMA* in their analyses of safety hazards in food, as we stated in the Supplemental Notice, some of the measures that industry uses in supplier verification programs, such as audits and sample testing, are used to guard against *EMA*. Moreover, we believe that the burden posed by having to analyze potential *EMA* hazards is limited because, as with hazards that occur naturally or that may be unintentionally introduced, we *define hazards to include only those agents that have the potential to cause illness or injury*. In the *EMA* context, we anticipate that importers will identify such hazards in rare circumstances, usually in cases where there has been a pattern of *economically motivated adulteration* of a food. Therefore, we conclude it is appropriate that importers consider *EMA* hazards under the FSVP regulation.

- **FFI Comment 17:** The *EMA/FF* requirement FSMA-FSVP compliance is limited. It will be important to monitor adverse health effects (“hazards”) that occur from “*EMA*”—or their “agents”—that were considered to NOT be “reasonably foreseeable hazards.”
- **FFI Comment 18:** It appears that full GFSI Food Safety Management System compliance – including the pending Food Fraud requirements – will meet the FSMA compliance FF/*EMA* requirements. To note, the GFSI Food Fraud requirements address all types of Food Fraud vulnerabilities regardless of their adverse health effect. GFSI will require a ‘Food Fraud Vulnerability Assessment’ and a ‘Food Fraud Prevention Plan.’
- Note: HACCP principles would categorize FF/*EMA* ingredient prevention and authentication testing as a “pre-requisite program” (PRP). While this testing could be conducted within the facility, the process would be outside the scope of the formal HACCP facility-specific plan. HACCP covers activities with a facility, to address human health hazards, for issues that are measurable and that preventative controls can improve. As noted in FSMA, the vast majority of Food Fraud incidents do not cause harm and the preventative control improvement would occur before the ingredient is received. Conducting species tests to verify authenticity would detect the fraud and prevent the product from entering the operation... but it would not directly address the root cause of the non-conformance.

**FSVP-173.1:** “(Comment 123) *Some comments assert that it would be more appropriate to address EMA hazards separately from the hazard analysis because they are not considered as part of the hazard analysis when designing a food safety plan; rather, the comments maintain that EMA should be considered as part of supplier verification. // (Response 123) We do not agree.* Importers are required to conduct a hazard analysis under § 1.504 of the final rule precisely to understand what manner of supplier verification under § 1.506 is needed and appropriate. Therefore, importers need to evaluate *EMA* as part of the hazard analysis for a food so that, if *EMA* is determined to be a hazard requiring a control for that food, importers can conduct appropriate supplier verification activities to obtain assurance that the food has not been intentionally *adulterated for economic gain*.”

- **FFI Comment 19:** The FFI will continue to review this concept as part of ongoing Food Fraud prevention research.

**FSVP-173.2:** (Comment 124) One comment asserts that looking retrospectively at instances of economic adulteration might not be effective because it would be less likely that others would engage in such activity in the future. (Response 124) We are not aware of evidence supporting the comment’s

assertion. *However, given that it would not be feasible or appropriate to require importers to speculate about, and guard against, any conceivable form of EMA of a food, we conclude that it is reasonable to require importers to consider, among other things, whether a food has been previously linked to EMA that might cause harm to consumers.*

- **FFI Comment 20:** Depending on the interpretation of this statement, this could be the most important FF/EMA statement in any FSMA final rule. A strict and literal interpretation of this statement means that “reasonably foreseeable hazards” may only need to be incidents that have that previously occurred. It is not clear whether one incident in all of recorded history counts (or one incident in recorded history that had at least one adverse health effect).
- **FFI Comment 22:** To address “given that it would not be feasible or appropriate to require importers to speculate about, and guard against, any conceivable form of EMA of a food” could be interpreted as a not requiring a “vulnerability assessment.” A vulnerability assessment provides insight on potential events rather than just a historical review of all known incidents.
- **FFI Comment 23:** But, the phrase “we conclude that it is reasonable to require importers to consider, *among other things*, whether a food has been previously linked to EMA that might cause harm to consumers.” This includes “among other things” that potentially broadens the scope to include possible incidences and strictly known incidents.
  - **Note:** The first step for GFSI Food Fraud compliance requires a “vulnerability assessment” where vulnerability is defined as an exposure to a risk regardless of whether it has occurred before or not.
- **FFI Comment 24:** The FFI will continue to review this concept as part of ongoing Food Fraud prevention research.

**FSVP-173.3:** “(Comment 125) Some comments assert that the analysis of hazards intentionally introduced for economic gain should be limited to whether there is a history of any particular EMA. *Some comments request that we limit the requirement to consider hazards that might be intentionally introduced for economic gain to such hazards that are “already known” or for which there is a “historical precedent.”* // (Response 125) *As with other hazards, importers need only consider EMA hazards that are known or reasonably foreseeable. This means that importers are not required to consider purely speculative hazards. ... We expect that EMA hazards will be identified in rare circumstances, usually in cases where there has been a pattern of EMA in the past.* The revisions suggested by the comments are unnecessary and could be interpreted to narrow the requirement that importers consider hazards that are known or reasonably foreseeable. We continue to believe that this requirement is appropriate, even for EMA, and we reiterate that we would not expect importers to consider *merely hypothetical EMA scenarios* for their food products. This is consistent with our position on EMA in the *preventive controls regulations.*”

- **FFI Comment 25:** The interpretation of this statement hinges on what is “known or reasonably foreseeable.” Also, new concepts to understand are “purely speculative hazards” or “merely hypothetical EMA scenarios.” In the absence of additional clarifying comments, there seems to be a wide berth for interpreting what meets compliance requirements.

- **FFI Comment 26:** The “Comment” requests being limited only incidents that are “already known” or with a “historical precedent.” The FDA “Response” was not so direct reiterating “known or reasonably foreseeable.” FDA had a direct opportunity but did not limit the incidents to only those that have been documented.

**FSVP-173.3:** (Comment 128) Some comments suggest that we publish a list of previous instances of *EMA* that importers should use in considering possible *EMA* hazards. // (Response 128) Although we agree that it would be useful to have a centralized list involving all previous instances of *EMA*, creating such a list would likely be unduly resource intensive for FDA and therefore would not be consistent with the efficient enforcement of section 805 of the *FD&C Act*. *We therefore decline this request.* We note, however, that information about incidents of *EMA* is widely available from public sources (Refs. 10-12).

- **FFI Comment 27:** FSMA rulemaking explicitly mentions the USP Food Fraud and NCFPD *EMA* database as resources. These should be a starting point for any food fraud vulnerability assessment for any FF/*EMA* hazard analysis.
- **FFI Comment 28:** The mentioned data sources are noted here
  - 10. U.S. Pharmacopeial Convention, “U.S. Pharmacopeial Convention (USP) Food fraud Database” (<http://www.usp.org/food-ingredients/food-fraud-database>), March 6, 2014.
    - **Note:** this was published in a journal article:
      - Moore, J, Spink, J, and Lipp, M. (2012). Development and Application of a Database of Food Ingredient Fraud and Economically Motivated Adulteration from 1980 to 2010, *Journal of Food Science*, Volume 77 (Number 4), pp. R118-R126.
  - 11. Congressional Research Service, “Food fraud and ‘Economically motivated Adulteration’ of Food and Food Ingredients,” January 10, 2014.
    - **Note:** This refers to the other two databases. The European Commission report also refers to these two databases and the other journal articles listed here.
  - 12. Everstine, K., J. Spink, and S. Kennedy, “Economically motivated Adulteration (*EMA*) of Food: Common Characteristics of *EMA* Incidents,” *Journal of Food Protection*, 76:723-735, 2013.

**FFI Comment 29:** The FFI will continue to review this concept as part of ongoing Food Fraud prevention research. **FSVP-285.1:** “(Comment) 3. Investigation - In proposed § 1.507(b), we proposed to require that, if an importer became aware that an article of food it imported was *adulterated* under section 402 or misbranded under section 403(w) of the *FD&C Act*, either through review of a complaint or by other means, the importer would have to promptly investigate the cause or causes of such adulteration or misbranding and document the investigation. (Comment 233) Some comments support requiring importers to investigate adulteration of food from foreign suppliers. However, some comments express concern that importers might not have the capacity to conduct an investigation. Some comments suggest limiting the requirement to conduct investigations to those that are related to food safety or, more specifically, to those related to adulteration or misbranding that might pose a risk to public health; the comments assert that not all *adulterants* pose a food safety risk. // (Response 233) *We are deleting the requirement to conduct investigations when importers become aware that food they import is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.* We

believe that the obligation to respond to negative information about food safety is partly addressed in § 1.505(c)(1) of the final rule, which requires importers to reevaluate the risk posed by a food or a foreign supplier's performance when they become aware of new information about these factors. ... *We believe that a requirement to conduct investigations as specified in proposed § 1.507(b) would be unnecessarily duplicative and would not substantially contribute to the public health.*"

- **FFI Comment 28:** These rules or acts do not require an investigation of the foreign supplier for a FF/EMA incident.
- **FFI Comment 29:** It is interesting to note that the focus of FSMA is adverse health effects but the FD&C act sections on "Adulterated Foods" and "Misbranded Foods" continue to be mentioned. There are instances where a product that violates those sections would not include an adverse health effect.
- **Note:** A situation—such as horsemeat fraud—would not be required by FSMA but would be a violation of the FD&C. Regardless of the health hazard and FSMA compliance requirements, species swapping are illegal in US Food Law.

**FSVP-410.1:** (Response 317) *We agree that it is possible that we might find based on an examination of samples or otherwise, that an importer's food appears to be adulterated, even in circumstances in which we had found the importer to be in compliance with the FSVP requirements during our most recent review of the importer's records. In such circumstances, we may take appropriate action in response to any such finding of an appearance of a violation, including, where appropriate, detention and subsequent refusal of admission of the food. ... However, we realize that there are circumstances in which the finding of adulteration in any particular shipment might not necessarily mean that the importer is in violation of the FSVP regulation.*

- **FFI Comment 30:** This states that even when there is compliance with the rule – or any rule or regulation – if the food "appears to be adulterated" it is unfit for commerce. Under this rule that product could be detained or refused entry to the USA. A supplier can be in FSMA compliance and still have their product subject to a rejection or recall.

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**FUTURE RESEARCH:** The FFI will continue to review other aspects of FSMA Final Rules such as changes in definitions of terms and specific reviews of concepts (e.g., "hazard," "reasonably foreseeable hazard," a "qualified person," and a "qualified auditor." The FFI will also continue to research other sections of FSMA that do – or could, address Food Fraud aspects such as smuggled food, supply-chain practices, and third-party certifications.

**Note:** *MSU's Food Fraud Initiative (FFI) conducts a wide range of teaching, research and outreach projects. The "FFI Report" 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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