

FFI Report

Review: Final Rule for FSMA *Produce Safety Rule* (FSMA-PS) Regarding Food Fraud and EMA

By Spink & Moyer
January 26, 2016

SUMMARY

The US Food Safety Modernization Act **Produce Safety Final Rule** (FSMA-PS) does **not** directly address Food Fraud (FF) or Economically Motivate Adulteration (EMA) other than referring to the FSMA Preventative Controls rule (FSMA-PC) and the US Food Drug & Cosmetics Act (FD&C). FSMA-PS focuses on biological health hazards only and not physical or chemical contaminants. As such, there are no additional FF/EMA regulatory compliance requirements for FSMA-PS. This Final Rule does provide insight to other FSMA compliance questions.

Compared to previously published FSMA rules, the FSMA-PS rule has much more emphasis on the FD&C. The FD&C has very broad definitions of what is unfit for commerce regarding “Adulterated Foods” and goes beyond

adulterant-substances to include unintentional root causes such as stolen goods, filthy, spoiled product, etc.). Another applicable FD&C section is “Misbranded Foods.” (Note: the act of stealing goods in intentional but any contamination is unintentional.)

CONCLUSIONS

1. Regarding FF/EMA, the focus should be on the FSMA-PC rule without neglecting FD&C requirements. The FDA continues to rely on the strong and broad requirements of the FD&C regarding intentional and unintentional food safety hazards.
2. Similar to our review of FSMA-PC, companies that are compliant with industry standards such as GFSI will be seem to be compliant with the FF/EMA aspects of the FSMA-Produce Safety rule.



Contact

Dr. John Spink
517-381-4491

FoodFraudPrevention.com

BACKGROUND

Introduction

This is 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) Produce Safety Final Rule (FSMA-PS). The formal title is: “***Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption***” [[FDA-2011-N-0921](#)]. This rule is effective January 26, 2016.

This review builds upon our previous report on 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](#)]. (See [www.FoodFraud.msu.edu/blog/.](http://www.FoodFraud.msu.edu/blog/))

FSMA PRODUCE SAFETY FINAL RULE REVIEW (FSMA-PS)

Keyword Search

The Final Rule contains more than 235,500 words with only 166 words covering a section on “Intentional Adulteration” that includes “EMA” and “Food Defense.”

Food Fraud/EMA is more directly addressed in the “Preventative Controls” Final Rule (FSMA-PC). Likewise “Food Defense” is the focus of the Intentional adulteration Rule (FSMA-IA). For this reason a keyword search was not conducted. The abbreviation “EMA” was not used.

Section-by-Section Review

The following is a section-by-section review of the FSMA-PS 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 character defines the source document as Produce Safety Rule (‘PS’).
- 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.)

Produce Safety Rule (FSMA-PC) (FDA-2011-0921)

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

PS-001.1: “SUMMARY: To minimize the risk of *serious adverse health consequences or death* from consumption of contaminated produce, the Food and Drug Administration (FDA or we) is establishing *science-based minimum standards* for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA is establishing these standards as part of our implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of *serious adverse health consequences or death*, including those reasonably necessary to prevent the introduction of *known or reasonably foreseeable biological hazards* into or onto produce and to provide reasonable assurances *that the produce is not adulterated on account of such hazards*. We expect the rule to reduce foodborne illness associated with the consumption of contaminated produce.”

- **FF Comment 1:** The “Summary” starts by defining the focus on “serious adverse health consequences or death.” This is a very definitive statement yet throughout the rule there is continued statement of the requirement “...to provide reasonable assurances that produce is not adulterated under section 402 of the FD&C Act [Food Drug & Cosmetics Act (FD&C)].” The FSMA-PS and FD&C prioritize health hazards and that companies “...must take appropriate actions to ensure that affected food does not enter commerce.” While this emphasizes the focus on “serious adverse health consequences,” the final rule continually reinforces full application of the FD&C.
 - **Note:** There were 19 mentions of “...not adulterated under section 402 of the FD&C Act.” Because the FSMA-PC final rule is an official document that references another official document (i.e. the FD&C), the definition of “adulterated” remains consistent and refers to “Adulterated Foods.” (This includes food safety hazards beyond adulterant-substances such “putrid foods.”) This is important to clarify since “adulterate” and “adulterated” are often casually intended to be any impurity from a substance. For example, Merriam-Webster’s Dictionary defines “adulterate” as “to make impure by mixing in a foreign or inferior substance.” There is nuance in the application of the terms since the May 2009 Federal Register definition—previously cited by FDA as their source—of Economically Motivated Adulteration only covers a “substance” for “economic gain.”
 - **Note2:** With that said, the FSMA-PS later paraphrases the FD&C, “Under section 402(a)(1) of the FD&C Act, a food is adulterated if it bears or contains any added poisonous or deleterious substance which may render it injurious to health, and such substances may include or otherwise result from physical and chemical (including radiological) contamination.” While this is clearly addressing only an “added... substance” there are more details later in the Adulterated Foods section of FD&C. Other aspects of that FD&C section 401(a) include: “(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to

health. “ A mishandled stolen genuine good with a health hazard would be covered by this second statement. Regardless of the focus of FSMA the full FD&C applies.

- **FF Comment 2:** The FSMA-PS summary does not mention “economically motivated” in the summary. That term was in the “Summary” of FSMA-PC.
- **FF Comment 3:** This rule specifically focuses on product “...for human consumption.” This does not cover animal food.
- **FF Comment 4:** The rule only focuses on biological hazards that are clarified in the text “...known or reasonably foreseeable biological hazards.” Even though there are mentions of the FD&C “Adulterated Foods” application, the singular focus on biological hazards is reiterated with the statement “...is not adulterated on account of such hazards.”

The Produce Safety rule “Intentional Adulteration” section—not to be confused with the FSMA Intentional Adulteration rule (FSMA-IA)—directly mentions Food Fraud or Economically Motivated Adulteration. Since it is short the entire section is included here.

PS-042.1: “B. Intentional Adulteration: (Comment 12) Several comments address *intentional adulteration* of produce. One comment contends that small farms are inherently more resilient to terrorism or other forms of intentionally introduced hazards than large farms due to their diversity, independence, and geographic decentralization. According to the comment, if the proposed produce safety rule negatively affects the viability of diverse small farms, in favor of large, centralized farms, then the net result may be an increase in the American food system’s vulnerability to terrorism. With regards to *economically motivated intentional adulteration*, one comment states that this type of adulteration is difficult to prevent and should not be addressed in this rule.” (Response) “FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C Act [technically the FD&C was amended by adding the FSMA concepts] in a separate rulemaking. *As such, neither intentional adulteration nor economically motivated adulteration in the context of fruits and vegetables that are RACs, during activities that occur on produce farms, are within the scope of the produce safety regulation in part 112.*”

- **FF Comment 5:** FDA states that “Intentional Adulteration” is not addressed in the FSMA-PS rule.
- **FF Comment 6:** This section mentions the FD&C and “separate rulemaking.” It does not directly state which rulemaking but it appears to be FSMA-PC for FF/EMA and FSMA-IA for Food Defense.
- **Note:** This section refers to the FD&C. Technically the FD&C was amended (added to) by including the FSMA text. For example, the FSMA “Intentional Adulteration” section states:
 - “SEC. 106. PROTECTION AGAINST INTENTIONAL ADULTERATION. (a) In General.-- Chapter IV (21 U.S.C. 341 et seq.), as amended by section 105, is amended by adding at the end the following: "SEC. 420. <<NOTE: 21 USC 350i.>> PROTECTION AGAINST INTENTIONAL ADULTERATION'.”
 - **Note:** The FSMA-IA rule draft defines the scope of that section to be only catastrophic events such as terrorist attacks. EMA, malicious tampering, and disgruntled employees are explicitly mentioned as not included.

Additional Related Text

PS-023.1: “C. Draft Qualitative Assessment of Risk: We conducted a ‘Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce’ (hereafter referred to as “the draft QAR”) to evaluate hazards related to produce production and harvesting. We published the findings of our assessment, and asked for public comment on our assessment and findings (78 FR 3504, January 16, 2013). The tentative conclusions of this assessment informed our proposed science-based minimum standards for the safe production and harvesting of produce commodities.”

- **FF Comment 7:** A “qualitative assessment of risk” is specifically mentioned and is assumed to be the preferred methodology. (This is reviewed later in more detail for application to FF/EMA.)

PS-028.1: “II. Legal Authority: The 2013 proposed rule contained an explanation of its legal basis under authorities in FSMA, the FD&C Act, and the Public Health Service Act (PHS Act). After considering comments received in response to the 2013 proposed rule and supplemental notice, FDA made changes in the final rule. The legal authorities relied on for the final rule is the same as in the 2013 proposed rule unless otherwise described in the paragraphs that follow.”

PS-028.2: “A. Relevant Statutory Authorities Other Than Section 419 of the FD&C Act and Section 105 of FSMA. The final rule requires that, to rely on the exemption in § 112.2(b) for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health concern, a covered farm must disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” (§ 112.2(b)(2)). This requirement is authorized by sections 419 and 701(a) of the FD&C Act (21 U.S.C. 371(a)).”

- **FF Comment 8:** There is much more direct application—or reminders-- that the previous food laws and regulations are still in effect, specifically the FD&C and the Public Health Service Act (PHS)

PS-114.1: “§ 112.3(c) – Definition of “hazard”: Revision to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard” by replacing “is reasonably likely to” with “has the potential to”.”

PS-114.2: “§ 112.3(c) – Definition of “known or reasonably foreseeable hazard”: Replacing the term “reasonably foreseeable hazard” with “known or reasonably foreseeable hazard”, Revision to more clearly distinguish this term from “hazard” - Revision to specify that for the purposes of this rule, such hazards are biological”.”

PS-179.1: “(Comment 94) Comments express a view that the terms “reasonably” and “likely” used in this proposed definition are ambiguous, and request clarification.” (Response) “We are revising the definition by replacing the phrase “that is reasonably likely to cause illness or injury” with “that has the potential to cause illness or injury” to more clearly distinguish “hazard” from “known or reasonably foreseeable hazard.” This increases the alignment of the definition of “hazard” in this rule with the Codex definition of “hazard” and the definition of “hazard” in the PCHF regulation.”

- **FF Comment 9:** These changes will be reviewed in relation to other FSMA, FD&C, and FDA reports.

PS-228.1: “(Comment 140) One comment states that the definition and application of the term “reasonably” is unclear in § 112.11, and expresses concern about disagreements between farmers and FDA over what measures are reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards and provide reasonable assurances that the produce is not adulterated.” (Response) “In § 112.3, we revised our proposed term “reasonably foreseeable hazard” and corresponding definition to now use “known or reasonably foreseeable hazard” to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food. We provide a definition for this phrase as it is used in section 419(c)(1)(A) of the FD&C Act and reflected in several requirements that we are establishing in part 112. The use of this phrase in the produce safety regulation is also consistent with its use in the PCHF and PCAF regulations.”

- **FF Comment 10:** This is a clarification of what is previously covered in FSMA-PC. Another part of FSMA-PS mentions a qualitative assessment of risk report to provide direction.

FUTURE RESEARCH: We 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.” We 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: *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.*

Contact Information: www.FoodFraudPrevention.com, Dr. John Spink (517) 381-4491