

FFI Report

Review: Final Rule for FSMA Accredited Third-Party Certification Regarding Food Fraud and EMA

By Spink & Moyer
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SUMMARY

This is a review of the US Food Safety Modernization Act **Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications** Final Rule [FDA-2011-N-0146] as it applies to Food Fraud (FF) and the subset of Economically Motivated Adulteration (EMA). FMSA-A3P does not directly mention or address FF or EMA so this is only a detailed review of the Summary, Executive Summary, and sections specifically concerning Private Food Safety Schemes (e.g., GFSI). FSMA-A3P was published on November 27, 2015 and is effective January 26, 2016.

CONCLUSION

FF/EMA related findings include:

5. FSMA-A3P clearly and explicitly requires “an accreditation” process but does not authorize or approve any specific system or scheme. This allows existing systems meets the FDA emphasis to “avoid unnecessary duplication of efforts and costs.”

1. Private food safety schemes were explicitly and directly addressed and accepted for regulatory compliance of this Final Rule.
2. Global Food Safety Initiative (GFSI) private food safety schemes are mentioned and defined.
3. The Final Rule mentions several times – including the emphasis that this is a statutory requirement and the expectation by Congress of – “promoting international consistency and tapping into an existing framework of consensus standards that is familiar to industry.” This then applies to using the “Food Fraud” term (i.e. all deceptions for economic gain using food; a globally recognized term) rather than just the sub-category of “Economically Motivated Adulteration.”
4. There is a continued and detailed reminder of the application and authority derived from the Food Drug & Cosmetics Act (FD&C). The FD&C has very detailed descriptions of “Adulterated Foods” and “Misbranded Food” that apply to FF/FMA.



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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) **Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications** Final Rule [FDA-2011-N-0146]. (Note: “FSMA-A3P” is used throughout this document as the FDA does not define a specific abbreviation.)

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], the *Produce Safety Rule* [FDA-2011-0921] (FSMA-PS), and the *Foreign Supplier Verification Program for Importers of Food for Humans and Animals* Final Rule [FDA-2011-N-0143] (FSMA-FSVP).

This FFI Report includes an overview of the rule as well as a section-by-section review.

MSU’s Food Fraud Initiative 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 (FSMA Section 309), supply-chain practices, and third-party certifications.

Keyword Search

The keyword search quickly conveys how much attention is given to FF/EMA in the FSMA-A3P Final Rule. The document is has 356 pages and contains over 101,000 words. No section directly address FF or EMA.

- Fraud = 3 (Food Fraud = 0)
- Economically Motivated = 0
- EMA = 0
- GFSI = 14
- Private food safety scheme = 5

Section-by-Section Review

The following is a section-by-section review of the FSMA-A3P 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 three characters define the source document as Accredited Third-Party rulemaking (i.e. “A3P”).
- 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 3rd concept. (Note: Any in-text emphasis (e.g., underlining) is added by the authors.)

Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications Final Rule (FSMA-A3P) [FDA-2011-N-0146]

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

A3P-001.1: SUMMARY: “The Food and Drug Administration (FDA or we) is adopting regulations to provide for *accreditation of third-party certification bodies to conduct food safety audits of foreign food entities*, including registered foreign food facilities, and to issue food and facility certifications, under the FDA Food Safety Modernization Act (FSMA). These certifications will be required for participation in the *voluntary qualified importer program (VQIP)* established under the *Federal Food, Drug, and Cosmetic Act (FD&C Act)*. In addition, when the Agency has determined that an imported food is subject to certification under FSMA, the Agency may require a certification under this rule as a condition for admitting the food into the United States. FDA also expects that these regulations will increase efficiency by reducing the number of redundant food safety audits.”

- **FFI Comment 1:** The rulemaking does not use the common phrase “third-party audit” and there is an important change for clarification to “accreditation of third-party certification bodies to conduct food safety audits.” This is important to note because the first focus is on approving independent investigators before FMSA-A3P addressed part of any audit scheme.
- **FFI Comment 2:** As with the other three final rules released at this time, there is a continued and direct reference to the FD&C. With respect to Food Fraud, this includes the “Adulterated Foods” (21 U.S.C. 343) and “Misbranded Foods” (21 U.S.C. 343) sections.

A3P-001.2: “DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].”

- **FFI Comment 3:** The effective date is January 26, 2016.

A3P-002.1: “Executive Summary: Purpose and Coverage of the Final Rule: ... In this document, [FDA] establish a program for accreditation of third-party certification bodies(1) to conduct food safety audits and issue certifications of foreign food facilities and foods for humans and animals for purposes of sections 801(q) and 806 of the FD&C Act. We are also codifying certain limited exemptions to mandatory import certification under 801(q) of the FD&C Act (21 U.S.C. 381). ... Note (1) As explained more fully in Response 1, in response to comments and for clarity, this final rule uses the term “third-party certification body” rather than either the term “third-party auditor” or the term, “third party auditor/certification body” (except that we will use the term “third-party auditor” in the definitions of “accredited third-party certification body” and “third-party certification body” in 21 CFR 1.600(c) and in the preamble discussion of those definitions in section III.A).”

- **FFI Comment 4:** Here FDA notes the focus on approving the certification body not the specific, individual auditor. This is addressed in more detail later.

A3P-002.2: “In addition, *facilities and importers may choose to use onsite audits conducted by third party certification bodies accredited under the program* set out in this rule in connection with meeting supplier verification requirements under FDA’s final rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (final human preventive controls regulation) (80 FR55907, September 17, 2015); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (final animal preventive controls regulation) (80 FR 56169, September 17, 2015); and the Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (published elsewhere in this edition of the Federal Register) (implementing sections 418 and 805 of the FD&C Act, respectively). Under those rules, in circumstances where an onsite audit is the appropriate supplier verification activity, such audit must be conducted by a “qualified auditor.” *The definitions of “qualified auditor” in those rules make clear that an example of a potential qualified auditor includes, but is not limited to, an audit agent of a certification body that has been accredited in accordance with regulations in part 1, subpart M of this chapter* (i.e., this rule implementing section 808 of the FD&C Act).”

- **FFI Comment 5:** This rule requires “a” process and does not approve or mandate any “one” in particular. The rule only specifies that the process must be certified. This provides flexibility for industry since they can select and use existing programs. It is also efficient for FDA as they do not need to specifically outline or provide additional guidance regarding enforcement or audition on any exact process.
- **FFI Comment 6:** This states that the requirements for a certification body and “qualified auditor” will be consistent among the foreign and domestic requirements. The same certification body and qualified auditor could be used for all.

A3P-020.1: “D. Public Comments. *We received over 150 comments* from accreditation bodies, certification bodies, members of the food industry, industry associations, foreign governments, State governments, public health organizations, public advocacy groups, individual consumers, consumer groups, and others. ... A number of comments focus on the overarching issues of: (1) *Alignment with voluntary consensus standards*; (2) *the use of private food safety schemes*; (3) the relationship between the third-party certification program, foreign competent authorities, and FDA’s international activities; and (4) the possible implications of the lack of qualified auditors on the third-party certification program. We address these comments generally below. ... We received several comments on the overarching issue of the use of voluntary international consensus standards issued by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) ...”

Also,

A3P-021.1: “*We agree with comments on the value of promoting international consistency and tapping into an existing framework of consensus standards that is familiar to industry*, which may make it easier for accreditation bodies, third-party certification bodies, and eligible entities to comply with this rule. Therefore, we are revising the rule to allow for accreditation bodies and third party certification bodies

to use documentation of their conformance with ISO/IEC standards in meeting the program requirements under this rule, supplemented as necessary. “

- **FFI Comment 7:** The rule states an effort for “promoting international consistency” that are “familiar to industry” and presumably includes harmonization of terminology. This could apply to using the more globally recognized “Food Fraud” term (i.e. all deception for economic gain using food) rather than just the sub-category of “Economically Motivated Adulteration” (i.e. previously defined by the US FDA and only addresses an adulterant-substance added for economic gain having a health hazard). The term EMA is not widely used outside the USA.

A3P-023.1: “We also received several comments on the overarching issue of using *private food safety schemes* as audit criteria for regulatory audits conducted under the third-party certification program. Some comments suggest that FDA should rely on *private food safety schemes*, particularly those that have been benchmarked by the *Global Food Safety Initiative (GFSI)*, as the audit criteria for regulatory audits of eligible entities under the third-party certification program. Other comments suggest that FDA should establish requirements for accreditation bodies and third-party certification bodies that are similar to those required by *GFSI*, such as *GFSI* requirements relating to accreditation under relevant ISO/IEC product certification or management system standards. ... Comments suggesting that we should rely on *GFSI*-benchmarked food safety schemes or other private food safety schemes as the criteria for certification under the third-party program are outside the scope of this rulemaking. *This rule establishes the framework for the third-party certification program, and not the food safety standards that accredited third-party certification bodies will use to determine an eligible entity’s compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.* We are however responding to relevant comments that address audit quality and auditor competency, consistency, and capacity, including comments referencing *GFSI*’s work in these areas.”

- **FFI Comment 8:** As noted above, this rule requires “a” process but not explicitly endorsing *GFSI* or any other specific private food safety scheme. Requiring “a” process—not a new or specific method—is efficient since the agency does not need to develop a new system yet still creates momentum for prevention plans that will protect the food supply chain.

A3P-024.1: “Section 808 of the *FD&C Act expressly provides for both public and private accredited third-party certification bodies*. Public accreditation bodies and third-party certification bodies, as well as private accreditation bodies and third-party certification bodies that meet the eligibility requirements for recognition and accreditation under section 808 of the *FD&C Act* and this rule are equally eligible to participate in the third-party certification program.”

- **FFI Comment 9:** This rule further emphasizes that private food safety schemes are not only allowed in the rule here but were already also allowed under the previous *FD&C*.

A3P-027.1: “We also received several overarching comments noting that the *lack of qualified food safety auditors* is a problem in many countries. Some comments suggest that we may face similar problems with the availability of accredited third-party certification bodies in our program.”

- **FFI Comment 10:** This rule identifies the “lack of qualified food safety auditors” as a concern. This is a concern that is being addressed globally, in public and private setting, and by non-governmental organizations and academics.

A3P-033.1: “A. Definitions, Generally: (Comment 1) Several comments encourage us to more closely align the definitions in § 1.600 with international standards to promote consistency and common understanding of the rule.... To that end, some comments encourage us to avoid using the term “third-party auditor” synonymously with “certification body,” to be consistent with international standards, which use the term “certification body” (e.g., ISO/IEC 17065:2012 (Ref.7)). *Similarly, some comments indicate that, the language of the statute notwithstanding, it is not correct to use the term “third-party auditor” when describing the activities of a “third-party certification body.” The comments explain that auditors are individuals contracted or employed by certification bodies to conduct audits, and they urge us to clarify the rule by substituting “certification body” for “third-party auditor.”* // (Response 1) We agree that alignment with the terminology used in international standards is preferable, wherever possible. *Congress recognized the value of international standards in accreditation and certification, having instructed us in section 808(b)(2) of the FD&C Act to look to existing standards in developing our model accreditation standards to avoid unnecessary duplication of efforts and costs. We believe it is particularly useful to rely on definitions and terminology from international consensus standards when possible where, as here, the rule is establishing a voluntary program with an international focus.”*

- **FFI Comment 11:** This statement clarifies the comment and response that this rule (and presumably other sections of FSMA) will try to align with common terminology. In this case it is to use the term “accredited third-party certification body” rather than “third-party auditor.”
- **FFI Comment 12:** This rule emphasizes that Congress has already stated an agreement with this previously in the FD&C. There is an emphasis to “avoid unnecessary duplication of efforts and costs.” This further supports this rule requiring *a process* and allowing currently developed public or private food safety schemes.

A3P:036.1: “(Comment 2) *Some comments encourage us to make the definitions in this rule consistent with the definitions in other FSMA proposed rules, such as the 2013 proposed FSVP regulation, the 2013 proposed human preventive controls regulation, the 2013 proposed animal preventive controls regulation, and the 2012 proposed produce safety regulation, where feasible.* // (Response 2) We agree with the comments on the overarching goal of alignment across regulations and accepted suggested revisions, where feasible and appropriate. *However, it is not always possible to develop uniform definitions due to the distinct statutory requirements and the framework of each program. In such cases where it was not feasible or appropriate, we declined the suggested revisions from comments. We discuss such comments and our responses under each relevant term.”*

- **FFI Comment 13:** This states that FSMA will try to harmonize terms and definitions with international practice but often cannot do this even within the USA or even within one regulation such as FSMA. This means that different parts of FSMA may have different definitions for the same terms. Where there are conflicts it will be important to confirm which definition from a particular FSMA rule is being used.

- **Note:** For an emerging issue such as FSMA or Food Fraud, it is important to clearly define the scope and definition of terms.

A3P-053.1: “1. Food: In proposed § 1.600(b), we stated unless otherwise defined in § 1.600(c) of the proposed rule, definitions of terms in section 201 of the FD&C Act would apply to terms used in this subpart. *Section 201 of the FD&C Act defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”* Proposed § 1.600(c) did not define the term “food.”

- **FFI Comment 14:** This is included to confirm the scope of the rule. Food for animals is clearly and explicitly defined as within the scope of this rule—regardless of whether that animal is raised for human consumption.

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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