

FFI Report

Review: FSMA Guidance for Industry – Describing a Hazard That Needs Control in Documents

By John Spink = DRAFT

Survey – anonymous contribution to MSU’s FDA ‘Request for Comments’:

<https://www.surveymonkey.com/r/FB9VFQX>

SUMMARY

FDA released “Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry.” Food Fraud (or EMA) was not directly addressed. This guidance defines how to disclose hazards (or not). This does **not** provide insight on what hazards actually require a preventive control. This guidance is one of many FDA/FSMA clarifications or statements that be published in the future.

The most important summary or conclusion is for industry to continue to watch for “request for comments” and to submit them. FSMA compliance is being defined by these public engagements.

The application of this guidance to Food Fraud is an example of the complexity, compliance gaps, and the assessment tools. Whether or not Food Fraud is (or isn’t) a compliance requirement of FSMA is important for FSMA but companies seek general regulatory compliance. For Food Fraud there are broader certifications or standards that cover the

full spectrum of food fraud types as defined in the Global Food Safety Initiative (GFSI) Food Fraud requirements.

CONCLUSION

Overall conclusions are:

1. This guidance does **not** – and was not intended to – provide new insight on FSMA compliance requirements related to Food Fraud.
2. This guidance does **not** – and was not intended to – provide new insight on what “hazards” require a “preventive control.”
3. This guidance demonstrates the complexity–or ambiguity–of addressing Food Fraud prevention in food safety or food defense laws and regulations.
4. This does not address broader document fraud.
5. ***For Food Fraud this guidance would seem to be expecting the criminal to confirm there is no criminal act.***

The compliance requirement regarding Food Fraud is addressed in FSMA-Preventive Controls rule –**not** in FSMA-Intentional Adulteration (Food Defense) rule. Other FSMA final rules provide some insight on FDA’s thinking regarding assessments, what is acceptable or unacceptable, and compliance priorities.



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BACKGROUND

“Draft Guidance”

The guidance continuously reinforces that this is “draft,” “only for discussion,” “not for implementation,” “explains our current thinking,” and “do not establish legally enforceable responsibilities.” Also “The use of the word ‘should’ in FDA guidance means that something is suggested or recommended, but not required.” This guidance also states that this is to help them “before we [FDA] begin work on the final version of the guidance.”

In general, “guidance” only offers suggestions and are not actual requirements. Those said, not many companies would ignore an agency “suggestion.” In general, it is important for industry to review and respond to “request for comments.”

Federal Register

On October 28, 2019 the Federal Register posted a [document](#) for “public inspection” that is really a pre-read before the official publication. The official publication will be on October 30, 2016. The actual guidance document is published on the FDA website. The actual guidance document is published on Federal Register notice mentioned – that was not in the FDA document – that this effort was sparked from a meeting with “a food trade association” (referenced as “Grocery Manufacturers Association, “21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements,” 2016”).

Summary of the Review

Draft FDA Guidance Document

This draft guidance document applies to four of seven “FSMA Final Rules” including (1) Preventive Controls for Human Foods, (2) Preventive Controls for Animal Foods, (3) Produce Safety Rule, and (4) Foreign Supplier Verification Program.

There are essentially two types of supply chain situations:

1. Manufacturers
2. Producers/ processors

There are essentially two types of hazards:

1. Biological
2. Chemical and physical

There are essentially two types of reporting:

1. What **general** hazards **have** to be addressed
 - a. E.g. conducted the hazard analysis, identified hazards that require a preventive control, and implemented the preventive control. For example “biological hazards” and not the specific pathogens.
2. What **specified** hazards you **have not** addressed
 - a. E.g. “relies on an entity in its distribution chain to address the hazard” which would include a statement such as “not processed to control [identified hazard].”

There are essentially two compliance reporting recommendations (emphasis added):

1. For *biological hazards* the manufacturer should usually control (or disclose)
 - a. “We believe that, in practice, the part 117 disclosure statement will be required **mostly** for biological hazards, because the part 117 disclosure statement only applies when a manufacturing/ processing facility **has identified** a hazard requiring a preventive control, **but has not applied that preventive control.**”
2. For *chemical and physical hazard* the producer/ processor should usually control (or disclose)
 - a. “In the case of most chemical and physical hazards, a chemical or physical hazard that a manufacturing/processing facility identifies as requiring a preventive control would **most likely be controlled by the first manufacturing/processing facility** in the supply/distribution chain.”

Not FSMA but Food, Drug & Cosmetics Act

FSMA maybe the overall act but this guidance constantly refers back to the Food, Drug & Cosmetic Act of 1938 (FD&C). Specifically all facilities “... provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated.” There is a stipulation that narrows some of the FD&C scope for this guidance based on the statement “...and that food is not misbranded with respect to food allergen labeling.” Thus, any other type of “misbranded foods” are outside the scope at least of this guidance.

FSMA compliance does not automatically equal FD&C compliance.

Product or processes may be FSMA compliant and still illegal.

Request for Comment Period

Comments are due 180 days later after publication so approximately April 30. To achieve the maximum impact on the agency and marketplace thinking it is recommended to submit public comments early.

For the MSU Food Fraud Initiative's comments, we will distribute our thinking (such as this blog post), solicit feedback, and then draft our final comments.

Application to Food Fraud

There were no mentions of Food Fraud or any of the variations of *Economically Motivated Adulteration* (e.g. *economically motivated food safety hazard* or *economically motivated hazard*). This is consistent with the Preventive Controls Rule that only applies to "hazards that require a preventive control." Thus, the source of the "hazard" is irrelevant to this new draft guidance.

Consider the bigger picture; if Food Fraud **does** have a human health hazard that requires a preventive control, the hazard is probably chemical or physical.

- *Species swapping* of seafood or horsemeat would probably be a physical hazard and usually with little or no health hazard.
- *Peanut allergen filler in cumin* would be a chemical hazard and would seem to be explicitly excluded from this guidance.
- *Melamine in infant formula and pet food* would be a chemical hazard. The chemical and physical hazards – where the Food Fraud act would seem to be occurring – would require that supplier to provide the preventive control.
- Any Food Fraud incident with a biological hazard would seem to be similar to regular biological hazards.

For Food Fraud this guidance would seem to be expecting the criminal to confirm there is no criminal act.

To be fair, this is the "Food Safety" Modernization Act not the "Food Integrity" Modernization Act. FSMA and FDA have focus on food safety health hazard. The Food, Drug & Cosmetics Act sections of "Adulterated Foods" and "Misbranded Foods" are still in effect – as FSMA final rules emphasize.

CONCLUSION

The analysis of the application of this guidance to Food Fraud emphasizes the complexity, compliance gaps, and the assessment tools. Whether or not Food Fraud a compliance requirement of FSMA – and how much -- is important companies seek overall regulatory compliance. For Food Fraud there are broader certifications or standards that cover the full spectrum of Food Fraud types as is presented in the Global Food Safety Initiative (GFSI) food fraud requirements.

Overall conclusions are:

1. This guidance does **not** – and was not intended to – provide new insight on FSMA compliance requirements related to Food Fraud.
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References:

FDA, Food and Drug Administration, (2016). Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry, Draft, [Accessed October 28, 2016], URL:

<http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM526490.pdf>

FDA, US Food and Drug Administration, (2016). Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry; 21 CFR Parts 1, 112, 117, and 507; Notification of availability; Federal Register notice publication, [Docket No. FDA-2016-D-2841], [Accessed October 28, 2016], URL: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-26245.pdf>

MSU’s Food Fraud Initiative will continue to inform global stakeholders as to the relationship between Food Fraud and Economically Motivated Adulteration, Food Crime, Food Integrity, and Food Authenticity in order to encourage a global set of terms and definitions that are consistent.

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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