



January 24, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2011-N-0143; RIN 0910-AG64, *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*; 78 Fed. Reg. 45730 (July 29, 2013)**

To Whom It May Concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States. In addition, some AMI members operate beef facilities in Brazil, Australia, and Canada, and many members import beef. Finally, approximately 80 percent of AMI member companies are small or very small based on Small Business Administration standards.

The safety of the meat and poultry products AMI members produce is their top priority. The Food and Drug Administration's (FDA or the agency) proposed rule (the proposal) does not directly affect Food Safety and Inspection Service (FSIS) inspected establishments but many federally inspected meat and poultry processing establishments use inputs from FDA regulated facilities and many of them import those inputs.

AMI generally supports establishing supplier verification requirements through the Foreign Supplier Verification Program (FSVP). FDA's approach to FSVP, however, should rely on many of the common and successful practices used by industry today. For the foregoing reasons AMI has a vested interest in the above-referenced proposed rule and AMI submits the following comments.

## **The Proposed Compliance Status Review Requirements are Unduly Prescriptive**

Assuming a compliance status review even warrants inclusion in the regulations, which is a questionable assumption, it would be better incorporated into the hazard evaluation. Such a change would provide the appropriate context for the review and allow companies to assess the risk based on positive and negative information associated with a supplier. Indeed, rather than prescribe reviewing certain sources of information the agency could provide guidance about information sources that importers and the agency should consider using.

As written, the proposed rule is too prescriptive and is unnecessarily focused on the negative. Analyzing risk requires assessing negative (*e.g.*, regulatory action) and positive (*e.g.*, history of strong performance) information about a supplier. The proposal directs importers to review regulatory information such as warning letters and import alerts and does not afford the flexibility necessary for a more effective and comprehensive compliance status review. Importers should determine the information that is necessary for review to assess a supplier's compliance status and, attendant to that, any risk associated with that supplier.

## **Elements of the Proposed Verification Activities are Problematic**

### **1. The Proposal Should not Exceed “One-Step Back” Limits.**

The proposal would define “foreign supplier” as “the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature.” This definition arguably requires verification more than “one-step back” in the chain.

Requiring more than one-step back is problematic because companies cannot always determine the specific entity or farm that manufactured, processed, or harvested a particular food. This problem can be exacerbated for smaller companies that are even more likely not to have the resources to conduct such analyses. A company that purchases ingredients from a broker or distributor may not have the ability to conduct the review set in the proposal and would have to rely on the broker or distributor for the information. Brokers and other “middlemen,” however, may be reluctant to provide such information because of confidentiality concerns and a desire to protect the broker's relationship with the supplier.

The proposal also raises questions with respect to traceability provisions found elsewhere in the Federal Food, Drug, and Cosmetic Act (FFDCA) and FSMA. Specifically, the FFDCA and its regulations require a facility to be able to trace food “one-step back.”<sup>1</sup> If the agency intends to require through the proposal that importers go further “back” such a provision conflicts with the Bioterrorism Act and the traceability provisions in FSMA. Indeed, FSMA specifically restricts FDA from requiring facilities to maintain records of the “full pedigree” of a food and it limits traceback requirements for commingled raw agricultural commodities to the immediate previous source of the food.<sup>2</sup> In short, proposal should only require importers to go “one-step back.”

## **2. Verification Activities Should Focus on the Supplier’s Entire Program and not on Controlling a Hazard.**

The proposal provides that when a supplier controls a hazard there is verification of that control. The proposal also recognizes that different verification activities may be needed for different hazards. Although applying different supplier verification activities as a function of risk is appropriate it is more important for verification activities to be focused on the supplier’s program as a whole.

The element of the proposal that treats supplier verification as if it controls the hazard is misplaced. Verification is not a critical control point and linking verification activities to hazards suggests that the verification controls the hazard -- it does not. Tying verification activities to a hazard likely will result in a multiplicity of largely unnecessary audits that will not enhance food safety nor will they contribute to the efficiencies and economies of scale that FDA anticipates. Moreover, the proposed hazard-based verification approach will significantly increase the number of documents generated, thereby increasing the expense and burden on the industry and, arguably, the agency. The better approach is to require an importer to verify each supplier based on the risk presented by the supplier and food.

## **3. Supplier Audits are a Means, Not an End.**

Although supplier audits are important for verification, the proposal is too focused on audits and more specifically, a supplier’s control of specific hazards. Audits should be conducted when necessary but they are simply one tool that can be used. Relying too heavily on audits can provide false signals about a supplier’s performance. In that regard, it should not be necessary to audit every supplier before using its product because there are other tools available to verify suppliers

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<sup>1</sup> FFDCA §414; 21 C.F.R. Part 1, Subpart J (§1.326 *et seq.*).

<sup>2</sup> FSMA §204(d)(1)(L).

and identifying the appropriate verification activity must be done on a case-by-case basis after considering the risk-factors associated with that supplier.

#### **4. Proposed Option 2 is Preferable.**

The proposal offers two different approaches to verification activities for hazards controlled by a foreign supplier. Option 1 would require suppliers to be audited before any food is imported and at least annually thereafter if they control hazards that will result in serious adverse health consequences or death to humans or animals (“Class I recall” hazards). Option 1 would allow other verification activities (*e.g.*, testing, records review) for other hazards.

Option 2 is less prescriptive in that it permits, but does not require, the Option 1 approach. Rather, Option 2 would require importers to choose the appropriate activities from a “menu” of verification activity options, including on-site audits, to verify that a hazard is adequately controlled.

Option 2 is the far better approach and should be adopted because it affords the necessary flexibility to determine the appropriate verification activities based on an assessment of risk – both food and supplier risk. Option 1 effectively eliminates that assessment by prescribing risk in the regulation, which could lead to a cookie cutter approach to food safety. Option 2, on the other hand, forces an importer to consider and justify its chosen verification activities instead of just putting an audit report in the files. Option 2 also provides greater flexibility to FDA in that specific information about when more rigorous verification activities may be necessary would be better offered through agency guidance, which can be amended as necessary more quickly than a position incorporated into a regulation.

In addition, the risk assessment included in Option 1 focuses on suppliers that control Class I hazards. A sound food safety system, however, looks beyond whether a supplier or an ingredient presents a Class I hazard. Many outcomes can result from balancing ingredient and supplier risk and those are difficult to quantify in a regulation.

Finally, Option 1’s requirement that a supplier be audited before its product can be used is not necessary for all suppliers nor is it practical because of the significant potential for supply chain disruptions. Situations routinely arise for any number of reasons where inputs must be purchased from a different supplier on short notice. If that supplier has not yet been audited by the importer Option 1 would preclude that importer from purchasing from the supplier if the importer is unable to verify the supplier within the time required for production. This artificial barrier could result in significant production disruptions or force the importer unnecessarily to pay a premium to source an ingredient from yet again a different supplier.

Option 2 will provide flexibility to industry and to the agency to develop the most effective food safety systems possible and for that reason is more appropriate and the better choice.

## **5. Testing has a Role as a Verification Activity.**

The proposal provides that periodic or lot-by-lot sampling and testing of imported food would be an appropriate verification activity and would allow importers to conduct testing or obtain documents (*e.g.*, certificate of analysis) about the test results. Certainly, testing can play a role as a verification procedure for ingredients if a potential hazard exists in the material that is not controlled by the importer or its customer, or when the incoming levels of the hazard can impact the effectiveness of process controls or finished product safety.

That said, the agency should recognize that ingredient testing done by the supplier is often more effective and appropriate. A supplier can generate Certificates of Analysis (COAs) that will help evaluate conformance of the lot to the importer's requirements. Importers can verify results through their own testing of the incoming ingredient but the need for, and frequency of, such testing should be based on the material risk, its intended use, and the supplier's performance history.

### **The Proposal Raises Questions Regarding Investigations and Corrective Actions.**

#### **1. The Complaint Review Process Should Focus on the Program and not Specific Incidents.**

The proposal would require an importer to conduct a "prompt" review of customer, consumer, or other complaints to determine whether the complaint relates to the adequacy of the FSVP. If the review shows that the imported food is adulterated or contains undeclared allergens, the importer must promptly investigate the cause or causes of the adulteration or misbranding and take appropriate corrective actions, which can include discontinuing the supplier. The proposal also requires that complaint records be kept and made available to FDA for review and that the importer document the above-discussed activities. Although reviewing complaints and taking decisive corrective actions if necessary are important, it also is important to appreciate the tenuous link between any individual complaint and the adequacy of an importer's FSVP.

In that regard, comments and complaints from consumers range widely and many are not food safety related. As a general rule, more than a single incident is necessary to determine whether there is an issue with a particular supplier or whether an importer's verification program may have a problem. Indeed, complaints generally suggest a problem with a particular individual supplier – not

with the FSVP. Moreover, complaints unrelated to food safety are outside the scope of FDA's legal authority because they are unrelated to a FSVP. The better approach is for FDA to limit its review of complaints during inspection and focus on whether an importer uses an appropriate program for reviewing the documents.

## **2. All Supplier Nonconformance is not the Same.**

The proposal would require prompt corrective actions in response to a foreign supplier nonconformance. An importer should take appropriate steps in the event of a supplier nonconformance and the proposal provides flexibility with respect to such actions. There are, however, different levels and types of nonconformance. Because food safety is not controlled through supplier verification, for that reason some types of nonconformance should not trigger discontinuing use of a supplier. FDA should develop guidance to explain its recommendations for appropriate responses in instances of supplier nonconformance and an importer should be afforded the flexibility to identify the appropriate action while documenting responses to supplier nonconformance, which would be available for FDA review.

### **Mandatory Reassessment Should be a Function of Risk, not the Calendar.**

The proposal would require an importer to reassess the effectiveness of its FSVP at least every three years. Reassessment also would be necessary when an importer becomes aware of new information about potential hazards associated with a food or a supplier. Although reassessing an FSVP's efficacy when there is new information about a potential hazard associated with a food or supplier is appropriate, an arbitrary reassessment tied to every three years is neither mandated by the law nor logically necessary because it is not tied to risk.

### **Certain Elements of the Proposal's Records Requirements Lack Practical or Legal Foundation.**

#### **1. Importers Should not be Required to Keep a "List" of Suppliers.**

The proposal would require an importing facility to maintain a list of foreign suppliers. Many larger companies do not keep a single supplier list but have a corporate-wide system in place to confirm ingredients are received only from approved suppliers. Maintaining a stand-alone supplier list creates unnecessary logistical challenges because suppliers who are approved are constantly evolving. The better way is for FDA to require importers to have a mechanism to ensure ingredients are received only from approved suppliers.

## **2. The Remote Records Access Provision is not Authorized by Law and is Impractical.**

The proposal would allow FDA to access FSVP records remotely upon written request via letter or email and would not require FDA to visit an importer's place of business. This concept should be rejected for the following legal and practical reasons: (a) requiring remote access to FSVP records is not expressly permitted by FSMA or any other part of the FFDCA; (b) the proposed authority is not authorized by FDA's implied legal authority under FFDCA section 701(a) because it will not promote efficient enforcement of the Act; and (c) allowing remote access to records presents significant practical concerns that will undermine the purpose of FSMA.

### **A. The Statute Does Not Provide Express Authority to Remotely Review Records.**

As an initial matter, there is no statutory basis granting FDA remote access to FSVP records. The statute requires that "Records of an importer related to a foreign supplier verification program . . . shall be made promptly available to a duly authorized representative of the Secretary upon request."<sup>3</sup> This language does not suggest that FDA has the authority to access records outside a facility. If Congress intended to expand the scope of FDA's ability to access records to include a simple submission requirement, it could and would have done so through statutory language. But Congress did not and instead chose the word "available," rather than "submit" or a similar term, when writing FSMA. That analysis is highlighted by the fact that in one section of FSMA Congress granted FDA remote records access authority. Specifically, FSMA expressly permits FDA to require an accredited third-party auditor that conducts a regulatory audit to submit records to the agency upon request:

Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.<sup>4</sup>

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<sup>3</sup> FSMA §301(d).

<sup>4</sup> FSMA §307 (emphasis added).

That Congress affirmatively granted FDA remote access authority in this instance reinforces the absence of remote access authority elsewhere, including access to an importer's FSVP.

**B. There is No Implied Authority Under the FFDCFA Allowing FDA to Remotely Review Records.**

FDA's unsupported conclusion that remote access to records is authorized by section 701(a) of the FFDCFA, which grants FDA authority to "promulgate regulations for the efficient enforcement" of the Act is simply bootstrapping. The legislative history of FSMA demonstrates that Congress did not intend what FDA contends because Congress expressly considered—and rejected—expanding the scope of the FFDCFA to give FDA remote access authority.

The food safety bill passed by the House of Representatives in 2010 contained language expressly granting FDA remote access to certain food records, including remote access in emergency situations and remote access to food safety plans, without cause.<sup>5</sup> In contrast, the Senate food safety bill, which ultimately became law, did not contain either of these provisions. The Supreme Court has held that selection of one chamber's version of legislation over that of the other is indicative of legislative intent.<sup>6</sup> Notably, even the House legislation that would have granted remote records access authority in some situations would not have extended that authority to importers' records. Accordingly, Congress's refusal to provide remote access authority must be considered in evaluating the legal basis for the proposal.

**C. Remote Records Review is neither Practical nor Efficient.**

Contrary to the opinion posited by FDA that remote access will be less burdensome on industry, such access is likely to increase the burdens on importers. FDA's longstanding enforcement of the FFDCFA through on-site inspections has afforded FDA inspectors the opportunity to interact with regulated facilities and in doing so allow FDA and plant personnel to discuss relevant information, address questions, and otherwise discuss inspection observations. These conversations generally help FDA inspectors make more focused requests for records, allowing the agency to be more efficient and lessening the burden on the company. The proposed remote access approach, however, is at odds with that approach and likely will result in a company being required to provide information without context and in doing so inviting more significant problems and misunderstandings, *i.e.*, FDA will not understand the importer's program and will only review select documents that do not provide adequate insight into the importer's FSVP.

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<sup>5</sup> H.R. 2749, 111th Cong. § 106(a) (2009).

<sup>6</sup> *See, e.g., INS v. Cardoza-Fonseca*, 480 U.S. 421, 441-42 (1987); *United States v. Riverside Bayview Homes*, 474 U.S. 121, 136-37 (1985).



In addition, remote records authority creates the possibility that massive requests will unduly burden an importer if FDA reviewers simply engage in “fishing expeditions.” For example, an FDA “request” for all records related to an importer’s FSVP would be extremely burdensome and a challenge to respond to (especially within a short time period such as 24 hours). Moreover, there is no limit on how often FDA could make such requests, raising the specter of countless demands simply to satisfy the regulator’s curiosity. In short, to promote efficiency and to ensure that FDA is accountable and has some “skin the game” when it comes to resource allocation the proposed remote records access should be abandoned.

### **3. The Requirement to Keep Records in English Should be Abandoned.**

The proposal would require all records to be maintained in English. This concept is not in the law nor does FDA provide a rationale for this requirement. Indeed, nowhere in the FFDCFA is there a requirement that food records be maintained in English, casting doubt as to whether there is a legal basis for the proposed requirement.

Moreover, the requirement would impose a significant burden on some importers and there are several practical concerns associated with it. First, for foreign suppliers without corporate offices that require English as the business language (often small and medium size companies), the native language often is not English. If neither the supplier nor the importer speaks English, requiring the records be kept in English introduces the possibility for misunderstandings that could affect food safety because the pertinent records will not be kept in the language most familiar to both parties. Second, requiring records to be maintained in English suggests an implied requirement for audit reports also to be in English, but foreign facilities may be audited by a person whose native language or main working language is the native language at the foreign facility being audited. Because audit reports and related records are most effective when provided in the native language between the audit team and company employees such a requirement is at odds with ensuring the most effective food safety system possible. Finally, translating documents into English will add cost at several levels and not improve food safety. For the foregoing reasons the proposal should not mandate a particular language for records.

### **Other Issues**

#### **1. Intra-Company (Multinational) Shipments Should be Exempt from an FSVP.**

The agency asked whether an importer should be required to conduct foreign supplier verification when importing food produced by entities under the same corporate ownership. Imports from suppliers that are subject to common corporate

or corporate-parent ownership (*e.g.*, subsidiaries, affiliates) should be exempt because those ingredients will have been verified or produced by another division of the company. To require verification in that context would be duplicative and not benefit public health.

**2. The Agency Should Consider a Transition Period Regarding Compliance.**

The proposed compliance date of 18 months after publication of a final rule is necessary to allow importers time to come into compliance. In that regard, industry and FDA likely also would both benefit from a transition period during which the agency and industry allow shipments to be imported under the regulations, but without penalties for any failures to comply. Such an approach would enable FDA to collect more information from industry and provide improved guidance.

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AMI appreciates the opportunity to submit these comments. If you have any questions regarding these comments or anything else regarding this matter, please contact me at (202) 587-4229 or [mdopp@meatami.com](mailto:mdopp@meatami.com).

Respectfully submitted,



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