The Impact of Importing Food and Dietary Supplements under the Proposed Foreign Supplier Verification Rule

By Marc Sanchez

The Food Safety Modernization Act (FSMA) continues to take shape and fundamentally shift the food safety landscape. Signed into law in 2011, FSMA sat quietly for two years. Deadlines for new rules came and went unnoticed with only minor provisions taking effect. The trickle of change is no more with the flow of information now gushing with each proposed rule. The latest proposed rules, the Foreign Supplier Verification Program (FSVP) and Accreditation of Third-Party Auditors, appear small, but present a dramatic change in the law.

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The two proposed rules dovetail neatly with the overarching aim of FSMA. Jointly and individually the proposed rules represent a monumental shift in food safety – the first real change since Upton Sinclair's *The Jungle* sparked a movement that lead to the passage of the Pure Food and Drug Act in 1906. The central intent throughout FSMA is to push responsibility for monitoring and maintaining safety solely from the shoulders of the The Food and Drug Administration (FDA) to industry itself. Reviewing the FSVP and Accreditation rules provides plenty of examples of this shift. No longer is the FDA solely responsible for verifying the safety of foreign food. Industry now stands at the center of proactively identifying and managing risks. This requires a new approach to food safety. Reading FSMA rules requires attention to both the

technicalities of compliance and for the first time strategies to avoid litigation.

More Rules, More Changes

No rule better exemplifies the broad and sweeping changes of FSMA than the proposed FSVP rule. At its simplest the FSVP rule requires importers to identify and control risks of its foreign suppliers. The proposed rule outlines seven required activities under an importer's FSVP. Those are: compliance history review; hazards analysis; verification activities; review of complaints, investigation of adulteration or misbranding, and taking of corrective actions; reassessment of the FSVP; ensuring that required information is submitted at entry; and recordkeeping. Among the list two activities stand-out as the core activities required by the rule – hazard analysis and verification activities.

Hazard analysis under the proposed FSVP rule is both old and new. Many larger importers already conduct a hazard analysis if they currently implement Hazard Analysis Critical Control Point (HACCP). As with HACCP the proposed rule requires an analysis of unintentional hazards reasonably likely to occur or commonly occurring. The proposed rule suggests going further than HACCP by looking at intentional hazards, in particular economic adulteration. Economic adulteration is the intentional addition of inexpensive ingredients to stretch or enhance a product. This type of adulteration was the impetus to passing the Pure Food and Drug Act. After a recent focus on microbial contamination it may not only be a nod to the past, but foreshadow the future phase of food safety, perhaps resulting in FSMA II.

Foreign Onsite Audits

The requirements for supplier verification in the proposed rule on FSVP are primarily based on two factors. The first is who controls the hazards that are reasonably likely to occur with a particular food and the second is the nature of the hazard. The rule provides three alternatives as to who may control the hazard: the foreign supplier, the importer, or the importer's customers. The most onerous of the requirements fall on verifying hazards controlled by the foreign supplier.

In the proposed rule, FDA puts forth two options for verifying hazards controlled by the foreign supplier. The first option requires annual onsite audits for hazards controlled by foreign suppliers that could cause serious adverse consequences or death (SAHCODHA) and for microbiological hazards in produce. The second option provides more leeway. It allows importers to choose from among the list of verification activities for all types of hazards controlled by the foreign supplier. Both options require maintaining a written list of foreign suppliers and the performance of supplier compliance status review, hazard analysis, and other standard verification requirements.

Parity with the Preventative Controls Rule

If there is a twin aim of the proposed FSVP rule it is parity with the proposed Preventative Controls rule. The drafters of the FSVP rule make it clear the rule is not intended to apply provisions of either the Preventative Controls or Produce Safety rules to foreign facilities. Instead it broadly seeks to ensure foreign food is as safe as domestic food. The Preventative Controls rule and FSVP share some common features. Both utilize a HACCP-style hazard analysis approach to managing foreseeable risks. The FSVP, however, requires supplier verification to ensure the hazard is properly managed. The Office of Management and Budget (OMB) struck out supplier verification from the Preventative Controls rule. The drafters seem aware of how this difference could lead to trade disputes or claims of an unfair advantage. In an unusual move the FSVP rule seeks comment on introducing supplier verification back into the Preventative Controls rule. This cross-rule comment request makes it clear the FDA believes supplier verification belongs in both rules.

Third-Party Auditors

Foreign onsite audits would be more onerous if not for third-party auditors. Importers complying with the FSVP will likely rely on third-party auditors to conduct audits of foreign facilities. The proposed Accreditation rule establishes a system for accreditation of third-party auditors and certification bodies. The FDA would only recognize audits and certifications verifying food is safe for entry if certified by a group accredited under the rule. The aim of accreditation is to establish confidence, competence, and consistency to the organizations and individuals conducting foreign food audits.

The rule begins by setting the eligibility requirements for third-party auditors and accrediting bodies. The proposed rule recognizes a third-party auditor or accrediting body could be a foreign government or private third-party. Eligibility for both is the same. Each must "meet standards for legal authority, competency and capacity, impartiality and objectivity, quality assurance, and records procedures." Accreditation bodies and third-party auditors also share a required duty to maintain and provide FDA access to records, protect against conflicts of interest, and assess and correct any problems in its own performance. Additional requirements specific to auditors and accrediting bodies are also provided in the rule.

The rule also establishes an authority to revoke recognition of an accrediting

body. The rule clearly states an intent for the FDA to exercise oversight. That oversight could extend to enforcement actions against accrediting bodies. The FDA reserves the right to revoke or withdraw the eligibility of any accreditation body or auditor "for good cause." What constitutes good cause is an area the FDA seeks comments, specifically examples of what does not constitute good cause.

Flexibility and Conflicts of Interest

Both rules will need refinement before implemented. In drafting the rules FDA struggled with how to write standards for a broad and diverse industry. The rule reflects a flexible approach. The flexible approach, however, may undermine compliance with the new rules. Too much flexibility creates a loophole. It also risks provisions becoming ineffective before ever going into effect.

The FSVP rule raises a conflict of interest by allowing the importer to decide if a risk qualifies as SAHCODHA. The FSVP proposes two alternative options to determine when a foreign onsite audit is required. Option one raises the question of who must identify whether a hazard is SAHCODHA or non-SAHCODHA. The proposed rule provides the importer the discretion to determine if the foreign supplier has a SACOHDHA hazard that would be subject to onsite auditing. The rule does provide examples of SACOHDHA, such as hazards that would lead to a Class I recall. The list, however, is only illustrative introducing flexibility and subjectivity for the importer to identify SACOHDHA hazards.

Option one places the importer in a difficult position. Most importers will want to avoid the damage that arises from serious adverse events - the damage to the brand, the cost of a recall, and the risk of litigation. Still the rule introduces a conflict of interest, which may undermine compliance with the proposed rule. An importer can make the determination to classify a hazard as non-SAHCODHA and avoid the cost and time of an onsite audit.

The Accreditation rule raises a conflict of interest between the facility audited and the auditor. Among the required responsibilities of an auditor is a notification duty when an auditor discovers a "serious risk to the public health." In an effort to provide elasticity the proposed rule does not define the term, instead leaving it to the auditor to interpret. The Agency requests comment on whether the notification requirement should encompass both Class I recall risks, those that present a reasonable probability of serious adverse health events or death, and Class II recall risks, which may cause temporary or medically reversible adverse events or the probability of serious adverse health events is remote. A broader definition, which includes both Class I and II risks, offers more flexibility and could be more preventative, but may also be problematic.

The proposed Accreditation rule creates distrust between the facility audited and the auditor if a broad definition is adopted. Currently it is the facility's decision whether to notify the FDA of a potential food safety concern through the Reportable Food Registry. The facility is only required to do so in a Class I scenario otherwise, such as in a Class II recall situation, notification is voluntary. Notification of Class I risks presents a smaller conflict of interest. Auditors' notifications would merely impact the timing or readiness of a facility to report and react to a Class I recall. At its worse it places pressure on a facility dragging its feet. If auditors, however, are required to notify the FDA of Class II risks there is conflict of interest that may lead to mistrust. This level of transparency may dissuade food and dietary supplement firms from using third-party auditors and certifying bodies accredited under the proposed rule. The proposed rule makes note of this conflict of interest, but states it is "duty bound" to implement FSMA. It goes on to argue, "To gain credibility with consumers and address industry views on sensitive information, this proposed rule seeks to balance disclosure and confidentiality concerns." In the FDA's view the rule strikes the right balance.

The Risk of No Comment

If there is one take-away from the new rules it is the need to comment. Right on cue, the D.C. Circuit Court of Appeals issued a ruling this year on the risk of no comment on new rules. The Court of Appeals dismissed a California farmer's challenge to USDA rules requiring pasteurization of almonds. The suit argued the rule provides an unfair advantage to almond importers, who are allowed to sell the untreated nuts in the U.S. The court dismissed the case on procedural grounds. It found the plaintiff's failure to object to USDA authority during the comment period meant the farmer waived the right to later challenge the rule. Failure to comment during the comment period wiped away any ability to challenge the rule. As FSMA violations enter 483s, warning letters, import detention notices, and other new enforcement tools under FSMA challenges to the rules will arise. The success of those challenges will first depend on whether a comment is submitted during the comment period.

Litigation Risks

FSMA presents an enormous risk of litigation to facilities. Specific standards,

metrics, and records replace outdated guidance documents and generalized statutory definitions. The ability to build class actions for minor economic damages took shape while the industry waited for new rules. Class actions for labeling claims provide the clearest example of this growing precedent in state and federal courts. Together, FSMA and new access to class action status, present a challenge to compliance. The hypotheticals are endless. Plaintiffs could sue for small bouts of food poisoning using discovery to find what risks were identified and controlled or mismanaged. Suits could also arise for economic adulteration as foreign imports come under scrutiny.

This background to the new rule requires strategic compliance over strict compliance. The aim remains the same – protect the consumer to protect the brand – but the means of achieving that aim has fundamentally changed. For example, a hazard analysis could serve as a roadmap to investigators and plaintiffs alike. FSMA is asking industry to do more and trusting the incentive to avoid litigation will ensure compliance with the new rules.

Conclusion

The rules are dense with details and areas for comment. It will be paramount for each facility to understand how the proposed rules will impact their industry and operations. The consequences for ignoring the new rules are real. Not only does the FDA carry new enforcement powers like facility registration suspension or high-risk facility designations, but the litigation risks are potent. Beyond FDA enforcement compliance now matters as a key component of avoiding litigation. The litigation terrain is mired with complications as the FDA entrusts enforcement of FSMA to facilities.