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NSMA
National Seasoning Manufacturers Association

January 27, 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–0146, RIN 0910-AG66
78*Federal Register* 45782 (July 29, 2013)

Submitted via eRulemaking Portal: http://www.regulations.gov

To Whom It May Concern:

The National Seasoning Manufacturers Association (NSMA) appreciates the opportunity to submit comments regarding the proposed rule for the "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, Proposed Rule," 78*Fed. Reg*. 45782 (July 29, 2013) in which the Food and Drug Administration (FDA) proposes to issue regulations to provide for accreditation of third-party auditors/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).

NSMA is a trade association representing the U.S. seasoning industry. Founded in 1973, our membership manufactures more than 98% of seasonings consumed in the United States. The NSMA is composed of member companies that produce food ingredients including but not limited to seasonings, spices, flavorings, additives, and other vegetable ingredients and derivatives. Given the vast array of ingredients incorporated into the products we produce our membership may be greatly impacted by the Accreditation of 3rd Party Auditors/Certification Bodies (A3PACB) proposed rules..

Food Safety – Our Highest Priority

NSMA shares FDA's commitment to food safety. The highest priority of NSMA and its members is providing safe seasoning and spice products to their customers: food manufacturers and consumers. NSMA continues to actively engage in the regulatory process by providing comment to FDA. NSMA also continues to provide needed resources to members to share with the entire supply chain including guidance to assist in the manufacturing, handling and processing of safe seasonings and spices.

Scope of FSMA Mandatory Import Certification Requirements

NSMA encourages FDA to apply the mandatory import certification (MIC) requirements under FSMA Section 303 only in very limited, narrow situations. FSMA provides that a mandatory import certification only is appropriate based on the risk of the food when considering factors such as: (1) known safety risks associated with food, (2) known food safety risks associated with country/territory/region of origin, and (3) findings by FDA that (i) the food safety programs in the place of origin of the food are "inadequate to ensure that the article of food is as safe as a similar article of food" from the U.S. and (ii) the certification would assist the agency in determining whether to refuse or admit the article of food. As an example, imported raw spices should not be considered to require an MIC when they will be subject to treatment and processing in

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the United States to control their hazards. When considering the needs for MICs, FDA should consider the entire continuum of the food chain and assess whether an "inadequate" food safety program in the country of origin justifies an MIC in situations where the food safety risks will be controlled by the importer in the United States. This would be a risk-based approach that is consistent with the philosophy underlying the FSVP proposed rule.

NSMA General Comments on the Proposed A3PACB Rule

The proposed rule provides that FDA-accredited auditors must be used for two purposes: MICs under FSMA section 303, and certifications for the Voluntary Qualified Importer Program (VQIP) under FSMA section 302. Under the proposed rule, these auditors would be mandated to (1) provide their audit reports to FDA, (2) immediately report to FDA all observations that could cause or contribute to a serious risk to the public health, and (3) use accredited laboratories (that must, in turn, provide FDA with all testing results) when the agency requires sampling and analysis. FDA also suggested in the proposed rule the immediate reporting standard be triggered by all identified findings associated with Class I and Class II recall risk levels. FDA also proposes that these requirements apply for consultative audits conducted by FDA-accredited auditors, except that reports from these audits are only available to FDA in emergency situations under the Bioterrorism Act (as provided by FSMA).

NSMA encourages FDA to limit the scope of third party accreditation regulation in the following three ways.

First, the requirement to use an FDA-accredited auditor should only apply for "regulatory audits" under FSMA, which are audits for MIC and VQIP. This is the scope provided for by the proposed rule and by the statute itself. Requiring use of an FDA-accredited auditor for Foreign Supplier Verification Program (FSVP) audits is beyond the scope of the statute. NSMA encourages FDA to allow the use of FDA-accredited auditors for FSVP, but these audits should be outside of the scope of these auditors' ties with FDA. That is, the FDA-accredited auditors should be able to take off their "FDA-accredited" hat during these audits. This would mean that none of the three accompanying mandates (provision of audit reports, immediate reporting, and use of accredited laboratories) would apply to FSVP audits.

Furthermore, although we support permitted use of FDA-accredited auditors for FSVP audits, use of such auditors should not be required. NSMA encourages that FDA continue to allow qualified third party audits (such as GFSI) to be used for FSVP purposes. This is critical to provide industry with autonomy to hire the most qualified auditor available for their intended purpose.

Second, NSMA encourages FDA to keep the current proposed codified language regarding direct reporting but to change its perspective on the issues that need to be reported to FDA. But we oppose FDA's tentative interpretation to use the Class I and Class II-recall standards as a surrogate for "serious risk to public health." This would be burdensome for auditors and likely would result in many unnecessary reports to FDA that do not address serious public health risks. Indeed, we believe that including Class II recall level of risk does not align with the statute, as Class II-recalls, by definition, occur when adverse health consequences are temporary or medically reversible and any potentially serious public health risk is remote.

Instead, we encourage FDA to clarify the meaning of "serious risk to the public health" in the preamble to align with the Class I-recall ("serious adverse health consequences or death to humans or animals") level of risk and to be the same scope as required in the reporting under the Reportable Food Registry (RFR). This standard is more consistent with the statutory language of "serious risk to public health." Under the RFR, reporting is mandated if it meets two requirements: Class I recall level of risk, and (2) product has left control of the party with whom the adulteration originated. The direct reporting standard for audit findings should be consistent with the RFR.

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Third, NSMA is seriously concerned about the effect of the proposed rule on consultative audits. By definition, these audits are for internal purposes only. So it does not make sense to bring these audits into the regulatory compliance and reporting process. Consultative audits play an extremely important role in the food industry. They are necessary to identify and fix internal problems, as well as to drive continuous improvement in food safety processes. In order to maintain the effectiveness of this tool in driving food safety improvement, it is essential that these audits remain a private function for industry. It is critical that the use of consultative audits would not invoke direct reporting, as this would be a strong disincentive to use FDA accredited third parties to conduct consultative audits. Direct reporting could result with FDA receiving information about confidential, internal audits that were not even related to product intended for shipment in interstate commerce. The direct reporting requirement could also discourage some consultative auditors from becoming accredited. Or, alternatively, it may drive companies to hire auditors that have lesser qualifications because the best (i.e., accredited) auditors would have a duty to directly report to the agency. Notably, if there is any serious risk to the public health, the food company itself would have an obligation to report to FDA under the RFR, so such reporting by the auditor would be redundant and unnecessary.

NSMA also opposes any requirement by FDA to use accredited laboratories for consultative audits. We expect that use of accredited laboratories for consultative audits would not be necessary, because any accompanying testing would be completely voluntary and not "required" by FDA, but we would appreciate confirmation of this interpretation in the preamble to the final rule.

Summary

NSMA and its members are committed to ensuring the safety of our dry and liquid seasoning products. In that regard, the National Seasoning Manufacturer's Association appreciates the opportunity to provide these comments and we respectfully request your consideration of these comments as you draft the final rule on the Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications . Due to the complexities of the proposed FSMA rules and the likely major modifications that these rules will undergo during the promulgation process, NSMA strongly encourages that the revised rules be re-published for further review before proposing a final rule.

If we can assist the agency with additional information or industry perspective, please do not hesitate to contact us.

Respectfully,

Richard Alsmeyer, Ph.D.
Executive Director
National Seasoning Manufacturers Association