January 27, 2014

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

Re: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Proposed Rule (Docket No. FDA–2011–N–0143; RIN 0910–AG64)

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on the food safety plan requirements as outlined in the Food and Drug Administration’s (FDA’s) proposed rule regarding Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (78 Fed. Reg. 45730 (July 29, 2013)).

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation’s economy.

GMA strongly supported the FDA Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable efforts to reach out to stakeholders during the pre-rulemaking stage of the proceedings and for the Agency’s willingness to continue that dialogue during the public comment period. We appreciate the Agency’s desire to develop a regulatory framework that is protective of public health, risk-based, and practical. We all share a common goal of providing safe food to American consumers.
Executive Summary of Comments

GMA supports establishment of supplier verification requirements through the FSVP. This program is a key component of an effective public-private partnership to protect the safety of imported food under FSMA. GMA has supported this concept since the infancy of the legislation.

FDA’s approach to supplier verification should incorporate current leading practices in place today that result in successful food safety programs. As our comments will highlight, several aspects of the FSVP regulation need to be reconsidered based on input from supply chain management experts to ensure the new requirements are practical to implement and will function to improve food safety. The Agency’s regulation of supplier verification should not establish a new paradigm, but rather should codify current successful industry-developed practices. FDA should regulate supplier verification in a comprehensive and meaningful, but flexible, manner because there are different approaches to supplier verification that can all result in safer food.

We encourage the Agency to consider the following guiding principles for the regulation:

- **The regulations should not require companies that currently have strong supplier verification programs to change their practices.** Many of GMA’s members have invested considerable resources in developing and implementing robust supplier verification programs that have proven effective. The regulations should focus on establishing minimum requirements to raise the floor for importers that do not have these kinds of strong programs in place today, rather than requiring companies that already have effective programs in place to modify their practices in ways that will not materially improve food safety, or worse, increases the risk of food safety incidents.

- **FDA’s supplier verification regulations should encourage appropriate behavior.** Everyone in the supply chain is responsible for making safe food and the regulations should require and encourage verification activities that will materially improve public health outcomes. FDA’s regulations should incentivize companies to increase their knowledge about good food safety practices and work with their suppliers and customers to drive continuous improvement in food safety.

- **Supplier verification should be based on a holistic assessment of risk (both ingredient and supplier risk).** Supplier verification programs should identify and evaluate the risks presented by the food and the supplier based on multiple factors, including the historical track record of the supplier. FDA’s hazard-analysis based approach is too narrow by focusing only on the risks presented by the ingredient.

- **Supplier verification cannot control hazards, but rather should focus on confirming suppliers follow effective food safety programs.** Supplier verification is successfully applied today as a prerequisite program, verifying that suppliers are following effective food safety programs. We are concerned that FDA’s approach in the FSVP proposed rule misses the mark by taking too narrow of an approach. Even if an importer controls a hazard, the supplier often still needs to be verified.
Audits are an important verification tool but they only offer a snapshot of a supplier’s performance at a given time and do not control any hazards. The role of audits should not be overemphasized and also should not be narrowly tied to a supplier’s application of specific controls. Effective audits are system-wide and risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency tailored to the risks presented by the supplier and ingredient.

Suppliers need to be assured of confidentiality of audits so as to promote food safety. Confidentiality protections also are necessary for supplier audits to be effective and to encourage robust scrutiny and an open dialog without creating fears about consequences from FDA’s review of the resulting paper trail. FDA’s records access should focus on information that demonstrates that significant corrective actions were taken as needed to assure food safety.

Supplier verification should not be a check the box exercise. A regulation that imposes regulatory requirements without encouraging thoughtful analysis and dialogue will miss an important opportunity to move food safety forward across the industry. Some aspects of the proposal, such as requiring mandatory annual audits and a detailed review of a supplier’s regulatory compliance, will result in a culture focused on compliance rather than prevention and continuous food safety improvements.

FDA inspections of supplier verification programs should focus on ensuring importers have and implement strong, risk-based supplier verification programs. The goal of FDA’s inspections should be to ensure importers have well-functioning systems in place. Unless there is cause, FDA should not routinely question the importer’s determinations about individual suppliers, such as assessments of risk and decisions about what verification activities to apply and the frequency for those activities.

Supplier verification should be the same regardless of whether a supplier is located domestically or internationally. We appreciate the position explained in the FSVP preamble that the agency intends to take a parallel approach to domestic supplier verification under the preventive controls regulation. This is important to facilitate compliance by industry and to meet World Trade Organization (WTO) obligations. FDA should tailor the regulations for FSVP and preventive controls to provide consistent requirements and eliminate redundancies. FDA should also avoid any unnecessary duplication between FSVP and preventive controls requirements so that if a foreign supplier was verified under an FSVP, including by a qualified third-party, the importer should not be required to engage in redundant verification under preventive controls.

Our comments emphasize that FDA’s supplier verification regulations should be built on successful practices in place today. Rather than the Agency’s proposed hazard-based approach, which looks only at ingredient hazards, a responsible manufacturer will also consider supplier risk and therefore may find it necessary to engage in appropriate due diligence for nearly all of their suppliers. In addition, proposed activities like continuous FDA compliance status review, that indirectly consider supplier risk, will not add value for food safety. We also think the
regulations should be simpler, by incorporating more flexibility for verification activities as determined appropriate by qualified individuals. The regulations should allow facilities to tailor their programs based on risk, evolve their programs in the years to come, and strive for continuous improvement in food safety without requiring future modification to the regulations to adapt to new developments.

There is some cross-over between these comments and our earlier comments submitted November 22, 2013 regarding the preventive controls proposed rule. Accordingly, we encourage the agency to consider both these comments and our comments on the preventive controls proposed rule in tandem.

Implementation

We want to emphasize the following essential points that should inform the Agency’s efforts for FSMA implementation:

- **The Final Rules Should Be Cost Neutral for Food Companies with Advanced Supplier Verification Programs**: FDA’s FSVP regulations should be essentially cost neutral for food companies that already have advanced supplier verification programs. The proposed alternate regulatory language we are suggesting will ensure the final rule is consistent with this goal – as well as consistent with both the letter and purpose of FSMA and the corresponding Preliminary Regulatory Impact Analysis (PRIA). If FDA were to adopt GMA’s proposed language, we believe the costs outlined in the PRIA would more accurately approximate the costs the food industry will incur to implement the final rule. However, if the Agency adopts the proposed rule as currently written, the costs would far exceed the estimates in the PRIA. As a result, we strongly encourage FDA to adopt GMA’s alternate FSVP regulatory language.

- **Effective Implementation Will Require Comprehensive Inspector Training**: FSMA can only be successful if it is enforced effectively, uniformly, and fairly by the Agency’s inspectorate on both the federal and state levels. FDA should start now—with stakeholder input—to develop and implement a comprehensive program to train investigators about a wide range of issues, including what the regulations require, how inspections should be conducted, and what types of observations are appropriate to include on FDA Form 483s. Investigator calibration also will be essential so that the law is enforced consistently from one region to another, and by both federal and state officials. FDA also should establish a mechanism for investigators to consult with experts from the Agency’s Center for Food Safety and Applied Nutrition (CFSAN) if they have questions about technical issues regarding a facility’s operations. We also strongly support development timely appeals mechanism so companies that disagree with an investigator’s conclusion can readily bring the issue to the attention of CFSAN experts. We believe it in everyone’s interest that the inspection process be transparent in both its planning and decision-making. Finally, FDA should establish a dedicated cadre of supplier verification inspectors that are specially trained in this area, who should inspect domestic and supplier verification programs concurrently on the corporate level.
• **Guidance Cannot Be Treated as Binding:** GMA strongly supports the use of guidance to assist importers with implementing the FSMA regulations, provided that guidance is appropriately treated as illustrative but non-binding. The Agency’s “good guidance practices” regulation, 21 CFR § 10.115, very clearly explains that guidance does “not legally bind the public or FDA” and companies “may choose to use an approach other than one set forth in a guidance document.” FDA’s inspectors need to understand this limit so that they do not seek to enforce guidance as imposing regulatory requirements, as has occurred at times in the past. Rather, inspectors should treat guidance as a “safe harbor” that represents an acceptable compliance approach but not the only compliant approach. The Agency should take particular precautions to educate its inspectors about this limitation.

* * *

We appreciate the opportunity to submit these comments and look forward to continuing to work with the Agency to ensure FSMA implementation is a success. Keeping food safe for consumers is our top priority.

Sincerely,

Leon Bruner, DVM, Ph.D.
Senior Vice President Science and Regulatory Affairs
GMA Feedback and Recommendations on Proposed Rule:
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals 21 CFR Part 1

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I. Introduction and Overview

GMA supports establishment of supplier verification requirements through the Foreign Supplier Verification Program (FSVP). This program is a key component of an effective public-private partnership to protect the safety of imported food under the FDA Food Safety Modernization Act (FSMA). GMA has supported this concept since the infancy of the legislation.

The U.S. Food and Drug Administration’s (FDA’s) approach to supplier verification should incorporate current leading practices in place today that result in successful food safety programs. As our comments will highlight, several aspects of the FSVP regulation need to be reconsidered based on input from supply chain management experts to ensure the new requirements are practical to implement and will function to improve food safety. The Agency’s regulation of supplier verification should not establish a new paradigm, but rather should codify current successful industry-developed practices. FDA should regulate supplier verification in a comprehensive and meaningful, but flexible, manner because there are different approaches to supplier verification that can all result in safer food.

We encourage the Agency to consider the following guiding principles for the regulation:

- The regulations should not require companies that currently have strong supplier verification programs to change their practices. Many of GMA’s members have invested considerable resources in developing and implementing robust supplier verification programs that have proven effective. The regulations should focus on establishing minimum requirements to raise the floor for importers that do not have these kinds of strong programs in place today, rather than requiring companies that already have effective programs in place to modify their practices in ways that will not materially improve food safety, or worse, increases the risk of food safety incidents.

- FDA’s supplier verification regulations should encourage appropriate behavior. Everyone in the supply chain is responsible for making safe food and the regulations should require and encourage verification activities that will materially improve public health outcomes. FDA’s regulations should incentivize companies to increase their knowledge about good food safety practices and work with their suppliers and customers to drive continuous improvement in food safety.

- Supplier verification should be based on a holistic assessment of risk (both ingredient and supplier risk). Supplier verification programs should identify and evaluate the risks presented by the food and the supplier based on multiple factors, including the historical track record of the supplier. FDA’s hazard-analysis based approach is too narrow by focusing only on the risks presented by the ingredient.

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1 These comments use the words “food” and “ingredient” interchangeably.
• **Supplier verification cannot control hazards, but rather should focus on confirming suppliers follow effective food safety programs.** Supplier verification is successfully applied today as a prerequisite program, verifying that suppliers are following effective food safety programs. We are concerned that FDA’s approach in the FSVP proposed rule misses the mark by taking too narrow of an approach. Even if an importer controls a hazard, the supplier often still needs to be verified.

• **Audits are an important verification tool but they only offer a snapshot of a supplier’s performance at a given time and do not control any hazards.** The role of audits should not be overemphasized and also should not be narrowly tied to a supplier’s application of specific controls. Effective audits are system-wide and risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency tailored to the risks presented by the supplier and ingredient.

• **Suppliers need to be assured of confidentiality of audits so as to promote food safety.** Confidentiality protections also are necessary for supplier audits to be effective and to encourage robust scrutiny and an open dialog without creating fears about consequences from FDA’s review of the resulting paper trail. FDA’s records access should focus on information that demonstrates that significant corrective actions were taken as needed to assure food safety.

• **Supplier verification should not be a check the box exercise.** A regulation that imposes regulatory requirements without encouraging thoughtful analysis and dialogue will miss an important opportunity to move food safety forward across the industry. Some aspects of the proposal, such as requiring mandatory annual audits and a detailed review of a supplier’s regulatory compliance, will result in a culture focused on compliance rather than prevention and continuous food safety improvements.

• **FDA inspections of supplier verification programs should focus on ensuring importers have and implement strong, risk-based supplier verification programs.** The goal of FDA’s inspections should be to ensure importers have well-functioning systems in place. Unless there is cause, FDA should not routinely question the importer’s determinations about individual suppliers, such as assessments of risk and decisions about what verification activities to apply and the frequency for those activities.

• **Supplier verification should be the same regardless of whether a supplier is located domestically or internationally.** We appreciate the position explained in the FSVP preamble that the agency intends to take a parallel approach to domestic supplier verification under the preventive controls regulation. This is important to facilitate compliance by industry and to meet World Trade Organization (WTO) obligations. FDA should tailor the regulations for FSVP and preventive controls to provide consistent requirements and eliminate redundancies. FDA should also avoid any unnecessary duplication between FSVP and preventive controls requirements so that if a supplier was

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2 Nevertheless, despite the agency’s indication that the regulations will be parallel, we strongly encourage the agency to issue a proposed rule on the role of supplier verification as a preventive control.
verified under an FSVP, including by a qualified third-party, the importer should not be required to engage in redundant verification under preventive controls.\textsuperscript{3}

Our comments emphasize that FDA’s supplier verification regulations should be built on successful practices in place today. Rather than the Agency’s proposed hazard-based approach, which looks only at ingredient hazards, a responsible manufacturer will also consider supplier risk and therefore may find it necessary to engage in appropriate due diligence for nearly all of their suppliers. In addition, proposed activities like continuous FDA compliance status review, that indirectly consider supplier risk, will not add value for food safety. We also think the regulations should be simpler, incorporating more flexibility for verification activities as determined appropriate by qualified individuals. The regulations should allow facilities to tailor their programs based on risk, evolve their programs in the years to come, and strive for continuous improvement in food safety without requiring future modification to the regulations to adapt to new developments.

There is some cross-over between these comments and our earlier comments submitted November 22, 2013 regarding the preventive controls proposed rule. Accordingly, we encourage the agency to consider both these comments and our comments on the preventive controls proposed rule in tandem. Where appropriate, these comments highlight some of the same issues we discussed in our comments on that proposal. As an Appendix to these comments, we are providing suggested revisions for the codified language of the FSVP. Our recommended codified language does not address all of our recommendations, but rather illustrates some of our main points and how they can be incorporated into the Agency’s regulations.

\section*{II. Core FSVP Requirements}

\subsection*{A. Compliance Status Review – § 1.504}

We appreciate FDA’s acknowledgement of the importance of considering supplier risk. Our members have found that supplier risk often is just as important as ingredient risk when assessing food safety for incoming ingredients. Many of our members’ current supplier verification programs seek information about a supplier’s regulatory compliance and require suppliers to advise them of any regulatory actions. In addition, many of our members consider regulatory non-compliance to be a triggering event that requires reassessment of the supplier’s suitability. However, as codified through the compliance status review, FDA’s proposed approach to supplier risk is too narrow and prescriptive. Given the current limitations on the availability of FDA’s regulatory information, the compliance status review, by itself, is given too much prominence compared to other supplier risk factors and would not provide meaningful value to justify the time required to comply with the proposed regulation.

In our experience, consideration of supplier risk involves assessment of both negative (e.g., regulatory action) and positive (e.g., long history of strong performance) information about a supplier. Instead of prescribing specifically that importers must review regulatory information

\textsuperscript{3} The preventive controls regulation should require verification of all suppliers, unless the supplier has been verified under the FSVP regulations or is exempt from the FSVP and preventive controls regulations (e.g., a food imported under the proposed multinational exemption).
like Warning Letters and Import Alerts, we support a regulation with more flexibility about how an importer may choose to consider supplier risk. Each importer should determine on their own what information is relevant to review about a supplier’s risk, which may reasonably include assessing their supplier’s compliance status.

As written, the proposed rule takes a check the box approach to assessing a supplier’s compliance status that may not promote thoughtful analysis of the supplier by qualified individuals to facilitate risk assessment. Instead of separating out this review under proposed section 1.504, we suggest incorporating consideration of the risk presented by a supplier based on their regulatory compliance into a new requirement to conduct an assessment of supplier risk under section 1.505. Specifically, when conducting an evaluation of supplier risk, importers may choose to consider the effect of their supplier’s compliance history, including their U.S. regulatory compliance status. This approach would be consistent with the approach that successful supplier verification programs follow today, where a supplier’s compliance history may be one of several factors evaluated when assessing supplier risk.

Incorporating the compliance status review into the supplier risk evaluation also will help avoid placing undue focus on a supplier’s documented regulatory compliance status. The absence of a Warning Letter or Import Alert, particularly given the small number of foreign facilities and imports inspected, does not necessarily indicate strong performance or that the supplier makes safe food (e.g., the facility just might not have not been caught). Similarly, the presence of a Warning Letter or Import Alert does not necessarily indicate weak performance or that the supplier makes unsafe food (e.g., the issue cited may have been corrected months before the Warning Letter is made public). Singling out the compliance status review as a stand-alone requirement implies that this information is determinative of the supplier’s risk profile. Our members know from experience that this is not the case.

Warning Letters and Import Alerts may function as a red flag that requires further inquiry. However, FDA needs to appreciate that (1) it is challenging and time consuming to find this information in current FDA databases, and (2) it is not possible for importers to determine the extent and current state of the alleged regulatory non-compliance from these documents. To understand the significance of a given Warning Letter or Import Alert, it is necessary to read between the lines and dig deeper to understand what precipitated the regulatory action, the extent of the original non-compliance, and the status of corrective actions. It can be challenging to understand the meaning of this information. For example:

- Warning Letters often are redacted to remove specific information, so the letters do not necessarily explain what products or lines are involved or the specific non-compliance identified (e.g., the Warning Letter may simply state that the facility is not in compliance with GMPs).

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4 We strongly recommend that any reference to regulatory compliance status in the final rule be limited to U.S. regulatory compliance. It is too burdensome and logistically challenging to ascertain and assess a supplier’s compliance status in other jurisdictions. This would present difficulties in terms of translation, navigating foreign websites to find information, and using consultants to interpret the meaning of regulatory actions. In addition, compliance with non-U.S. requirements is irrelevant for assessing compliance with FSMA. We note that FDA’s PRIA implied that the review would be limited to only domestic compliance.
• Companies may be subject to Import Alerts for gray market goods that they did not try to import themselves. Simply because there is an Import Alert for the company’s products, does not mean that they did anything wrong.

• Neither Warning Letters nor Import Alerts are updated in real time. The information often is posted after-the-fact (sometimes many months after it was created), so further investigation and inquiry with the supplier is needed to understand whether the issue that precipitated the regulatory action is ongoing.

Our proposed approach would allow importers to evaluate the risk impact of both positive and negative information about a supplier, in contrast to FDA’s approach that is limited to only negative and often outdated regulatory information. Positive information to consider about a supplier can include more than just the U.S. regulatory compliance status of the foreign supplier, but also may include:

• The foreign supplier’s performance history (including audit performance) and length of relationship with the importer;
• The level of regulatory oversight of the foreign supplier in their country of origin;
• The depth of the importer’s knowledge about the foreign supplier’s food safety programs and culture;
• Recent management changes for the foreign supplier; and
• Whether supplier operates as a contract manufacturer for the importer.  

Thus, both positive and negative information can be helpful as part an evaluation of supplier risk. We encourage FDA to incorporate these elements into the regulation as a parallel requirement for the mandate to evaluate ingredient risk through a hazard analysis, so that supplier risk also must be considered.

As noted above, there are logistical challenges involved with reviewing Warning Letters and Import Alerts. Importers would need to affirmatively search FDA’s website or subscribe to a third-party notification service to find this information. FDA’s website also does not contain all Warning Letters, as some older Warning Letters are only available in private databases that require paid subscriptions. Currently, there are no electronic systems in place to provide immediate notification if a Warning Letter or Import Alert is posted affecting a specific food or

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5 Many of our members require their finished product suppliers (contract manufacturers) to meet the same food safety requirements as their own plants.

6 FDA’s PRIA acknowledged that it is unclear how long it would take to ascertain this information, stating “We do not know how much time an importer would need to conduct the required compliance status review for a given foreign supplier or imported food. To derive our estimates, we assume that an importer will need, on average, approximately 2 hours to conduct a review of a foreign supplier or imported food. We request comment on this estimate.” We believe this value underestimates the time needed to conduct ongoing searches of Warning Letters and Import Alerts for a foreign supplier.

We also note that the PRIA greatly underestimated the total number of compliance status reviews that will need to be conducted by importers. The PRIA estimates that for all companies with over 500 employees, only 8,962 compliance status reviews will be needed (meaning that this is the total number of foreign suppliers these companies have). This would be an average of only about 18 foreign suppliers per importer. Many of our members with over 500 employees each have over 1,500 foreign suppliers, making this number a massive underestimation of the number of foreign suppliers for all companies with over 500 employees.
company. Rather, it would be necessary to search supplier-by-supplier on a regular basis to find new information. The Import Alert system is even more challenging to navigate, as it is not updated consistently and is quite difficult to search. Without an ability to search for obvious identifiers, an importer cannot be sure that it has satisfied its obligations to review the compliance status of its foreign supplier without an unnecessarily exhaustive review of all available materials. Thus, this information is not readily available as stated in the preamble and the Preliminary Regulatory Impact Analysis (PRIA). Using the current systems on FDA’s website, we expect it will take a company more than the estimated two hours per year to regularly search and determine whether any new information has been posted involving their suppliers. Since many of our member companies have in excess of 1,500 suppliers, the estimate of two hours per year is a gross underestimate of the time that would be needed by many companies for a very limited benefit. Indeed, two hours per supplier may even be an underestimate considering the ongoing nature of the requirement.

If FDA determines that it will require a review of Warning Letters or Import Alerts, for the reasons noted above, FDA first will need to develop a more efficient system alerting importers to new information posted on its website and implementing upgrades for its online electronic database systems. GMA welcomes the opportunity to work with FDA as it considers possible information technology solutions, as well as opportunities to make this type of regulatory information more relevant for importers considering supplier risks. We also encourage the Agency to invest resources in updating its online database systems regardless of whether this requirement is included in the final rule.

We also are concerned by the use of the word “including” in the proposed rule (“you must review the compliance status of the food and the foreign supplier, including whether they are the subject of an FDA warning letter”), suggesting that the review must encompass more than Warning Letters, Import Alerts, and requirements for Mandatory Import Certifications (MICs). The preamble explains that other information relevant to the compliance status of a food or foreign supplier could include FDA Form 483s, Establishment Inspection Report (EIR), recall notices, and documents relating to injunctions or seizures. As with Warning Letters, such information is difficult to find and may have limited utility to provide relevant insights about a supplier or food.

For example, an observation on a Form 483 may not include enough information for the importer to understand whether the specific ingredient/product the supplier produces for the importer is affected and whether the observation was an isolated occurrence appropriately corrected or an ongoing concern. Similarly, EIRs are posted long after the inspection occurs, after the inspection is closed and any alleged regulatory noncompliance has been corrected, and they are (appropriately) heavily redacted to protect confidential business information. Review of this additional information may sometimes be helpful, as is the case for Warning Letters and Import Alerts, but should not be required. At most, this information should trigger the importer to question whether or how the information affects the ingredient/product the supplier makes for them, but it may not necessarily necessitate any responsive actions.

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7 Yet, currently, there is no option to search either the Import Alerts website or the Warning Letters website by FDA registration number, FDA product code, or facility name.
8 We note that consideration of such additional information is not addressed in the PRIA.
Instead of prescribing that importers must review certain sources of information to assess their supplier’s compliance status, we suggest that specific recommendations about sources of information to review if the importer determines this information is material for assessing supplier risk can be provided through guidance. This approach allows importers the flexibility to review the information sources that are most relevant for their programs when they determine that such information is relevant for their supplier risk assessment.

The proposed rule states that companies “must continue” to monitor and document the compliance status as long as they import the food from the foreign supplier. This suggests that the monitoring requirement is continuous, which is not realistic and will not promote food safety. In contrast, the PRIA assumes that facilities will reassess their suppliers’ compliance status only once per year. If this is the expectation, the regulation should be clearer in this respect. From our experience, continuous monitoring is not necessary because the compliance status review is only one aspect of an FSVP. Information provided by Warning Letters can be unreliable and untimely. Therefore continuous review will not materially help improve food safety. Rather than requiring continuous review, importers should be required to reassess their supplier’s compliance status under proposed section 1.508(a)(2) as part of a supplier FSVP reassessment when they become aware of new information about potential hazards associated with the food or supplier.

In summary, we support evaluation of supplier noncompliance as an element of an analysis of supplier risk, but do not support a stand-alone requirement that suppliers must review Warning Letters and/or Import Alerts. This review is time consuming and does not provide information that cannot be more easily obtained directly from the supplier. With a more updated information technology system, however, Warning Letters and Import Alerts could be a valuable input for some importers to consider in their assessment of supplier risk.

B. Hazard Analysis – § 1.505

Under section 1.505 of the proposed rule, the supplier verification would flow from a hazard analysis regarding the hazards “reasonably likely to occur” with the food. This is too narrow of an assessment because it suggests that the risks presented by the food are the only concerns when evaluating risk under a supplier verification program. We also are concerned that this incorporates a food safety plan concept into supplier verification and further confuses things by using HACCP language.

GMA feels strongly that a successful food safety program requires supplier verification for almost all suppliers, not just for suppliers that present hazards that are “reasonably likely to

\[9\] Furthermore, to the extent the Agency will require importers to document the compliance status review, we do not believe it would be a worthwhile exercise to require documentation of negative findings. Rather, the Agency should only require documentation in the event an importer identifies information that informs their risk assessment. We also do not believe it would be appropriate for the Agency to require the importer to keep copies of each of the supplier’s records that were evaluated, particularly where the records are available on FDA’s website. This requirement would simply be a paperwork exercise.

\[10\] “The proposed rule does not specify how frequently this must be done, but we assume that the monitoring will take the form of an annual review comparable in scope to the original review.” Preliminary Regulatory Impact Analysis (PRIA) at 18.
occur” (RLTO) based on an assessment of the ingredient risks.\textsuperscript{11} As discussed in our Food Safety Plan comments, the term RLTO has typically been used as a HACCP filter for determining critical control points (CCPs).\textsuperscript{12} Just as this term does not fit with a Food Safety Plan hazard analysis, it makes little sense here for a prerequisite program like supplier verification. The phrase RLTO focuses more on ingredient specific hazards, whereas a robust supplier verification program focuses on both the ingredient risk and a supplier’s overall food safety system. In the preventive controls preamble Appendix, FDA notes several high profile supplier-related recalls that are a result of failures in prerequisite programs, not CCPs. A supplier verification framework that only requires verification of hazards that are RLTO misses out on an important opportunity to improve the safety of the supply chain through a focus on the importance of prerequisite programs.

Our members view FDA’s FSVP proposed rule to be too narrow by limiting supplier verification requirements to only suppliers that present risks that meet a certain threshold (i.e., those risks that would be RLTO absent any supplier controls). We agree that supplier verification needs to be risk-based, with verification activities tailored for each supplier, but believe FDA’s approach will inadvertently create gaps in the food safety system by focusing only on ingredient hazards that will not be controlled by the importer. Risks also can be presented by the supplier itself (e.g., GMP failures) or by aspects of an ingredient that will not be addressed by a kill step (e.g., foreign material, undeclared allergens). Even if all hazards presented by an ingredient will be controlled at the importer’s facility, our members generally would engage in some level of supplier verification to ensure the supplier has an appropriate food safety program and does not introduce any unanticipated hazards.\textsuperscript{13} Notably, FSMA provides that FSVPs apply for all imported food—without limiting this to only suppliers that present certain hazards. It is unclear how the proposed approach is consistent with the statute. We also disagree that FDA’s hazard-based approach is truly risk-based.

The determination of what verification steps apply for a supplier should not be based on an ingredient hazard analysis, but rather should be based on the risk presented by the ingredient and the supplier. There is no way to effectively manage food safety using a one-size-fits-all RLTO standard and only the ingredient hazard analysis framework. The framework in the proposed rule mirrors the type of assessment conducted to identify the severity and probability of hazards for purposes of a hazard analysis in a food safety plan. This is very different from the holistic risk assessment needed to determine supplier risk for purposes of assigning appropriate supplier verification activities. None of our members, who have vast experience with supplier verification, simply conducts a hazard analysis in the way proposed by FDA without also considering supplier risk.\textsuperscript{14}

GMA agrees with the Agency’s intent not to require importers to consider intentional hazards, including economically-motivated hazards. Economically motivated adulteration

\textsuperscript{11} See our comments in Section IV below regarding recommended exemptions from the FSVP requirements.

\textsuperscript{12} We also note that the term RLTO does not appear in the statute for either preventive controls or FSVP.

\textsuperscript{13} Unanticipated hazards could include allergen cross-contact or chemical hazards that are not known or reasonably foreseeable. Even if hazards are controlled by the importer, supplier verification also is important to ensure appropriate implementation of programs like GMPs.

\textsuperscript{14} FDA’s economic analysis should account for the fact that no importers are currently in compliance with the regulation as proposed, though many importers have existing and robust supplier verification programs.
requires different kinds of preventive measures than those traditionally employed as part of supplier verification programs. We are providing separate comments on the food defense proposed rule at a later date.

C. Qualified Individual – § 1.503

We believe it is important that a qualified individual prepares and oversees the FSVP. We agree with the proposed definition of “qualified individual,” although we suggest using a different term so as to prevent confusion with the qualified individual who develops the food safety plan (who may have different credentials). We believe any more specific requirements about the qualifications for this individual are more appropriate to include in guidance, rather than the regulation itself.

We also note that a broad scope of activities is required for supplier verification. Audits need to be conducted by an appropriately qualified individual, but this person needs specific auditing experience and training. These are different skills than are needed to develop and implement the FSVP on a day-to-day basis.

We believe that the requirements for FSVPs to be developed and implemented by qualified individuals are essential for successful supplier verification programs. All of our members invest in food safety training and hire experts to manage these supplier programs, assessing risks, developing programs, and improving capabilities. We believe additional guidance and training from FDA will be essential in this area, so that importers with less experience in supplier verification can understand that investment is needed to improve their operations. We encourage FDA to develop a supplier verification-specific component of the Food Safety Preventive Controls Alliance (FSPCA) curriculum, to focus on training in this area. We also would support development of a supplier verification-specific alliance to increase capacity building and provide a means for qualified individual credentials to be benchmarked. This would be a strong complement to the alliance programs already underway, addressing preventive controls, produce safety, and sprout safety.

D. Verification Activities

1. Identifying the “Foreign Supplier” to be Verified – § 1.500

In order to apply verification activities, you first need to determine the entity that requires verification. FDA proposes defining the term “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.” We are concerned by this requirement to verify further than one-step back in the chain.

Sometimes our members are not able to ascertain the specific entity or farm that manufactured, processed, or harvested a given food. For example, our members often purchase ingredients from brokers, distributors, or traders rather than directly from the ingredient
manufacturer/harvester.\textsuperscript{15} As noted in our preventive controls comments, we believe that a person buying from a co-op, broker, distributor, trader, or analogous entities, where this entity is unwilling or unable to disclose the identity of the ingredient manufacturer/harvester, should not be required to engage in supplier verification other than to verify and document that the entity from whom the food was purchased has implemented a risk-based supplier verification program in compliance with the final FSVP regulations. Because of the lack of transparency in the supply chain today, there is a significant hurdle to completing supplier verification in the manner envisioned in the proposed rule.\textsuperscript{16}

We also are concerned that this requirement is contrary to the traceability provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) and FSMA. Under the FFDCA (as amended by the Bioterrorism Act and FSMA) and FDA’s implementing regulations, a facility is only required to be able to trace food “one-step back.”\textsuperscript{17} Requiring importers to engage in supplier verification further back to the source of the food would be contrary to the Bioterrorism Act and the traceability provisions in FSMA. Notably, FSMA specifically restricts FDA from requiring facilities to maintain records of the full pedigree of a food—even for high-risk foods—and also limits traceback requirements for commingled raw agricultural commodities to the immediate previous source of the food.\textsuperscript{18} Going further than “one-step back” simply is not feasible oftentimes and establishing different traceback standards for supplier verification would lead to confusion and inconsistency.

The FSVP regulation should only require importers to go one-step back in order to be consistent with the Bioterrorism Act recordkeeping requirements. Part of supplier verification should include ensuring that the direct supplier (e.g., broker, trader, distributor) has its own system in place to verify its suppliers—so that every step in the chain considers and implements supplier verification.

2. Party Controlling Hazards – § 1.506(e), (f)

Under the proposed rule, verification activities are only required for hazards controlled by the importer’s foreign supplier. If the hazards are controlled by the importer or its customer, no verification activities are needed. This is an outgrowth of the Agency’s hazard analysis based approach to supplier verification, where the verification activities flow from a preventive controls-like hazard analysis under proposed § 1.505. As discussed above in section II.B., we

\textsuperscript{15} Brokers help importers procure ingredients but typically do not take possession of actual raw materials or ingredients. Rather, brokers provide a service by managing import requirements and connecting importers with suppliers. Traders often play a similar role. Another similar entity is a distributor, which may provide for warehousing of raw materials or ingredients as a conduit between suppliers and manufacturers/importers.

Another example of this challenge is with certain commingled raw agricultural commodities, like spices and coffee. For example, many hundreds of small farmers may grow a certain crop and then deliver it to a co-op where the food is commingled and shipped to the importer. Sometimes the importer is unable to determine the specific identity of each individual farmer to engage in supplier verification (e.g., to audit their program for appropriate application of pesticides) or the number of individual suppliers is resource-prohibitive to verify directly.

\textsuperscript{16} We are incorporating by reference our discussion of this issue in our comments regarding the supplier verification aspects of the preventive controls proposed rule, as the same concern applies equally for food sourced domestically and internationally.

\textsuperscript{17} FFDCA § 414; 21 C.F.R. Part 1, Subpart J (§ 1.326 et seq.).

\textsuperscript{18} FSMA § 204(d)(1)(L).
disagree with this approach because it is too narrow. Nearly all suppliers need to be subject to verification activities.

We agree that if the importer or its customer is controlling the hazard this may affect the importer’s determination of the appropriate rigor and type of verification activities to apply, but this should not mean that the foreign supplier does not require any verification. This narrow approach fails to consider important issues like the supplier’s basic compliance with GMPs and the need for adequate programs to avoid introducing any unforeseen hazards. For example, if a supplier does not have the right programs in place for foreign material control, the food may end up containing an unanticipated hazard like glass.

Another challenge with this aspect of the proposed rule is that the intended use of the product may not be known at the time of entry, or different parts of the batch may be destined for different customers with different processes. For example, an importer bringing in a shipment of vegetables may sell part of the batch to a soup maker, who will thermally process the vegetables applying a kill step for the microbiological hazards, and another part of the batch to a company that will individually quick freeze (IQF) the vegetables for a frozen vegetable medley. Is this supplier supposed to verify part of the lot but not the other part? Or what if the vegetables are imported with the intent of solely being sent for soup, so no verification is needed, and then after entry the soup manufacturer cancels their order and the vegetables are sold to the IQF company? In other cases, the importer may not know who the customer will be or what their intended uses are at the time of entry. Or their customer’s use may change. This obligation to confirm the intended use by a customer downstream is unique, as supplier verification traditionally looks back in the chain at the previous user rather than forward at the next party. No other parts of FDA’s regulations impose such forward-use focused burdens. These examples show that the approach FDA proposed is unnecessarily complicated. We think that nearly every supplier should be subject to some level of verification regardless of the intended use – if for no other reason than to ensure the ingredient is produced in compliance with the produce safety/preventive controls rules and/or GMPs/good agricultural practices.

3. **Hazard-Based Supplier Verification – § 1.506(c)-(g)**

FSMA requires importers to verify that the imported food is (1) not adulterated, (2) is not misbranded due to undeclared allergens, and (3) is produced in compliance with the preventive controls and produce safety regulations, as applicable. In contrast, the proposed rule requires that verification activities “provide adequate assurances that the hazard is adequately controlled.” This is a totally different focus, which is inconsistent with the statute and does not focus on the key issues affect safety of imported foods.

By requiring verification that the hazard is controlled when it is managed by a supplier, the proposal contemplates that different supplier verification activities will be needed for different hazards. For example, under Option 1 an annual on-site audit would be required to verify a supplier’s application of a pasteurization processing step (CCP) for milk, but another verification activity like testing may be needed to verify control of antibiotic drug residues. This hazard-based approach to verification activities does not reflect the more complete analysis.
conducted under leading supplier verification programs today that also places a strong emphasis on general performance like GMP compliance.

We agree that it is appropriate to apply different supplier verification activities based on risk. However, the proposed approach is too linear and not holistic. Although verification activities may be tied to individual ingredient hazards that are not controlled by the importer or its customer, supplier verification activities should consider the supplier’s program as a whole in order to assess not only the inherent ingredient hazard but also supplier risk. The Agency’s proposed approach treats supplier verification as if it functions solely to ensure that the supplier has a process in place to control discrete ingredient hazards and does not adequately consider supplier risk.

Supplier verification should be considered a prerequisite program. As noted in our comments to the proposed preventive controls regulations, a number of very important food safety management programs are not CCPs and do not function like CCPs. Tying supplier verification activities solely to ingredient hazards implies that the verification controls the ingredient hazard, which it does not, and also suggests that there are no other material food safety risks that may be introduced by the supplier (e.g., unanticipated problems that could arise from issues like failure to comply with GMPs).

This aspect of the proposal creates the potential for tremendous redundancy and is not necessary for food safety. Requiring verification of each individual hazard may mean that importers will be engaging in specialized audits, based on the nature of the hazards and the intended use of the ingredient, rather than auditing the supplier’s whole food safety program. This is not the best approach. For example, an audit focused on only the line producing food for an importer could miss important GMP violations in other parts of the facility, such as standing water on the floor or drips/condensation. These conditions are relevant for the importer’s assessment of the supplier because they are indicative of the general condition in the facility and the supplier’s food safety culture.

Requiring hazard-based audits could mean that each importer will have to conduct its own tailored audit of its suppliers (through a second- or third-party audit), depending on the hazards identified, or will have to assess whether reports of previously conducted audits adequately address the hazards they are required to verify. Duplication of audits is an inevitable outgrowth of this proposal. There also will be considerable burdens for suppliers who will be subject to separate audits from many different customers. FDA will fail to achieve the economies of scale it anticipates will occur from shared audits, resulting in significantly increased costs. Instead, audits should assess the supplier’s relevant food safety program as a whole.

Additionally, a hazard-based verification requirement would require an immense amount of documentation, none of which is necessary to have an effective supplier verification program. We interpret the proposed rule as requiring each importer to have a file for every ingredient from every supplier itemizing the hazards and corresponding verification activities. That is a tremendous burden that certainly goes beyond what FDA contemplated in the regulatory
analyses supporting the proposal. Instead, each importer should simply be required to verify each supplier as appropriate based on the risk presented by the supplier and food.

4. Role of Supplier Audits – § 1.506(g)

We agree that supplier audits are an important verification activity, but believe FDA’s approach in the FSVP proposed rule places too much focus on audits at the expense of a fuller picture of supplier verification activities. We support a requirement to engage in audits when appropriate and necessary, but not all suppliers need to be audited before use depending on the type of hazard they may control. It is important to recognize that supplier audits are not the only tool available to verify suppliers. Other verification activities also serve an important function for supplier verification. The need for an audit depends on whether it is a good allocation of resources. Resources are best expended on conducting in-depth verification of the highest risk suppliers—which (as discussed in the next section below) does not necessarily align with FDA’s definition of risk under Option 1.

Over-reliance on audits can provide a false sense of security about a supplier’s performance. Audits are only a tool used to gain more information about a supplier. We agree with FDA’s recognition that additional verification activities besides an audit (e.g., supplier certificate of analysis (COA); periodic testing by an importer), may be necessary depending on the risk presented by an ingredient and the supplier. Conversely, routine audits may not be needed at all for some suppliers, depending on risk. For example, if a supplier is providing a low-risk ingredient and the company has a long history of successfully providing that ingredient without any food safety concerns, the importer may not audit the supplier or may only conduct an audit intermittently (but not routinely). The same may be true for a “high risk” ingredient where the supplier controls a hazard, such that it may be appropriate to audit a supplier less often than annually.

Audits, like all other supplier verification activities, do not control hazards or change the inherent risk of an ingredient. Rather, they capture the performance of a supplier’s system at a specific point in time. An audit is a snapshot in time that provides insight on a supplier’s program at the time the audit was conducted. This is why supplier verification is just one aspect of a broader food safety program—because a prerequisite program alone cannot make food safe.

Problems can still occur with a supplier that passes an audit—and this does not necessarily mean that their customer’s supplier verification program was inadequate. Consider the numerous recent high-profile situations where companies with passing audit scores still were involved in outbreaks and recalls. For this reason, GMA’s members are careful not to over-rely on audits and to structure their supplier verification programs in a manner that recognizes the inherent limitations of audits. This also is why our members sometimes choose to do their own second-party audits, rather than solely relying on third-party audits. Accordingly, sometimes an audit alone will be determined to be a sufficient verification activity, while in other

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19 See, PRIA at 34 (explaining that it would be “prohibitively difficult” to document verification procedures an importer would follow for every possible hazard in every food they might import).
20 For example, the Peanut Corporation of America received a “superior” rating in several third-party audits. More recently, Sunland, Inc. received high ratings from an audit under a GFSI-benchmarked accredited certification and Jensen Farms received a “superior” rating from Primus Labs.
situations an audit may need to be coupled with additional verification activities that provide assurance a supplier has the appropriate controls and food safety program in place.

Consider the following examples that illustrate how our members tailor their programs based on risk, and why they need the flexibility to tailor their programs accordingly:

- If an importer is controlling a *Salmonella* hazard, it would not focus its supplier verification efforts based on whether the supplier is controlling that hazard although it may assess the supplier’s GMPs to ensure they are not increasing the risk presented by the pathogen. It also may be responsible for the importer to engage in verification of non-microbiological hazards that the supplier’s activities can mitigate, such as foreign material control. Indeed, a number of costly product recalls have been due to physical hazards that are not adequately controlled by the supplier. The specific program applied to the individual supplier will depend on the supplier and ingredient’s risk.

- An importer may conduct a third-party audit and also require a COA regarding a certain hazard that is inherent to an ingredient and controlled by the supplier (e.g., *Salmonella*). The importer also may have other controls in place to address the hazard, such as hygienic zoning, enhanced GMPs, and a lethality step because the importer knows that supplier verification itself is never able to adequately control the hazard.

- Additional verification activities beyond a third-party audit may not be required for a supplier with a long history of safely supplying a moderate risk ingredient, even if the supplier is responsible for controlling some hazards, or for a supplier of an ingredient that has a low inherent risk.

- Even if a supplier has a long history of safely supplying an ingredient, additional steps beyond a third-party audit may be necessary if the ingredient has a high inherent risk or may be subject to other uncertainties (e.g., crop year variation).

- Additional verification steps beyond an audit may be required for a new supplier of an ingredient, even an ingredient with low inherent risk, until an acceptable performance history can be established.

As with all verification activities, determining the appropriate approach to follow requires a case-by-case evaluation of the risk-factors specific to the supplier. Professionals with experience in supplier verification are best situated to make these assessments. This is another areas where ensuring every importer’s program is developed by a qualified individual will make a significant impact for food safety.

Additionally, our experience has taught us that the most effective audits focus on a supplier’s overall food safety system, especially as you evaluate a supplier’s food safety culture, knowledge, and their management’s commitment to continuously improving their program. This differs from the proposed rule, where audits would focus only on a supplier’s control of specific hazards. (That is, under the proposal, audits would need to be tailored to assessing certain hazards—rather than considering the supplier’s overall program.) This approach could overlook
significant aspects of a supplier’s program that could have an important impact on food safety. For example, audits typically assess compliance with prerequisite programs like GMPs and sanitation, which are foundational to enable a company to make safe food. If an audit only considers whether the supplier appropriately applies its CCPs, it may overlook basic deficiencies for essential foundational programs.

5. **Option 1 Versus Option 2 – § 1.506(g)**

FDA has co-proposed two alternative approaches to verification activities for hazards controlled by a foreign supplier. Under Option 1, suppliers must 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 (“SAHCODHA” or “Class I recall” hazards). For other hazards, an audit or other verification activity (e.g., testing, records review) is required. Option 2 is less prescriptive, permitting *but not requiring* an importer to take the approach under Option 1. Option 2 requires importers to conduct whatever verification activities are appropriate to verify that the hazard is adequately controlled from a “menu” of verification activity options that includes on-site audits.

GMA strongly supports Option 2. We agree that the frequency of supplier verification activities should be risk-based, but importers need flexibility to determine what verification activities are appropriate based on their own assessment of risk – both food and supplier risk. These two factors counterbalance each other, so that a high supplier risk but low ingredient risk will require more stringent verification and, conversely, a high ingredient risk but low supplier risk would require less stringent verification. Making the determination of the appropriate verification activities to apply is the role of qualified individuals, who have intimate knowledge of their ingredients and product applications. Importers need flexibility to tailor their verification activities based on risk, and this flexibility is lost in Option 1.

Option 1 usurps the role of independent judgment by prescribing risk in the regulation, eliminating the need for independent thinking about the appropriate verification activities for suppliers. We are concerned that this will lead to a check the box approach to supplier verification, where importers will simply view their suppliers as passing the test if they’ve been audited rather than critically analyzing the results of the audit and considering whether additional verification activities are needed. This approach is not good for food safety. We also are concerned that less experienced importers may simply expect that because their suppliers do not control a Class I hazard, less verification is needed—and this is not necessarily the case. Because Option 2 is inherently more open ended, it forces importers to actually think about verification activities (or seek out qualified individuals that can assist with this exercise) instead of just putting an audit report in their files. This type of critical thinking should be encouraged by the regulation to improve the safety of our food supply.

The risk assessment codified in Option 1 focuses only on those suppliers that control Class I hazards. We agree these are significant hazards, but this approach is too simplistic. Our members consider more factors when they assess risk than just whether a supplier or an ingredient presents a Class I hazard. For example:
- If a supplier uses a new process, line, or equipment that an importer is not familiar with, the importer may decide it is responsible to conduct an audit to gain additional insight into the process, sanitation, and functionality of this equipment. The supplier may be audited periodically until the importer gains comfort with the safety of this system.

- If a supplier had to recall food it produced due to a Class II foreign material hazard, this issue will remain on the importer’s radar as a key process to watch carefully for many years to come. The importer may choose to audit this supplier to ensure the problem is not repeated and the foreign material program is under control.

In both of these situations, Option 1 would not require an audit but conducting an audit is the responsible thing to do. By being too prescriptive and establishing a bright line about the need for audits, many less experienced importers likely would think nothing more was needed in these situations.

There are a wide range of possible outcomes that can result when balancing ingredient and supplier risk, which are not readily quantifiable in a regulation. For example, there are situations where a supplier should be subject to stringent verification activities even though they do not control a hazard that presents a Class I recall risk. Conversely, there are situations where a supplier needs less verification even though they do control a hazard that presents a Class I recall risk. We are concerned that importers will not engage in this analysis if the regulation is written as a bright line.

Additionally, Option 1 will be overkill resulting in audits that are not necessary for food safety and that are not a good allocation of resources. For example:

- A vast majority of suppliers control allergen hazards to some extent, unless their facilities are allergen-free or only handle a single ingredient. Because allergen cross-contamination and misbranding typically results in Class I recalls, this would mean that the vast majority of suppliers would be subject to on-site audits under Option 1 regardless of the actual risk presented by the supplier, the risk presented by the food, or the rigor of the supplier’s allergen management program. This may bring the majority of suppliers under the requirement to be audited annually.

- An importer may bring in an allergen-containing cookie from a supplier that only makes this one product. The allergen is appropriately declared through labeling. Even though a Class I recall would be needed if there was a problem with management of this allergen, the risk is obviously being managed through the proper labeling. There is no need to conduct an audit for the allergen hazard.

- An importer may purchase an ingredient from a supplier that they have done business with for many years, without any problems, that has a strong and valid reputation for food safety compliance. If the supplier controls a Class I hazard, it should be permissible to audit this supplier at a less than annual frequency depending on their risk. For example, if annual audits for the last 10 years have always been pristine and
all other factors remain constant (e.g., no management change, no regulatory actions), there should not be a prohibition against decreasing the auditing frequency to every 18 months or 2 years as appropriate based on risk.

- The volume of a product purchased from a given supplier can have an impact on the frequency of audits for a given supplier. There are many circumstances where a company (even large companies) may purchase a very small amount of product from a given supplier (e.g., due to the nature of the ingredient, due to infrequent production of a product the ingredient is used in). In these instances, an annual audit may not be a good use of resources. For example, the audit may cost more than the value of the ingredient sourced annually. An audit may still be an appropriate verification activity, but a frequency of less than annually could be appropriate.

These examples explain why Option 2, with flexibility, is more appropriate. It is unnecessarily prescriptive to codify the risk analysis as in Option 1. Specific direction of the factors that trigger more rigorous verification activities are better left for guidance issued by FDA and developed with the input of industry. Option 2 incentivizes suppliers to have robust food safety programs so that they receive the benefit of reduced customer oversight. It also provides an incentive for importers to build their knowledge, work with their suppliers, and improve their food safety programs, so that over time less robust supplier verification is required and the food they produce is safer for consumers.

Option 1 also presents practical implementation difficulties to apply because the definition of SAHCODHA is not always known—particularly to importers who may not be food producers. While there is general agreement that pathogen presence and undeclared allergens are SAHCODHA hazards, even these dividing lines are not necessarily bright. Our research identified both Class I and Class II recalls involving potential \textit{E. coli} contamination, for example. The same is true for recalls with undeclared wheat and soy allergens. We question whether the SAHCODHA standard is really workable in day-to-day application. Determining whether a hazard would trigger a Class I or Class II recall could deflect attention from the more important parts of supplier verification, such as thoughtfully considering a supplier’s risk and carefully analyzing audit reports.

Another challenge presented by Option 1 is the requirement to audit all suppliers before use. This simply may not be necessary for all suppliers. Such a requirement presents a significant potential for supply chain disruptions. There are emergency situations where it is necessary to purchase goods from a supplier that has not yet been audited, for example when there are serious food safety concerns with an approved supplier and a new source needs to be found as soon as possible. Under the proposed rule, if an importer is not able to verify the supplier within the time required for production, there may be significant production disruptions or the importer may have to pay a premium to source an ingredient that has already been verified by another entity in the United States. Either way, these are important concerns that the Agency should take into account for its economic analysis. We encourage FDA to modify the FSVP

\textsuperscript{21} The exception in the statute for products imported in low volumes for research and evaluation purposes recognizes the low risk that such products present.
regulation to provide flexibility to purchase from non-approved suppliers when necessary, to avoid production disruptions.  

In summary, only Option 2 will encourage companies to have a strong management culture and commitment to understand their suppliers and the risks they present. Codifying the “check the box” approach in Option 1 will eliminate the incentive and direction for qualified individuals to engage in critical thinking. Our proposed approach is implementable with the development of clear guidance that educates suppliers about how to determine the appropriate verification activities for their suppliers. We also would support a statement in guidance that encourages importers to err on the side of auditing more, rather than less, frequently and that challenges importers to document their reasoning for situations when they do not audit a supplier that controls a risk that could result in a Class I recall. Strong guidance is preferable to a prescriptive codified approach to establish a regulation that is sustainable, preventative, and encourages long-term improvements. This approach also allows importers the flexibility to adjust the resources spent on supplier verification activities based on risk.

6. Regulatory Inspection in Place of an Audit – § 1.506(g)

Under proposed section 1.506(g), importers could substitute an inspection by FDA or an officially recognized or equivalent food safety authority for an on-site audit. Essentially, if a supplier were inspected by FDA (or the food safety authority of a comparable food safety system) within 1 year, no audit is required. The proposed rule does not specify whether other verification activities may still be required.

Although this proposal would potentially lessen the burden under Option 1, we are concerned that a given FDA inspection may not assess the line or process at issue, as it may or may not be operational at the time of the FDA inspection. We also are concerned with the timely ability to review EIRS to assess the inspection results. Currently, EIRs are produced and released sometime after the inspection takes place, often months later, so the supplier may not be able to provide the importer with a copy of the EIR in a timely manner. Accordingly, the EIR process would need to change in order for importers to rely on this content as a verification activity.

We are concerned that the proposed rule requires only that the facility be inspected, but does not establish any parameters regarding the results of the inspection. A facility may be inspected and found to have insanitary conditions, but it will still have been inspected and thus preempt the supplier audit requirement under Option 1 of the proposed rule. Further, as noted above, the importer may not receive the EIR until months later, so that they could be relying on the fact that the foreign supplier was inspected without being able to assess the results of this inspection.

Because our members are accustomed to reading and assessing audit reports, rather than EIRs, to assess supplier compliance, we expect that most of our members would opt to verify

22 This would be consistent with current third-party audit standards. For example, Safe Quality Food (SQF)’s code states: “The receipt of raw materials, ingredients, and packaging materials received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use.”
their suppliers using an audit instead of relying on this option under the regulation. However, we are concerned that suppliers may not allow their importers to audit their facilities for FSVP purposes if they were subject to an FDA inspection in the last year even though importers may find it prudent to conduct an audit.

Because the proposal to substitute an inspection for an audit will not reduce supplier verification burdens, given that most companies will still choose to conduct audits, and could actually increase burdens (i.e., making it challenging for suppliers to agree to be audited), we encourage FDA to omit this provision from the final rule. We would support such a requirement in the future if inspection reports can be provided in a more timely manner and the regulation would still provide an incentive for suppliers to agree to an audit even if they have been recently inspected.

7. Testing

Under both Option 1 and Option 2, FDA proposes that periodic or lot-by-lot sampling and testing of imported food would be an appropriate verification activity. The proposed rule would allow importers to conduct the testing or to obtain documentation (e.g., certificate of analysis) from their foreign supplier of the testing results.

We agree that testing can be an important verification activity in some situations, however, ingredient testing cannot ensure the hygienic status of a product lot. Like supplier verification, testing is a verification activity and does not directly prevent the conditions that lead to contamination with or growth of pathogens. Testing programs also are constrained by the statistical limitations of selecting a defective sample in a consignment or lot and results are only reflective of the sample evaluated at the time the sample was collected. Ingredient testing is most effective as a component of a supplier verification program that includes other activities to verify a supplier’s program.

The utility and frequency of ingredient testing for supplier verification depends on many factors, including:

- Nature of the material or ingredient (for example raw commodity versus processed ingredient, microbiologically sensitive ingredient versus non-microbiologically sensitive ingredient);
- Identified hazards, their severity and likelihood of occurrence;
- Origin of the material;
- Processing applied to the ingredient by the importer or its customer;
- Potential for the pathogen to grow during storage and distribution;
- Final use of the finished product; and
- History of supplier performance.

Testing is typically relevant as a verification procedure for ingredients when 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. Testing is generally not useful for the verification of ingredients where a process control measure
is in place in the importer’s facility that is sufficient to eliminate levels of the hazard potentially present in the material.

Ingredient testing often is more effective and appropriate when conducted by the supplier rather than the importer. When testing is conducted by the importer on their incoming ingredients, lot control cannot be maintained. A prudent establishment should have all potentially implicated product under its control when pathogen testing is conducted and test results should be received prior to releasing product into commerce. Based on this testing, suppliers generate COAs using valid analytical methods to evaluate conformance of the specific lot to the importer’s requirements. Sometimes importers verify the results of the COA by conducting their own testing of the incoming ingredient. The need for and frequency of such testing is determined based on inherent material risk, intended use of the material by the importer, and the supplier’s performance history. Testing is just one possible verification activity and other effective verification activities may be appropriate instead.

FDA tentatively concludes that it is not appropriate to specify testing standards in the regulation. We agree with this conclusion. Testing standards will change over time and should not be codified. Furthermore, different testing standards are appropriate for different customers and uses. These are usually identified in a specification.

8. Auditor Qualifications

No matter the nature of the audit, whether it is second- or third-party, it is important that it be conducted by an appropriately qualified individual and that appropriate checks be in place to account for their independence. We note that the individual who is qualified to develop and implement the FSVP may require different qualifications than the individual who actually conducts the audits. Auditor competence is necessary to ensure the individuals conducting the audit have the necessary knowledge and skills to recognize and evaluate problems in the supplier’s facility. Unfortunately, there have been numerous high-profile food safety problems in recent years that are linked to lapses in auditor competence. This does not mean that audits are unreliable, but rather underscores the need to establish robust standards for auditor competence. It also highlights the need for qualified individuals to fully review these reports and assess the scope of the audit and risks identified and how they apply to finished product safety.

In the preamble, FDA suggests that importers may eventually choose to use FDA-accredited third-party auditors to conduct their FSVP audits, to ensure that they are receiving high-quality auditing services. We support the Agency’s proposal to allow use of FDA-accredited auditors to conduct FSVP audits. However, there will be a strong disincentive against doing so unless these auditors can take off their FDA hat when conducting audits for FSVP purposes so that none of the related section 808 requirements apply. That is, if an FDA-accredited third-party auditor conducts an audit for FSVP purposes, there **must not** be an

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23 We encourage FDA not to define requirements for the content of the COA in this regulation. This may change over time and is better left to industry to decide between each supplier and importer.
24 For example, Jensen Farms is suing its third-party auditor alleging that the auditor was not competent to conduct the audit and failed to observe or note multiple conditions or practices that are in violation of audit standards.
obligation for the auditor to: (1) report serious findings to FDA, (2) submit the audit report to FDA, or (3) use an accredited lab for any related testing.

In the PRIA, FDA explains its expectation that adoption of the FSVP regulations will increase the demand among importers and foreign suppliers for the services of [FDA-accredited third-party auditors] once FDA’s accreditation system is in place. Rather than have each importer request individual audits of their suppliers, we anticipate that the system ultimately will evolve into one in which the foreign supplier obtains an audit by an accredited third party that will be acceptable to, and used by, most of its customers. . . . We expect that such a system will be more efficient because it will leverage the resources of importers and suppliers.

If FDA requires FDA-accredited third-party auditors to engage in direct reporting, submit audit reports to FDA, and use accredited labs, any cost efficiency will be lost. There will be a strong incentive to avoid use of FDA-accredited third-party auditors for FSVP purposes, as many of the best auditors may not seek FDA accreditation (because there likely will be more business from FSVP audits), and there will be a corresponding increase in the number of second-party audits. This will result in significant redundancy in the system and burdens for supplier who may be “audited to death.” We discuss this issue further in our comments on the Accreditation of Third-Party Auditors Proposed Rule, which are being submitted to docket FDA-2011-N-0146.

We oppose a potential future requirement to only use FDA-accredited third-party auditors. While we are hopeful that the new system will work well, it is premature to consider such a major restriction. We urge the Agency to allow the new system to be in operation for several years before revisiting this potential option. In particular, this would greatly narrow the number of auditors that could be hired and may result in limitations on the use of smaller auditors that have particularly specialized knowledge. Additionally, if at some point in the future FDA limits use of third-party audits to only auditors accredited by the Agency, we urge the Agency to continue to allow use of second-party audits to fulfill FSVP verification responsibilities.

E. Investigations and Corrective Actions

1. Consumer Complaint Review – § 1.507

The proposed rule would require that importers conduct a prompt review of all customer, consumer, or other complaints to determine whether the complaint relates to the adequacy of their FSVP. If this review reveals that an imported food is adulterated or contains undeclared allergens, the importer must conduct a prompt investigation of the cause or causes of the adulteration or misbranding and implement appropriate corrective actions including

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PRIA at 40. See also, PRIA at 97 (“Widespread participation and broad acceptance of audits and certifications will help increase efficiency and reduce costs by eliminating redundant auditing to assess foreign suppliers’ compliance with the FD&C Act. . . . So the existence of a widely credible and acceptable standard for third-party audits (under the Third-Party proposed rule) dramatically reduces the number of audits that we have estimated in this analysis.”).

PRIA at 52-53 (explaining the inefficiencies of multiple audits).
discontinuing the use of a supplier. FDA proposes that complaint records must be kept and made available to FDA for review to document the required complaint management activities. GMA supports FDA’s proposal to require prompt review of all food safety-related complaints, the development of appropriate corrective actions, and for complaint review and analysis to be conducted as part of activities to verify the effectiveness of a supplier’s preventative controls. However, FDA needs to understand that the link between any individual complaint and the adequacy of an importer’s FSVP is likely very tenuous.

Our member companies routinely receive a wide range of comments from customers and consumers, many of which are not complaints or do not relate to food safety. When considering the connection of a complaint to the adequacy of the FSVP, there is a low likelihood of correlation. Typically multiple data points are needed in order to appropriately conclude that the supplier verification program may have a problem. Furthermore, complaints are most likely to signal a problem with an individual supplier — not with the FSVP. (The FSVP does not control any hazards. It is just a verification activity.) Appropriately utilizing consumer complaints as a check on the system requires considerable knowledge about the nature of the food, nature of the supplier, ingredients, and processing.

We note that FDA’s PRIA does not seem to recognize the nature of complaint review as a complex activity conducted typically by a multi-functional team. The PRIA states:

Reviewing a complaint probably requires little time because most complaints simply report an issue and would not be very long or technically complex. Similarly, it should be readily apparent to a competent reviewer whether or not a given complaint relates in some way to the adequacy of an FSVP.28

While this is true, the investigation typically done by our members often goes beyond reviewing an individual complaint, looking at trends and conducting a root cause analysis to avoid recurrence. Considerable time and resources are needed when complaint investigation is required.

GMA strongly urges that FDA’s investigators limit their review of complaints during inspection and only focus on whether an importer employs an appropriate program for review of these documents and takes appropriate corrective actions when needed. Furthermore, complaints that do not relate to food safety are beyond FDA’s legal authority because they are not relevant for the FSVP. FDA’s review of complaints not related to food safety would dilute resources best focused on food safety and would discourage robust collection of complaint information.

We support sharing of individual complaints with the Agency only in emergency situations, as needed under FFDCA section 414 (Bioterrorism Act). In most cases, consumers make complaints in confidence and have not provided permission to share the complaint with a third-party. FDA’s routine review and access of complaints could be counterproductive in importers’ efforts to proactively collect and react to complaint information. Consumers in particular might be reluctant to share that information if they knew it was not to be held in confidence. GMA strongly urges that all records accessed by FDA should remain confidential.

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28 PRIA at 82.
and not subject to FOIA review in order to protect consumer and company confidential information.

2. Supplier Nonconformance – § 1.507

FDA proposes requiring prompt corrective actions in response to a foreign supplier nonconformance, which could include discontinuing use of the foreign supplier until the cause of the noncompliance has been adequately addressed. We agree that importers should take appropriate measures in response to a supplier nonconformance and appreciate the regulation’s flexibility about the appropriate responsive action to take. We want to emphasize that discontinuing use of a supplier is an extreme response that should be reserved for only the most serious situations, when other solutions that would protect the public health are not available.

There are many different levels of supplier nonconformance. For example, a supplier may fail to deliver goods that meet quality expectations, which may result in business concerns but would not necessarily raise concerns related to food safety. On the far other end of the spectrum, a supplier may supply repeated shipments that test positive for a pathogen that the supplier is responsible for controlling, which may result in the importer deciding to discontinue use of the supplier. Our members recognize the importance of investing resources in supplier development. Oftentimes supplier nonconformance is an indication that further supplier development resources are necessary. We believe that a culture of continuous improvement needs to be encouraged under FSMA. Requiring importers to discontinue use of a supplier simply because of a single nonconformance would be a disincentive for importers to invest resources in supplier development.

Because food safety is not controlled through supplier verification, many types of nonconformance do not trigger the need to discontinue use of a supplier. Our members regularly work with their suppliers to identify the root cause of problems and to help develop programs the supplier can implement to improve their processes. For example, if periodic testing conducted by the importer as a verification step finds problems with the supplier’s product, the importer could work with the supplier to identify why the problem occurred and how it can be prevented in the future. Certainly the importer would make any required Reportable Food Registry reports and would not use the lot that tested positive in its own production (unless they can control the hazard or recondition the ingredient). However, working together with the supplier to improve their processes will be a more beneficial result for food safety for all of the supplier’s customers, by driving improvement throughout the supply chain, than simply discontinuing use of the supplier following a nonconformance and hoping that the supplier’s other customers take similar action. Provided that a supplier implements appropriate corrective actions following a nonconformance, it should be permissible to continue to source from that supplier.

Follow-up actions based on supplier nonconformance can be affected by business issues, such as unavailability of an adequate replacement vendor. If a supplier provides nonconforming

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29 There also are instances where a customer may have very high quality standards (above the minimum regulatory requirements) and a given supplier may not be meeting these higher standards. In these cases, the supplier may be temporarily subject to additional verification activities; however, this does not mean that it is not acceptable to source from these suppliers as a matter of food safety.
goods but an adequate replacement vendor is not immediately available, an importer may continue to purchase from the supplier but also may engage in additional verification activities and oversight. In our members’ experience, it often is better to continue receiving food from a supplier who has experienced a nonconformance but took appropriate corrective actions (and for which additional verification steps may be applied), than to switch to using a new supplier with whom the importer may have less or no experience or confidence.

We encourage FDA to develop guidance explaining its recommendations for appropriate responses in instances of supplier nonconformance in order to help less experienced importers, but we do not believe any specific cause/response requirements should be included in the regulation itself. Importers should be given the flexibility to determine the appropriate action to take, assuming they have qualified individuals (as required) that must have the requisite knowledge and expertise to do so. Importers should document their responses to supplier nonconformance and this documentation should be available for FDA’s review.

F. Reassessment – § 1.508

FDA proposes requiring importers to reassess the effectiveness of their FSVP at least every three years. This requirement seems to go to a reassessment of the whole program. Reassessment also is required when importers become aware of new information about potential hazards associated with the food. This requirement seems to go to a reassessment of the program as applied to a specific supplier. We support the latter requirement, to consistently reassess the specific supplier verification risk assessment and verification activities for a given supplier based on new information, but do not support a requirement to reassess the entire FSVP at a set interval. This is not a requirement provided in the statute for FSVP.

By requiring periodic reassessment of the whole program, FDA has incorporated a concept that FSMA provides for food safety plans that does not really fit with supplier verification programs. We support a requirement to reassess the effectiveness of an FSVP whenever an importer becomes aware of new information about potential hazards associated with the food and/or potential risks associated with the supplier. We do not support a requirement to reassess the FSVP every three years because such a specified timeframe is arbitrary, beyond the statute, and not tied to risk.

Reassessment is a concept that makes sense for a food safety plan, but does not get applied the same way, at a set interval, for supplier verification. Importers should continuously be monitoring their suppliers to ensure the program still fits and does not need to be revised to address changes in risks. Reassessment is a dynamic process, not a timed event as under HACCP programs and food safety plans. This is why we recommend deleting section 1.508(a) from the regulation.

30 Sometimes it is necessary to import food from a non-approved supplier in emergency situations, such as when there are serious food safety concerns with an approved supplier. FDA’s regulations should provide flexibility to import food from non-approved suppliers when necessary, to avoid production disruptions. This would be consistent with current third-party audit standards. For example, SQF’s code states: “The receipt of raw materials, ingredients, and packaging materials received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use.”
Deleting the three-year reassessment requirement from the FSVP regulation would be consistent with the preventive controls regulation, which requires reassessment of the entire food safety plan—not any individual preventive control. When reviewed against the preventive controls reassessment requirement, it is particularly odd here that one preventive control (that is not a CCP) is singled out for reassessment in the FSVP rule. Reassessment is only needed in situations where the food safety program has failed, the program has the potential to fail, or where a gap exists in the program. The changes made to the program should be commensurate with the risk identified.

In addition, the requirement to periodically reassess a facility’s food safety plan would include a reassessment of the potential hazards for foods used at the facility (whether from domestic or foreign suppliers). Any new information about potential hazards for a specific food would be addressed under the preventive controls food safety plan reassessment. To the extent that a food is determined to present new hazards, the food safety plan and the actions needed to manage those risks would need to be updated. That, in turn, would drive the need for a review of supplier verification for the particular supplier(s) with foods at issue—but not for the entire program.

In proposed section 1.508(a)(2), FDA would require importers to “promptly” reassess their FSVP if they become aware of new information about potential hazards associated with the food. We interpret the word “promptly” to be context specific so that the timing of a response does not necessarily have to be immediate (same day) but rather must be directly related to the level of risk and severity represented by the issue. For example, a discovery that a supplier fails to apply process parameters for a sterilization or pasteurization system for the control of a pathogen would require immediate action. But, in contrast, learning about a change in a supplier’s environmental sampling program can be responded to over a period of days or perhaps weeks. The degree of responsiveness should be related the severity of the risk identified.

It also is important that suppliers communicate changes to their program with their customers so that importers can reassess their FSVPs when necessary. For example, if a supplier comes under new management, installs a new line, or validates a new process, it is important that the supplier inform the importer of these facts. Such requirements are typically included in commercial contracts and/or supplier expectation manuals.

Our members reassess application of their programs for given suppliers all of the time based on new information that they receive daily. This is done, for example, when new product applications are launched, products are reformulated, uses are discontinued, materials are moved between plants, supplier production capacity changes, or suppliers move to new locations. Requiring documentation for such reassessments will be a challenge given that many of these activities are informal and occur through email. We ask that the Agency take a practical approach when considering the documentation needed for a reassessment. For example, if a supplier emails an importer to inform them that the company has come under new management by a well-known multinational food company with a strong reputation for food safety, the importer may conclude that the FSVP for that supplier does not require any modifications. A simple email or note to file in this respect should be adequate to meet the reassessment requirement. In contrast, if a supplier receives a Warning Letter for a food safety problem, the
importer may determine that additional verification activities are needed and additional documentation and justification may be appropriate.

We also note that the PRIA does not include an estimate for the time or cost associated with reassessing an importer’s FSVP. FDA requests comment on whether the general reassessment requirement generates additional costs beyond those incurred in the context of maintaining particular elements of the FSVP. We believe that a reassessment every three years, as proposed, would indeed generate additional costs. A typical reassessment would require assembling a cross-functional team to specifically analyze the program for each individual ingredient (of which there may be thousands). We expect this process would require considerable resources without, as discussed above, resulting in a corresponding food safety benefit. In contrast, revising the regulation as we propose so that reassessment is only needed based on trigger activities would be cost-neutral because companies with strong supplier verification programs already operate this way today.

III. Records-Related Requirements – § 1.510

A. General Program Documentation

We understand and appreciate the need for all FSVP activities to be documented, so that FDA can inspect programs and assess compliance. However, FDA should take caution to train its investigators to understand that there will be a wide range of documentation approaches that importers take, each of which should be viewed as acceptable under the rule. For example, there will not be any common forms and each importer will keep and document activities in its own way. In particular, it should be acceptable for importers to document their program as a whole (e.g., use a matrix approach to assessing supplier and ingredient risk and determining the corresponding verification activities) rather than maintaining a separate file for each individual supplier or food. A document that shows risk tiering or a risk matrix for the company’s program as a whole should be adequate to demonstrate why a specific supplier was subject to a certain set of verification activities. Moreover, the documentation requirement should not turn into a paperwork exercise where the importer needs to keep a narrative file explaining their reasoning and conclusions of their determination for which verification activities to apply for each supplier and food. Similarly, importers should be able to document that they reviewed a supplier’s food safety records, but should not have to maintain copies of those records in the file.

The practical suggestions outlined above are not intended to conceal information, but rather are meant to keep the FSVP from becoming a huge paperwork burden that would distract focus from the true purpose of improving food safety. We agree with, and greatly appreciate, the recognition of this point in the PRIA:

It would be prohibitively difficult for an importer to develop a general written document that would provide the verification procedures they would follow for every possible hazard in every food they might import because the verification activity will vary at least with the food and the supplier of that food. Therefore, most importers will probably develop written verification procedures as needed

31 PRIA at 88-89.
based on the hazards in the particular imported products they are currently importing or intending to import.\textsuperscript{32}

\textbf{B. List of Suppliers – § 1.506(a)}

We disagree with the requirement to maintain a list of foreign suppliers, although we agree with the principle underlying FDA’s proposal that a list of approved suppliers is a useful tool to ensure only materials from verified suppliers are received. Many of our members do not maintain a single supplier list but instead have another corporate-wide system in place to confirm ingredients only are received from approved suppliers. FDA should simply require importers to have a procedure in place to ensure ingredients are only received from approved suppliers.

Maintaining a single standalone list of suppliers presents numerous logistical challenges given that the suppliers who are approved are constantly evolving. Instead of maintaining a facility specific list, many importers have centralized, controlled processes that ensure only approved suppliers can deliver products to their facilities.\textsuperscript{33} FDA should require importers to maintain and implement procedures to ensure only approved supplier facilities are permitted to supply ingredients or raw materials, rather than maintaining a written “list” that can soon become out of date. There are multiple ways that an importer can achieve this goal other than maintaining a single list. We agree that it is important that this information be maintained in real time, so that there is no delay between an importer’s disapproval and their discontinuance of receipt of food from that supplier.

Additionally, we do not believe that the name of a foreign supplier needs to be maintained on such a list or database when no verification activities are required for that supplier. As noted above, we are concerned that the proposed definition of “foreign supplier” would require importers to determine the identity of a supplier many steps back in the chain (e.g., the name of the person who harvested the spices). Fortunately, in some of these instances the supplier will not be controlling any hazards and therefore no verification activities are needed under the proposal. It would be a waste of resources and an incredible burden to require the importer to determine the name of the supplier simply for purposes of maintaining this list when no supplier verification activities are needed. (And, of course, these challenges also reinforce why we support a simplified definition of “foreign supplier.”)

\textbf{C. Confidentiality of Supplier Audit Documentation}

The FSVP documentation requirements should not provide a disincentive for engaging in robust supplier verification programs. In particular, FDA should modify the regulation to provide protection for the content of audit reports. A legal requirement to provide certain supplier verification information to FDA during inspections could discourage open, honest, and complete audits. Instead, FDA should follow an approach modeled after FDA precedent established for audit reports in the context of infant formula and medical devices. Such an

\textsuperscript{32} PRIA at 34.
\textsuperscript{33} These processes are centralized because supplier verification typically is managed company-wide on the corporate level.
approach would strike the right balance of protecting supplier relationships and giving FDA the information necessary to conduct inspections and assess compliance.

Requiring audit reports to be shared with FDA will undermine the ability for importers to conduct the robust type of audits that are sometimes necessary as a verification activity. Suppliers usually only allow their customers to conduct an audit on the condition of confidentiality. If the importer is required to share its audit report with FDA, the supplier will likely resist the audit or seek to severely restrict the scope of the audit. Without a promise of confidentiality, importers could lose the ability to conduct a candid and thorough audit.

Further, supplier audit reports often include confidential business information and may include findings that indicate the audited facility may have had one or more gaps in their program. This is important information that enables the importer to assess appropriate verification activities and/or corrective actions for a supplier. However, if a supplier knows that the audit report will be available to FDA they may be less likely to allow an honest and accurate audit to be conducted (or may decline to be audited at all). The fact that public disclosure of these audits would be protected by FOIA is not enough to ensure that suppliers will continue to allow importers to conduct audits of their facilities. It is not only a supplier’s concern about public disclosure that could have a chilling effect, but also their fear of disclosure of these reports to FDA itself. 34

Even if audits are required under this regulation, a disclosure requirement could result in lowest common denominator audits being conducted that are less robust than needed for food safety. For example, some suppliers may choose to use hygienic zoning in their facility. Hygienic zoning is not required by the cGMPs and also may not be required by the importer’s supplier requirements. However, if a supplier chooses to implement hygienic zoning, the importer may want to audit the program. Because this program is not legally required though, the supplier may not allow the importer to audit it because of a concern that any gaps in the program will be made available to FDA through the audit report. Suppliers also may reject requests from second-party auditors to conduct audits, as third-party audits are less likely to audit this type of program. 35

Protection of audit reports will encourage cooperation and visibility by suppliers, allowing for importers to conduct full due diligence. As FDA recognizes in the proposed rule, complete and candid audits are an essential part of the food safety system because they allow importers to learn from first-hand assessments of their suppliers’ systems. Confidentiality is an important part of these audits to encourage suppliers to allow their customers open access to their

34 To the extent that FDA disagrees and concludes that audit reports will be accessible to the Agency, we urge the Agency to reaffirm its intent to protect the content of these audits from public disclosure under FOIA because they contain confidential commercial information and/or trade secret information that is exempt from disclosure. 5 U.S.C. § 552; 21 C.F.R. Part 20.
35 Confidentiality is particularly important in order to conduct robust second-party audits. Without confidence and adequate assurances from the importer that confidential information will not be disclosed (often in the form of a nondisclosure agreement), suppliers will decline to allow their customers sufficient access to their facility and records to engage in a comprehensive food safety audit. Both second- and third-party audits play an important (and sometimes complementary role) for supplier verification, so it would be disappointing if FDA sets up a system that encourages third-party audits and discourages second-party audits.
facilities. If suppliers cannot be assured of the confidentiality of audits, they are less likely to allow importers to conduct thorough assessments. This will mean that importers will lose an important opportunity to identify problem areas for their suppliers. Sharing audit reports with FDA could, therefore, chill the behavior that supplier verification activity is designed to encourage.

Of note, Congress has recognized the importance of maintaining confidentiality for food-related audit reports in the context of infant formula. The Drug Enforcement, Education, and Control Act of 1986 (Pub. L. No. 99-570) required FDA to establish regulations regarding retention of records of routine mandatory audits to confirm regulatory compliance, but also specified that a manufacturer need only provide written assurances that the regularly scheduled audits are being conducted by the manufacturer, “and need not make available to the Secretary [of Health and Human Services] the actual written reports of such audits.” Accordingly, FDA’s regulations require firms to maintain “audit plans and procedures,” but not the actual written reports of the audits.

FDA also recognizes the value of protecting audit confidentiality in the medical device industry where it is the Agency’s policy generally not to review quality audit reports. The Agency’s medical device Quality System Regulation provides that facilities must prepare a report with the results of each internal quality audit and document their supplier evaluations and control activities. However, this documentation (including supplier audit reports) is not subject to review and copying by FDA. Rather, upon request from FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

This regulation was based on the recognition that FDA access to audit reports would weaken the audit system and there is a “need to maintain a degree of confidentiality if audits are to be complete and candid.”

We encourage FDA to follow the precedent established in the medical device and infant formula context and to exempt audit reports from disclosure to the Agency. The Agency should

37 21 C.F.R. § 106.100(j).
38 61 Fed. Reg. 52602, 52613 (Oct. 7, 1996). (FDA “believes that refraining from routinely reviewing these [supplier audit] reports may help ensure that the audits are complete and candid and of maximum use to the manufacturer”); id. at 52637 (“disclosure of the audit reports themselves would be counterproductive to the intent of the quality system”).
39 21 C.F.R. §§ 820.22, 820.50(a).
40 21 C.F.R. § 820.180(c).
41 Id. See 61 Fed. Reg. at 52625 (“FDA recognizes that quality audits of suppliers have a significant and demonstrated value as a management tool for corrective action, quality improvement, and overall assurance of component and service quality, and does not seek to undermine their value. Therefore, based on the concerns raised by the comments, FDA will not review supplier audit reports during a routine FDA inspection for compliance with part 820, as noted in § 820.180(c), ‘Exceptions’ [requiring documentation of corrective actions].”).
be able to review (1) documentation that demonstrates an audit was conducted (i.e., the date(s) of the audit and name(s) of auditor(s)), and (2) documentation that demonstrates any corrective actions in response to any significant deficiencies (i.e., issues that would trigger a Reportable Food Registry report) were completed. However, FDA should not have access to the content of the audit report itself. Such disclosure would provide a disincentive against thorough auditing. If necessary, FDA can access the content of audit reports under its broader emergency records access authority under FFDCA section 414.

D. Remote Records Access – § 1.510(b)

FDA has proposed to allow the Agency to access FSVP records remotely upon written request. Specifically, the proposed rule states in section 1.510(b): “If requested in writing by FDA, you must send records to the Agency electronically rather than making the records available for review at your place of business.” As a result, FDA would be able to simply request records at any time via letter or, more likely, via email, without actually visiting an importer’s place of business. As discussed below, GMA opposes remote records access by FDA for the following legal and practical reasons: (1) the proposed authority to access FSVP records is not expressly permitted by FSMA or any other part of the FFDCA; (2) 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 (3) application of this regulation presents significant practical concerns.43

1. FDA Lacks Express Authority to Remotely Review Records

First, GMA is unaware of any legal basis for 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.”44 The plain language of this section does not suggest the agency’s ability to access records outside of a facility—for example, it does not require facilities to “submit,” “send,” or “provide” records to FDA. Furthermore, the phrase “made promptly available” does not reasonably suggest any kind of submission of records. There is a significant difference between making records available (a passive act that necessarily implies a physical presence) and submitting records (an affirmative act). Congress could have expanded the scope of FDA’s records access to include a submission requirement through FSMA. However, the legislation uses the word “available,” rather than “submit” or a similar term, in the records access language in this section of FSMA.

In contrast, there is one section of FSMA that does grant FDA with remote records access, using very specific language. FSMA expressly permits FDA to require an accredited third-party auditor that conducts a regulatory audit to submit records to the Agency upon request, as follows:

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

43 As discussed in our comments on the preventive controls proposed rule, we also oppose remote records access for preventive controls records.
44 FSMA § 301(d).
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.45

This provision reinforces the absence of remote access authority for FSVPs. Such authority would be clearly indicated if the legislation used terms like “submit.” However, FSMA does not include such a term or similar phrase in the preventive controls provision or any other section of the FFDCA.

2. FDA Also Does Not Have Implied Authority to Remotely Review Records Under the FFDCA

Second, GMA respectfully disagrees with FDA’s conclusion that remote access to records is authorized by section 701(a) of the FFDCA, which grants FDA authority to “promulgate regulations for the efficient enforcement” of the Act. GMA believes that remote access authority is contrary to the purpose of FSMA. Both the courts and FDA have recognized the purpose of the law is a key factor that must be considered when assessing whether FDA’s exercise of authority under section 701(a) is appropriate. As FDA stated in the preamble to the seafood HACCP regulation, “It is true that a deliberate refusal by Congress to authorize a specific program would at least be one factor to be weighed in determining the validity of a regulation.” The Supreme Court also has stated, “Whether Congress refused to include a specific section of the Act authorizing [a certain authority]” is “surely a highly relevant [factor]” when assessing whether a regulation is justified under section 701(a).46

The legislative history of FSMA demonstrates that the legislation does not give FDA remote records access authority in any context. Congress expressly considered - and rejected - expanding the scope of the FFDCA to give FDA remote access authority. The food safety bill passed by the House of Representatives in 2010 would have expressly granted FDA remote access to certain food records, including remote access in emergency situations and remote access to food safety plans, without cause.47 In contrast, the Senate food safety bill, which ultimately became law, did not contain either of these provisions. Neither the House nor Senate contemplated giving FDA authority to remotely access importers’ records. 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.48

The facts at hand are distinct from the situation in the seafood HACCP context, where FDA relied on its section 701(a) authority even though Congress had recently considered, but did not enact, legislation on seafood safety. In that situation, FDA concluded that Congress meant for FDA to have the authority to require mandatory food safety controls for seafood, even though

45 FSMA § 307 (emphasis added).
47 H.R. 2749, 111th Cong. § 106(a) (2009).
48 A requirement to electronically submit records to FDA would be a dramatic change to the FFDCA inspection paradigm, which has always required onsite review of records. The House of Representatives would not have written legislation to authorize FDA to have “remote access” to records if it already viewed FDA as having such authority, because Congress is expected to consider its bills in the context of the existing statutory scheme.
it had not yet adopted the seafood safety legislation.\textsuperscript{49} FDA stated that even though the 101st Congress ended before competing seafood bills could be reconciled, this did not amount to a refusal on the part of Congress to authorize a mandatory HACCP program.

In contrast, with FSMA it is not the case that a Congressional session simply expired before Congress could grant FDA remote records access authority. Instead, Congress specifically considered legislation that would grant the Agency with this authority and instead adopted legislation from the other chamber that did not contain this authority. The fact that the Senate did not adopt the language of the House passed bill into its legislation is indicative of the fact that FSMA is not intended to provide FDA with remote access authority. The Supreme Court has held that selection of one chamber’s version of legislation over that of the other is indicative of legislative intent.\textsuperscript{50} Accordingly, Congress’s refusal to provide remote access authority must be considered in evaluating the legal basis for the proposed rule.

3. Remote Records Review is Not Practical or Efficient

Third, we are concerned with the practical application of remote access authority. The preamble states: “We also believe that such access would reduce the burden on importers posed by a visit by Agency representatives to an importer’s place of business.”\textsuperscript{51} GMA is concerned that remote records access actually will increase burdens on importers rather than promoting efficiency.

FDA has historically enforced the FFDCA through on-site inspections. Such inspections allow for interpersonal interactions, which typically is a more efficient way for FDA inspectors to interact with regulated facilities. During on-site inspections, FDA and plant personnel (or corporate personnel responsible for the supplier verification program) are able to discuss the relevant background information, address questions, and otherwise engage in a dialogue regarding the inspectional observations. In addition, on-site inspections also allow FDA to review related records as a whole rather than reviewing any single record in isolation. Although some FSVP importers will not be operating a manufacturing facility with production equipment for FDA to observe in operation, it is equally important for FDA to visit importers in person in order to fully assess the importer’s program, organization, and veracity.

By contrast to on-site inspections and requests for information, FDA’s proposal for on-demand review of select documents provides information without context and presents the risk that FDA will not fully understand the importer’s complete program and will only review select documents that do not provide full insight into the importer’s FSVP.

Under the proposed rule, an FSVP will involve many different types of records, including written procedures, compliance status reviews, hazard analyses, verification activity

\textsuperscript{49} 60 Fed. Reg. at 65099.
\textsuperscript{50} See, e.g., \textit{INS v. Cardoza-Fonseca}, 480 U.S. 421, 441-42 (1987) (rejecting Senate language limiting the Attorney General’s discretion in granting asylum in favor of House language authorizing grant of asylum to any refugee); \textit{United States v. Riverside Bayview Homes}, 474 U.S. 121, 136-37 (1985) (attaching significance to the conference committee’s choice of the Senate version of legislation, retaining the broad definition of “navigable waters” then in current law, over a House version that would have narrowed the definition).
\textsuperscript{51} 78 Fed. Reg. at 45763.
documentation, investigations and corrective action documentation, and periodic reassessments. These documents all work together to create a cohesive program, making it problematic to review individual documents in isolation.

Additionally, we are concerned that remote records requests have the potential to overburden importers based on the potential for a large volume of demands from FDA. As discussed above, we are concerned about FDA only selectively reviewing select FSVP records out of context. However, if FDA were to request all records related to an importer’s FSVP, this would be an extremely burdensome request to respond to (especially within a short time period like 24 hours). Even requests that are more seemingly limited, such as all verification documentation, could result in a tremendous amount of documentation. There also is no limit on how often FDA could make such requests, raising the possibility that the Agency could make ceaseless demands of a given importer that is under particular regulatory scrutiny and this could ultimately interfere with their ability to operate their business. To manage the process and ensure timely responses, importers may need to designate a specific employee that is solely tasked with responding to FDA document requests.

Furthermore, a broad records request from FDA could overload the Agency with documents that are not particularly helpful or relevant for the purpose of the Agency’s inquiry. Our experience with facility inspections has taught us that FDA’s investigators often benefit from discussing the types of records they are seeking with our personnel so as to limit the scope of the request to only useful documents. In the facility context, it is more helpful to understand the specific incident an investigator is assessing and to provide relevant documentation rather than to, for example, provide all corrective action reports since the investigator’s last visit. The same principle holds true for FSVP records, where a dialogue between the importer and FDA will be important to help focus the scope of the inspection and narrow provision of records to only those that will truly help the Agency with its investigation.

Even when the House of Representatives considered expanding the FFDCA to allow remote records access in limited situations, they recognized the need to establish constraints on the use of this authority. The report from the House of Representatives Committee on Energy and Commerce explained that the Committee expected FDA

when notifying the company of the need for such ‘remote access’ to records, to specify which types of food safety records FDA seeks, including for what product(s) and over what time frame. This was intended to ensure that the records collection is properly tailored to assist FDA in its investigation and that the Agency will not waste time sorting through a broader array of records that are not pertinent to its investigation.\(^\text{52}\)

\(^\text{52}\) H.R. Rep. No. 111-234, at 48-49 (2009) (“This authority is intended to provide FDA with a mechanism to gain a better understanding of a facility’s food safety program, but it is not intended as a substitute for an on-site inspection. The Committee expects that FDA would use this authority as an initial survey and triage tool, to help the Agency prioritize which facilities to inspect and where to focus the inspection, when conducted. The Committee underscores the importance of on-site inspections for FDA to have a clear and complete understanding of the facility’s food safety program.”).
This demonstrates that even if FDA did have legal authority for remote records access, it would need to exercise restraint on the use of the authority. Constraints on the scope of FDA’s authority are critical, but no such boundaries are proposed or discussed in the FSVP preamble.

Finally, we also have a practical concern on the basis of the considerable risk of fraud and document security lapses for records provided to the Agency electronically. Importers may not be able to verify that an email from an “@fda.hhs.gov” email is legitimate and has not come from an impersonator. In fact, there have been some reports of impersonation of FDA officials via email with respect to recent foreign facility inspection notifications. In contrast, with in-person inspections it is possible to validate investigator credentials (through badge and photo identification review) at the beginning of the inspection. Additionally, given the highly confidential nature of the documents FDA may be requesting, there is heightened concern from sharing this information electronically in a format that may be accessible through hacking or other methods of unapproved data access by third-parties.

In summary, FDA should not finalize the remote records access proposal because it is contrary to the Agency’s legal authority and will increase burdens on importers, rather than promoting efficient enforcement of the Act.

E. Place of Storage – § 1.510(b)

Proposed section 1.510(b) provides flexibility for where records must be maintained. The proposed rule states: “You must maintain records at your place of business or at a reasonably accessible location; records are considered to be at a reasonably accessible location if they can be immediately retrieved from another location by computer or other electronic means.” We support including flexibility in the regulation for importers to maintain records at any reasonably accessible location. This is particularly important for our members, given that their supplier verification records typically are maintained at a central corporate location. We encourage FDA to take the same common-sense approach for all records under preventive controls except the food safety plan, as further discussed in our comments on that topic.

The preventive controls proposed rule in section 117.315(c) provides that it is permissible to store certain records offsite provided they “can be retrieved and provided onsite within 24 hours of request for official review.” This is different than the FSVP proposal, which allows records to be stored offsite “if they can be immediately retrieved from another location by computer or other electronic means.” We encourage the Agency to revise the FSVP regulation to align with the more flexible approach in the preventive controls regulation, so that storage offsite is allowed so long as the records are available within 24 hours of FDA’s request. The FSVP approach is too limiting, as it would require importers to store all paper records onsite for the entire retention period because offsite paper documents would not be immediately retrievable by a computer or other electronic means. The FSVP approach also presents practical enforcement challenges, given the possibility for differing interpretations of what an “immediate” response should be.

53 Emails from FDA also could get diverted to “SPAM” and unintentionally ignored by importers, which should not be a basis for regulatory sanctions.
F. Records Retention – § 1.510(d)

Proposed Section 1.510(d) would require certain records to be kept two years after their use is discontinued and other records to be kept two years after they are created or obtained. This division is unnecessarily complicated and we are concerned that it will cause confusion for importers. Rather than establishing a two-tiered structure, the regulation should simply provide that all records must be maintained for two years after use of the records is discontinued. This approach is consistent with FSMA, which requires records to be “maintained for a period of not less than 2 years.” 54 This also would be clearer and simpler than the proposed rule because it accounts for the time that records are being used, no matter the nature of the document.

We also encourage the Agency to modify the phrase “after their use is discontinued” in the regulation. The word “their” is unclear because it could refer to use of the supplier or use of the records. If the former, this would mean that all records regarding use of the supplier must be kept until two years after the supplier is no longer used. Thus, if a supplier is used for 20 years you must always keep all 20 years of documents. If the word “their” refers to the records, such that you have to keep records two years after use of those records is discontinued, we would support such a requirement provided the regulatory language is clarified as requested above. We note that this second interpretation is consistent with the preamble, which states that records must be maintained “for as long as the records remain in use and are not revised or replaced.” 55

G. Requirement for Records to be Kept in English – § 1.510(b)

In section 1.510(b), FDA proposes requiring records to be maintained in English. This requirement is not provided for by the statute, nor does FDA explain its reasoning behind the proposal in the preamble to the proposed rule. Additionally, no parts of the FFDCA require food records to be maintained in English so this is an entirely novel proposal. We question whether FDA has a legal basis for implementing this proposal. We note that FDA does not provide a justification for requiring English records in the preamble, nor does the Agency cite any legal authority for doing so. There does not seem to be a basis for this proposal under FFDCA section 701(a) given the extreme burden English recordkeeping will impose on some importers. Further, this proposal creates a potential incongruity under WTO SPS standards, given that preventive controls documents can be maintained in any language. 56 We also have several practical concerns with this requirement.

First, GMA believes records should be maintained in the native language in which they were created. For foreign suppliers that do not have corporate offices that require English as the business language (these tend to be small and medium size companies), the native language often is not English. An importer’s verification activities may include reviewing their supplier’s food

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54 FSMA § 301(c)(4).
56 We do not support a requirement for preventive controls records to be in English, for similar reasons. These records are used in the facility day-to-day and it is essential that they are in the language most familiar to the facility personnel that are implementing the food safety plan. If FDA were to require registered facilities to maintain all food safety plan records in English, this could have very dangerous effects for food safety (if employees are maintaining records in a language that is not their native tongue) and also would introduce tremendous redundancy into the system (as all records created in the native language would need to be translated).
safety records or audit report and importers also may have their supplier share their hazard analysis. If neither the supplier nor importer speaks English, FDA could be introducing the potential for dangerous misunderstandings 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 to be in English. GMA believes that foreign facilities are ideally audited by an auditor whose native language or main working language is the native language at the foreign facility being audited. Similarly, audit reports and related records are best shared in their native language between members of the audit team and employees of the facility. Records of corrective actions and records related to verification activities must use a language easily understood by personnel working at the facility and to eliminate potential misunderstandings resulting from translation into English. Notably, the requirement to maintain records, including onsite audit reports, in English is not consistent with industry standards such as the British Retail Consortium (BRC) and Safe Quality Food (SQF) schemes that require that documents are to be kept or written in a language or languages spoken by the organization’s staff. Certification to the International Featured Standards (IFS) also is carried out by auditors locally in the native language of the country where the audit takes place.

Third, translating records into English will add cost and not improve food safety. GMA believes that it will be costly and burdensome for an importer to translate all records into English or to generate all records in dual languages. This requirement could mean that native-language speaking foreign suppliers will need to recruit dual language speaking personnel so that they can provide English language records to their importers. Further, based on our members’ experience, recruiting English-speaking personnel in non-English speaking countries comes at a premium in terms of salary and recruitment costs since there is a high level of competition for experienced personnel that have dual language capabilities. Another potential impact is that importers will need to enlist specialized resources to engage in translations, which also can be costly. Requiring all records to be translated into English also would be duplicative and could have the unintended consequence of leading to confusion and misunderstanding as well as diverting resources away from food safety oversight and thus would not contribute to protection of public health.

Therefore, GMA believes that FDA’s regulations should not address the language in which records are maintained. Ensuring that importers maintain and respond to requests for required records in a timely manner should be a higher focus for the Agency than mandating specific language requirements. As an alternative, GMA would support a requirement for facilities to translate records into English upon request from FDA provided the agency allows a reasonable time for this activity to take place.

57 The BRC and SQF certification process involves a number of steps including a formal onsite audit to determine compliance with aspects of their standards. Manufacturing sites receive a report of findings along with observations for improvement including any identified non-conformities. To fully appreciate the nature of the findings, observations and non-conformities, it is imperative that the audit report be written and communicated in the language or languages understood by the facilities staff and not translated and maintained in English.

58 We note that the cost of maintaining records in English is not considered in FDA’s Preliminary Regulatory Impact Analysis (PRIA). As an illustration of translation costs into English, we refer the Agency to the following website that lists average rates of over $30 per hour: http://search.proz.com/employers/rates.
H. Compliance with 21 C.F.R. Part 11

There is no reference in the FSVP preamble or PRIA to compliance with 21 C.F.R. Part 11 for electronic documents. We read this as meaning that the FSVP records do not need to be compliant with Part 11 and ask the Agency to confirm this interpretation. As explained in our preventive controls comments, Part 11 imposes a considerable burden and should not apply to FSMA-related electronic records. Instead, FDA should require facilities to have appropriate systems to protect the security of electronic records, where used.

I. FOIA

FOIA provides protections for trade secrets and confidential commercial or financial information. Many FSVP records will be protected by FOIA. For example, supplier lists, audit reports, and other verification records all meet the definition of “commercial or financial information that is privileged or confidential” under 21 C.F.R. § 20.61(b) because they are customarily held in strict confidence, regarded as privileged, and not disclosed to the public. It is imperative that FDA engage in appropriate training of its personal to protect inadvertent release of such information. We encourage FDA to work with GMA to develop internal protocol that specifies which supplier verification records can and cannot be released under FOIA. A consistent and transparent policy would further the objectives of both FOIA and the FFDCA.

We also encourage FDA to make the FOIA protections explicit in the FSVP regulations, as it has in the preventive controls proposal, juice HACCP regulation, seafood HACCP regulation, and shell egg rule. We support codification of the same language that is used in the current HACCP regulations, which is much clearer than the language proposed for preventive controls.59 Or, in the alternative, we would support the following language: “Records required by this part are subject to the disclosure requirements under part 20 of this chapter, including protections for trade secrets and privileged or confidential commercial or financial information.”

IV. Exemptions

A. Food Contact Substances60

The FSVP proposal would define the term “food” as having the same meaning given in section 201(f) of the FFDCA. FDA’s proposed definition would exempt “pesticides as defined in 7 U.S.C. 136(u)” because, as explained in the preamble to the proposal, “pesticides, including those used in or on food for human and animal use, are comprehensively regulated by the Environmental Protection Agency.”61 FDA requests comment on the pesticide exemption and whether there should be additional exemptions. GMA agrees that pesticides should be exempted from the definition of “food” for FSVP and, for the reasons set forth below, requests that food

59 For additional comments regarding the regulatory language on FOIA, please see our comments regarding the records and registration aspects of the Preventive Controls proposed rule, submitted November 22, 2013, at pages 32-33.
60 GMA supports the comments filed by the Society of the Plastics Industry, Inc. on this issue, which also request exclusion of food contact substances from the definition of “food” for purposes of the FSVP.
contact substances (as defined in 21 U.S.C. § 348(h)(6), including packaging\textsuperscript{62}) also be excluded from the definition of “food” for purposes of the FSVP rule.

As support for the pesticide exemption, FDA references the Prior Notice of Imported Food Interim Final Rule (IFR) that was issued pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.\textsuperscript{63} The prior notice IFR contains a lengthy discussion on the meaning of food that is instructive for purposes of the FSVP definition of “food.”\textsuperscript{64} As the IFR explains, the Bioterrorism Act referred to food differently in its various sections, e.g., section 415 on facility registration refers to “food for consumption” while section 801(m) on prior notice refers to an “article of food.” In fact, as FDA went on to explain, even before the Bioterrorism Act amendments to the FFDCA, the term “food” was not defined identically throughout the FFDCA.\textsuperscript{65} Because of the ambiguity created by these various definitions, the Agency determined it could define food in a “reasonable manner.”\textsuperscript{66} For purposes of the prior notice IFR, FDA determined it would be reasonable to define “food” as excluding pesticides and food contact substances as defined in section 409(h)(6) of the FFDCA.

FSMA amended the FFDCA which, as FDA has noted, does not define food identically in its various sections. Accordingly, FDA has the same opportunity to define food in a reasonable manner for FSVP as it did for prior notice. GMA believes it would be reasonable for FDA to exempt food contact substances from the definition of food for purposes of the FSVP rule in addition to exempting pesticides. Food contact substances such as food packaging have not historically been an area of concern from a food safety perspective. Therefore, requiring supplier verification of food contact substances would not be risk-based, would diminish the focus on higher-priority suppliers, and would not achieve FSMA’s intended purpose to improve food safety.

Moreover, substances such as processing aids are typically incorporated into finished food products for which the importer controls the hazard and, as such, would not be subject to the requirements of the FSVP rule as proposed by FDA. Exempting food contact substances in this context also would harmonize FDA’s regulations, so that only food made by facilities required to register under the Bioterrorism Act would be subject to supplier verification. Because the Agency has an opportunity to define food in a manner that is reasonable, and food contact substances will either not be subject to the rule’s requirements or present very little food safety risk, we request that the Agency define “food” as excluding food contact substances for purposes of the FSVP rule.

In the alternative if FDA does not accept our request for an exemption, we urge the Agency to establish modified supplier verification requirements for food contact substances. If supplier verification is required for this category, verification activities would focus on ensuring the materials are not adulterated. This is because food contact substances are not covered by the

\textsuperscript{62} The FFDCA defines the term “food contact substance” to mean “any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.”
\textsuperscript{64} See id. at 58984-87.
\textsuperscript{65} Id. at 58984.
\textsuperscript{66} Id. at 58986.
preventive controls and the produce safety regulations, and are unlikely to present risks of undeclared allergens or pathogens. Accordingly, the key issue that needs to be verified is that the substance is sold in compliance with the FFDCA and FDA’s regulations. The fact that FDA has established modified requirements for other categories of products, such as dietary supplements, under the proposed rule demonstrates that the Agency has determined it has the legal authority to take this approach.

B. Commingled Raw Agricultural Commodities (Except Fruits and Vegetables)

Section 1.500 of the proposed rule would define “foreign supplier” as the establishment that “harvests the food that is exported to the United States without further manufacturing/processing by another establishment,” unless that subsequent activity is de minimis (e.g., labeling). This means, unless there is an intervening activity that is not de minimis in nature, importers will be required to verify each grower of commingled raw agricultural commodities (RAC) regardless of the length or complexity of the supply chain.

As discussed in section II.D.1. above, such a requirement is contrary to the traceability provisions of the FFDCA and FSMA. Under the FFDCA (as amended by the Bioterrorism Act and FSMA) and FDA’s implementing regulations, a facility is only required to be able to trace food “one-step back.”

Requiring importers to engage in supplier verification further back to the source of the food would be contrary to the Bioterrorism Act and the traceability provisions in FSMA. Notably, FSMA specifically restricts FDA from requiring facilities to maintain records of the full pedigree of a food even for high risk foods and also limits trace back requirements for commingled raw agricultural commodities to the immediate previous source of the food. Any regulation that would require an importer to verify a grower of RAC, violates these traceability restrictions since importers will be required to go more than one step back.

In addition to the legal restrictions on FDA’s ability to require traceback more than one step in the supply chain, a requirement to conduct verification of RAC growers presents significant practical and logistical obstacles regardless of the length of the supply chain. The costs and complexity to verify activities of each grower of an RAC far outweigh the minimal (if any) increase in the ability of a supply chain to deliver safer food to consumers – especially since (i) FSMA only requires an importer to have to verify a single foreign supplier for a particular shipment of food, (ii) RAC are considered by FDA to be low-risk food, (iii) FDA has not established any requirements/standards for growers and traders of RAC and requirements/standards for others in a RAC supply chain are minimal, (iv) RAC are further processed by the importer or its customer(s) prior to reaching consumers and (v) if RAC are not

67 In this section, the term “raw agricultural commodities” means all raw agricultural commodities excluding fruits and vegetables that are subject to the Standards for Produce Safety regulation. When we refer to commingled raw agricultural commodities in this context, we are referencing any commodity that is combined or mixed after harvesting but before processing.

68 In the supply chain, RAC are likely to be cleaned and potentially dried to a specific moisture level for the purposes of storage and transportation. Such activities do not transform the RAC to a processed food. This conclusion is acknowledged by the FDA in the preamble to the preventive controls proposed rule. 78 Fed. Reg. 3646, 3678-3683 (Jan. 16, 2013).

69 FFDCA § 414; 21 C.F.R. Part 1, Subpart J (§ 1.326 et seq.).

70 FSMA § 204(d)(1)(L) and FSMA § 204(d)(6)(D)
exempted than every farm producing RAC in the United States will need to be verified under the domestic supplier verification rules.

Complexity of RAC Supply Chains. A typical supply chain for RAC (e.g., coffee, cocoa, spices, grain) involves many growers delivering RAC to an aggregator (e.g., a grain elevator). At this step, RAC from multiple (and potentially hundreds) of growers are commingled. After the initial aggregation, there may be additional aggregation steps and commingling before the RAC is loaded in a vessel/container for export. During transport from the foreign location to the United States, an RAC may be traded (i.e., bought and sold) many times. As result, the importer will find it very difficult to impossible to identify each grower of the commingled RAC.

Costs of Verifying Growers of RAC. Even if it were possible to identify each of the many growers of a commingled RAC, it is simply not feasible from a time or cost standpoint for an importer to conduct supplier verification of each of potentially hundreds of growers. The costs incurred by in supplier verification of each of these growers by each importer would significantly increase the price of these RAC.

Congress Intended the Importer to Verify a Single Foreign Supplier. For the reasons given by FDA in the preamble to the proposed FSVP regulations, "Congress intended the importer to verify a single foreign supplier" for a particular shipment of a food. Since most (if not all) RAC that are imported are commingled RAC from multiple growers, FDA’s failure to exempt RAC from the proposed FSVP regulations would violate FDA’s conclusion regarding what Congress was trying to accomplish.

RAC are Low-Risk Foods. FDA has acknowledged that RAC as low risk foods. As such, supplier verification for RAC should not be required. Examples of FDA’s acknowledgement that RAC are low risk foods are found in (i) proposed 21 CFR Section 117.5(k) which exempts “the holding or transportation of one or more RAC” from the new proposed GMPs, (ii) proposed 21 CFR Section 117.5(j) which exempts facilities that are “solely engaged in the storage of RAC (other than fruits and vegetables” intended for further distribution or processing” from the new proposed hazard analysis and risk-based preventive controls, and (iii) 21 CFR Sections 117.5(g) and 117.5(h), which both acknowledge that the holding and/or drying of grain (whether for storage or transport or for creating a distinct commodity) is a low-risk activity.

FDA has not Established Verifiable Standards for RAC. Since the FDA has not established standards for the growers of RAC and has only limited standards for registered facilities who handle RAC, an importer has little or no guidance to help determine whether or not a grower is adequately controlling a hazard. FDA’s failure to establish standards reflects that, as a practical matter, the hazards inherent in RAC – e.g., salmonella or mycotoxin contamination and foreign material – cannot be reasonably controlled by a grower.

Risks of RAC are Managed by Importers and/or their Customers. The preventive controls proposed rule requires that each registered facility conduct a hazard evaluation and
develop a food safety plan to appropriately manage its hazards, including any hazards of RAC used at that facility. As such, every facility receiving RAC will have identified the hazards that are inherent in those RAC and have a plan/activities for managing those risks. For example, a facility receiving corn will monitor aflatoxin levels in the drawing area for the facility and implement – as necessary – an aflatoxin screening protocol to minimize the risk of receiving corn with unsafe levels of aflatoxin.

WTO Obligations. FDA must also keep in mind that WTO obligations require that domestic and foreign supplier verification programs are the same. As such, requiring verification of growers of RAC under the FSVP would also require verification of growers under the domestic supplier verification activities of the proposed preventive controls rules. Requiring verification of every grower of RAC used by FDA registered facilities is simply not feasible.

In conclusion, we encourage FDA to exempt all suppliers of RAC (excluding only those subject to the produce safety regulation as noted in footnote 69) from the FSVP and the domestic supplier verification requirements for the following reasons:

- FDA intended importers to verify only a single foreign supplier;
- RAC are low risk foods;
- FDA has established no standards for growers and traders of RAC and limited standards for others in RAC supply chains;
- RAC are further processed at registered facilities that manage the RAC hazards prior to reaching consumers; and
- Given the complexity of RAC supply chains, grower verification is not feasible for RAC and would be prohibitively expensive.

Further support for this proposed exemption, including discussion of the scientific support for this approach, is discussed in comments being filed to this docket by other trade associations that specialize in these commodities.

C. Intra-Company (Multinational) Shipments

FDA requests comments regarding whether importers should not be required to conduct foreign supplier verification when importing food produced by entities under the same corporate ownership. We strongly support an exemption for imports from suppliers who are subject to common corporate or corporate-parent ownership (e.g., subsidiaries, affiliates) and are subject to a single, integrated company-wide approach to food safety. Any ingredients will already have been verified or produced by another division of the company, so it would be duplicative and would not benefit public health if a company has to verify itself. There are several situations where such imports may arise:

- Company A USA imports packaged frozen meals produced by Company A Mexico for sale in the U.S. with no further processing or packaging.
- Company A USA imports chocolate icing made by Company A Mexico, which is applied as a topping for cookies made domestically by Company A USA.
- Company A USA imports cereal made by Company A Mexico that will be packaged and sold in the U.S.
When a foreign supplier is part of the same corporate structure as the importer and operates under a single, integrated company-wide approach to food safety, both entities often are managed by a single corporate team of food safety experts and hazards are controlled and verified by the same supplier verification system. Therefore, it would be redundant and would not improve food safety to require companies to verify themselves. Internal supplier verification would add an additional layer of administration, not more food safety insight. Importing from another entity under the same corporate parent is not an arm’s length transaction where the importer needs to engage in verification to “know” their supplier. Rather, the importer already knows the supplier (itself) intimately. Requiring supplier verification in these situations will functionally be a paperwork exercise that will not improve food safety or public health.

For example, some companies use different corporate entities for different parts of their production process for various legal reasons. One facility/entity may bake cookies that are then packaged by another facility/entity owned by the same corporate parent. No food safety benefit would result if the packaging facility is required to engage in supplier verification for the baking facility. If the packaging facility were required to engage in supplier verification under Option 1, they would be required to audit the baking facility to ensure they appropriately controlled the hazard of Salmonella in the raw flour and eggs. This would just increase costs without improving food safety.

FSVP is intended to establish a mechanism for companies to have additional insight to their suppliers to ensure safe food enters the country. Supplier verification considers risks presented by the supplier and the food. Companies already have full insight about the foods they make themselves. Consider the following examples comparing the insight an importer has into a foreign supplier that is and is not owned by the same corporate parent:

- If Company A USA brings in food from Company Z in Mexico (a third-party), the importer has no visibility into the supplier’s food safety program and processes unless they engage in supplier verification.

- Similarly, if Company A USA imports excess supply of an ingredient purchased by (but not manufactured by) Company A Mexico, foreign supplier verification should be required because Company A Mexico did not manufacture the product. (If Company A Mexico already engaged in supplier verification as a preventive control, Company A USA should simply confirm that this activity occurred to meet its FSVP obligations.)

- If Company A USA and Company A Mexico have the same corporate parent, Company A USA already has visibility into Company A Mexico’s food safety programs and how food is manufactured by its facilities. Supplier verification will not add any new information to the equation. In fact, Company A USA likely already has more insight about Company A Mexico than it does about any of its other suppliers.

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73 This example also illustrates why Option 1 goes beyond what is needed for food safety by requiring audits for all Class I risks. If a facility is baking cookies, an audit may not be necessary to ensure the properly applied their kill step. It would be obvious if there was a lapse in the baking process that did not achieve lethality because the cookies would not be baked.
These examples demonstrate why an exemption makes good sense for food safety.

Additionally, requiring supplier verification for imports from the same corporate parent may increase trade burdens in violation of WTO agreements. For example, if Company A in San Diego imports finished packaged cereal from Company A in Tijuana, under FDA’s proposal the company would be required to engage in supplier verification of itself. But if Company A had simply made that cereal across the border in California, it would not be required to engage in supplier verification of itself. Without an exemption, US-produced products would receive favorable treatment because no additional supplier verification would be required to sell products in the US when made by the same company. FSVP is simply an extra paperwork burden for imports in these intra-company situations.

D. Research and Evaluation – § 1.501(c)

Proposed § 1.501(c) exempts “food that is imported for research or evaluation use” from the FSVP requirements. To be covered by the exemption, the food must “not [be] intended for retail sale,” “not sold or distributed to the public,” and “imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose.” GMA recommends that “small quantity” and “research, analysis, or quality assurance purpose” both be interpreted broadly.

GMA supports this exemption, and recommends that FDA define “small quantity” to be sufficiently flexible to allow various quantities of samples based upon the particular product and the specific research and evaluation purpose. For example, food samples imported solely for testing and evaluation of suitability in mass-production equipment are imported in comparatively larger quantities. Moreover, foods come in different weights and sizes and have different monetary values. A strict limit on the size, weight, or value of a shipment for research and evaluation purposes would affect foreign suppliers differently. If “small quantity” is to be defined at all, the definition should be general enough to not unfairly inhibit foreign suppliers of any food. What is most important is that the product will not be used for sale or public consumption, versus delineating specific limits for what constitutes a “small quantity” of any particular food type.

GMA further recommends that FDA provide clear guidance as to the scope of “research and evaluation use.” Specifically, FDA should acknowledge that food imported for purposes of promoting sales and marketing research or similar uses are protected by the exemption for research and evaluation purposes. Such foods, such as samples used in focus groups, are not intended for retail sale and are not sold or distributed to the public. Rather, they are used for assessing markets and soliciting potential future sales. While these foods may be distributed to and consumed by a subset of company employees or consumers, they are consumed in very small quantities and under tightly controlled conditions and do not present a material food safety risk to U.S. consumers.

We also encourage FDA to revise its Prior Notice CPG (110.310) for consistency with the FSVP regulations. This CPG explains that FDA exercises enforcement discretion if prior notice is not submitted for food imported for quality assurance, research, or analysis purposes only and that is not for human or animal consumption or resale. Under the CPG, “samples of
food are considered to be imported or offered for import for quality assurance, research or analysis purposes when they are imported in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis or is destroyed after analysis or a reasonable retention period after analysis.” The FSVP exemption does not require the entire small quantity to be destroyed or used up in the analysis. FDA should revise the scope of this enforcement discretion so that prior notice is not required for imports exempt from FSVP on the basis that they are imported for research and evaluation purposes.

E. Overlap with Preventive Controls

It is essential that FDA harmonize the supplier verification requirements in the preventive controls regulation and the FSVP so that ingredients only need to be verified once. It currently is unclear how the regulations will work together, in part because the preventive controls regulation has not been proposed yet. This is an essential area to work out before the final rule is published. Given the complexity of supply chains, we urge the agency to engage in additional outreach to industry on this point to consider the many different scenarios that will arise regularly.

The preventive controls regulation should have an exemption for any food that was already subject to supplier verification under the FSVP—even if it was verified by a third-party and not the facility itself. Requiring otherwise would be incredibly redundant. In the most basic example, if Company A imports an ingredient in compliance with the FSVP for use in manufacturing at their U.S.-based facility, Company A should not also have to verify the supplier under the preventive controls regulation; Company A should be exempt from doing so.

The same should be true when third-parties are involved. For example, Importer A may bring in a shipment of a food that is held in the company’s warehouse pending receipt of purchase orders. Eventually, 15 different customers may purchase this food for further processing in their own facilities. Those 15 customers should not be required to engage in supplier verification for this food because Importer A already did so. A requirement for each of these customers had to verify the ingredient’s foreign supplier under the preventive controls regulation would very repetitive. Rather, the customer’s sole obligation should be to ensure Importer A complied with its FSVP obligations. The same should be true if one of these 15 customers then sold the food to another customer further down the chain. The fact that the food from this foreign supplier already was verified does not change.

F. Transshipments and Exports

Under proposed § 1.501(f), foods that are “transshipped through the United States to another country” or “imported for future export and that is neither consumed nor distributed in the United States” are also exempt from the FSVP regulations. While GMA strongly supports these exemptions as well, but as of now, these categories are not currently exempt under Prior Notice (PN). In the interest of harmonization, GMA encourages FDA to extend these

74 This scenario also raises another concern about the regulation, as the importer may not know the identity of their customer or their intended use at the time of import and this would complicate their determination about their verification obligations under the regulation.
exemptions to the PN program. Further, GMA requests guidance as to whether this transshipment exemption applies to all imports or just those bonded by CBP, which permits merchandise to be moved from one port to another without the merchandise being appraised or duties imposed.

G. Very Small Foreign Suppliers – § 1.512

FDA proposes modified requirements (but not an exemption) for imports from “very small foreign suppliers” that have an average of under $500,000 of sales annually. Notably, this exemption is not the statute. Based on the broad definition of “foreign supplier” proposed, this would require importers to go all the way back in the chain to very small farms. Currently, the identities of many of these facilities are not known. Under the proposal, however, their identities would be needed to comply with the documentation requirements.

Even assuming that FDA takes a more practical approach to the definition of “foreign supplier,” we are concerned that these modified requirements would give a free pass to many high risk suppliers. Just because a supplier is small does not mean that they cannot make many people sick and cause significant damage for consumer confidence regarding the safety of a given food. Everyone, regardless of size should be responsible for making safe food. Accordingly, we do not support the proposal to establish modified requirements for very small foreign suppliers based on their size.

V. Customs-Related Comments

A. Definition of “Importer”

Developing a clear and practical definition of the term “importer” is fundamental to successful implementation of the FSVP. Proposed § 1.500 defines the FSVP “importer” as:

the person in the United States who has purchased an article of food that is being offered for import into the United States. If the article of food has not been sold to a person in the United States at the time of U.S. entry, the importer is the person in the United States to whom the article has been consigned at the time of entry. If the article of food has not been sold or consigned to a person in the United States at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry.

We are concerned that this definition may be inconsistent the definition of “importer” in the statute, as:

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or
(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner
or consignee of the article of food at the time of entry of such article into the United States.\textsuperscript{75}

In contrast to the proposed rule, the statute does not create different rules for U.S. owners and consignees in their responsibilities for maintaining a FSVP. Nor does the statute define importer as the person who purchased the food article. Indeed, neither the statute nor the proposed rule defines the term purchased, creating uncertainty as to who is responsible for ensuring compliance with the FSVP. This ambiguity is particularly acute as supply chains become increasingly complex with multiple downstream entities that, without further clarity, may or may not be considered purchasers.

Instead of creating a new definition of “importer,” FDA should adopt a definition that parallels the definition used by U.S. Customs and Border Protection (CBP). Under 19 U.S.C. §1484(2)(B), “importer of record” is defined as “the owner or purchaser of the merchandise or, when appropriately designated by the owner, purchaser, or consignee of the merchandise, a person holding a valid [customs broker] license.” An importer of record is the party that has the legal right to file the entry, and must demonstrative a financial interest in the import transaction. The statutory definition of “importer” for CBP purposes is substantially similar to the statutory definition of “importer” under FSMA. Accordingly, FDA’s proposed regulations should provide a comparable definition of “importer” as those provided by CBP. The CBP regulations define “importer” as “the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf.”\textsuperscript{76} Under this definition, an importer is the party primarily responsible for the import transaction, which may be the importer of record or the consignee.

CBP’s definition has been effective in ensuring proper enforcement in collection of customs duties and the importing industry is already familiar with how the definition operates in practice. CBP’s definition also provides certainty in that it defines a single party responsible for entry of the imported product. Moreover, CBP’s definition resolves issues with consignment arrangements, placing the responsibility on the party in the best position to conduct oversight of the import.

The statutory definition of “importer” under FSMA is akin to CBP’s statutory definition except that FSMA requires the importer be a U.S. entity. This additional clarification may be easily added to the proposed regulations while ensuring that the FDA definition is parallel to CBP’s definition of “importer.” Modifying the proposed FSVP definition of importer to parallel CBP’s definition has numerous advantages, including: (1) increased certainty because importers are well aware of CBP’s definition and practice, (2) decreased burdens and greater efficiency for both importers and the government agencies because harmonizing the definitions will increase the likelihood that the importer will be the same for both CBP and FDA purposes, and (3) increased compliance because having the same party act as the importer for both CBP and FDA purposes will ensure proper and timely filings and declarations, and will lessen the potential miscommunications between the agencies and parties (one of which is the CBP importer and one

\textsuperscript{75} FSMA § 301(a); FFDCA § 805(a)(2).
\textsuperscript{76} 19 C.F.R. § 101.1.
of which is the FDA importer). Importantly, these benefits may be realized while meeting FSMA’s objectives.

**B. Identification of Importer**

Under proposed § 1.509(c), importers “must ensure that, for each line entry of food product offered for importation into the United States, your name and DUNS number identifying you as the importer of the food is provided electronically when filing entry with U.S. Customs and Border Protection.”\(^77\) GMA recommends that FDA revise this rule to require an importer’s identification information on a line entry basis only when there is more than one importer for a shipment or when the CBP importer differs from the FSVP importer.

Requiring importers to identify themselves repeatedly for each entry line adds unnecessary data and costs for all parties and goes beyond what is required by FSMA. If FDA adopts our proposal above permitting the importer for FDA purposes to be the same as the importer for CBP purposes in most cases, then there is no need for FDA to require this additional identifier.

GMA understands that FDA is statutorily obligated to “publish and maintain on [the agency’s] Internet Web site … a current list that includes the name and location of, and other important information deemed necessary by [FDA] about, importers participating under [Section 805].” GMA, however, encourages FDA to comply with this mandate in a manner that does not conflict with CBP’s regulations regarding confidentiality.\(^78\) This will allow companies to continue protecting sensitive shipping details, such as product sourcing and distribution details. GMA further recommends that FDA issue guidance that clarifies the relationship between FDA and CBP’s regulatory requirements regarding importer responsibilities.

**C. DUNS Numbers**

Proposed § 1.509(b) requires importers to “obtain a Dun & Bradstreet Data Universal Numbering System (DUNS) number” and as noted above, proposed § 1.509(c) would require importers to “ensure that, for each line entry of food product offered for importation into the United States, your name and DUNS number identifying you as the importer of the food is provided electronically when filing entry with U.S. Customs and Border Protection.”

GMA recommends that FDA utilize CBP’s existing identification number system,\(^79\) rather than requiring DUNS numbers. CBP identifies importers of record by using the U.S. importing entity’s ten-digit U.S. tax identification number. CBP’s existing system of identification numbers is sufficient to meet FSMA’s directives, while being less burdensome and more secure. New importers that do not already have a CBP identification number can be assured that they are signing up for a system that is already well-established and in widespread use by for importing purposes. FSMA does not specifically require a DUNS number, but mandating their use is likely to cause confusion when combined with the other identification numbers required for importers such as CBP and PN, increasing the burden to trade.

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\(^77\) Emphasis added.

\(^78\) See, e.g., 19 C.F.R. §§ 111.24 and 143.4.

\(^79\) See 19 C.F.R. § 24.5; CBP Form 5106.
Another alternative for FDA to consider would be to utilize the existing PN system. As part of the PN declaration, the name of the owner and consignee for the article of food must be declared. FDA can simply import this information into a new system, in the same manner proposed for DUNs. This would be more efficient than DUNs, however, because it utilizes information already in FDA’s control. When the owner is not a U.S. entity, the system can be programmed to use the name of the consignee as the FSVP importer. To address the rare instances where the consignee also is foreign, we recommend adding a box to the PN form to identify the name of the U.S. agent for FSVP purposes for situations where there is neither a U.S. owner or consignee. This approach would be easily integrated into the existing system, minimizing burdens on importers and using information technology to build the new database FDA desires.

GMA also does not believe that there is any benefit to FDA or public health by requiring use of DUNs number. The DUNs number will typically provide less information to FDA than the information already collected by CPB. For example, FDA will have access to the destination of the food through the current information submitted to CPB. By contrast, if an importer has multiple U.S. locations, the importer will only have a single DUNs number that will not provide information about the food’s destination. There is no reason to require importers to sign up for and keep track of another identification number. Further, the use of an additional, publically available identification number at the border increases security, health safety and fraud (e.g., identity theft) risks.

**D. Electronic Submission of Information**

Proposed § 1.509(c) would require an importer to provide information “identifying you as the importer of the food . . . electronically when filing entry with U.S. Customs and Border Protection.” GMA supports FDA’s proposal requiring importers to submit identifying information electronically, but GMA recommends that FDA permit importers to submit the necessary information prior to filing entry with CBP as part of the PN form. In addition, FDA should ensure that it will provide timely admissibility determinations about imports shipped under the FSVP regulations. Commonly importers do not file the formal CBP entry summary until after arrival of the imported products into the United States. If importers have to wait to file the FSVP information until filing the entry, it may delay release of the imported goods. Allowing early submission of the FSVP information would give FDA and the importer additional time to make admissibility determinations, resolve any perceived failures to comply with FSVP requirements, and, if the admission is refused, would give the foreign supplier more time to react to the delivery disruption. This would reduce the number of shipments delayed at the ports, while reducing congestion, costs, and risks to food quality. These benefits are similar to those generated by the early submission of PN information and should be adopted in the FSVP context.

Should FDA decide to permit filing of the FSVP information on the PN form, GMA recommends that FDA maintain the current format of the PN form and use the information it already receives as much as possible. The PN form identifies both the owner and the consignee

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80 19 C.F.R. Part 141 (formal entry summary (CBP Form 7501) is not due until 15 days after arrival or 10 days after entry of goods).
of the food article imported. Thus, FDA would be able to identify which party is responsible for the FSVP simply by reviewing the existing information. To address situations where there is no U.S. owner or consignee, FDA may provide another field in the PN form for the name of the U.S. agent responsible for the FSVP. The current PN forms are designed to accommodate repetitive information by allowing importers to save basic information for use on subsequent PNs. Therefore, modifying the PN forms to include information required by FSVP purposes would result in dramatic cost and time savings. FDA itself estimates that each importer will have to provide the necessary information for an average of 157 line entries per year, resulting in a total annual burden of more than 178,000 hours.\footnote{PRIA at 196.}

VI. Implementation

A. Guidance, Education, and Training

Considering the complexity and the magnitude of impact of the FSVP regulation, GMA requests that FDA provide sufficient guidance and training to importers of food products to help familiarize them with the new requirements. Clear agency guidance is vital for industry to ensure it is compliant and to maximize predictability. These concerns are particularly acute where, as here, industry must comply with regulations imposed by multiple agencies (and applied in multiple countries). GMA appreciates FDA’s past decisions to provide industry guidance on new regulations and believes that industry would similarly benefit from agency guidance on these FSVP regulations.

We support a regulation that provides a broad framework, flexible enough to consider the wide range of importers and imported products, with additional details and recommendations provided through guidance. Together with guidance, education and training also are crucial. Providing adequate resources for these efforts is especially important given the size and complexity of the FSVP regulation. It is essential that its principles and objectives be clearly understood and recognized by those required to comply.

We share FDA’s concern about the ability for small importers and suppliers to comply with the new requirements. The availability and accessibility of educational and training programs will be essential to decrease the risk that these companies develop and rely on incomplete or ineffective programs. GMA welcomes the opportunity to work with FDA to help improve understanding and, ultimately, compliance rates.

Education and training are highly interconnected and inseparable to ensure success. Training can enhance and increase the probability that the execution of new programs and initiatives will be successful. Without the necessary training and education, the process of introducing compliance will be haphazard. We support the efforts of the Food Safety Preventive Controls Alliance and encourage supplier verification-specific training as part of their programs. We have the following recommendations for the content, delivery, and timing of education and training:
• **Content.** Materials should be designed for simplicity of understanding but also should be complete in the requirements explained. Examples should be provided when and where necessary, with graphical content to further reinforce meaning and comprehension. Case studies could be used where applicable to provide linkage to real life situations.

• **Delivery.** We encourage FDA to take advantage of the wide range of methods available for distribution and dissemination of educational and instructional materials. For example, we support use of training workshops, publications/media, joint educational programs (e.g., webinars) developed by FDA and industry, website materials, and on-site trainings/consultations.

• **Timing.** FDA should start its educational and training efforts as soon as the final rule is published, well in advance of the compliance dates. Training applied too late will not provide adequate time to assimilate the information into new programs.

In addition to training and education programs conducted by FDA, training programs conducted by importers for their suppliers will be essential and should be encouraged by the Agency. As discussed above, we are concerned that Option 1 for verification activities could provide a disincentive against supplier training programs because many suppliers will be subject to mandatory annual audits regardless of whether they make their programs more robust. In contrast, Option 2 provides a strong incentive for importers to work with their suppliers to help raise the bar so that less verification resources are needed in the future, an approach that is better for food safety.

**B. Customs-Specific Guidance**

In addition to the areas identified above, GMA requests guidance specifically on enforcement and how the FSVP regulations interact with CBP regulations. As listed below, the regulations leave open a number of questions regarding enforcement issues that would be helpful for industry to know the answers to in advance of an enforcement action:

- When is a violation determined?
- What happens after an import is refused admission?
- Who is notified about a violation?
- Who is responsible for remedying a violation?
- What role does a CBP bond play?

GMA would also appreciate guidance on how FDA will coordinate with CBP about these regulations. For instance, FDA should explain how FSVP recordkeeping obligations align with CBP recordkeeping obligations involving retention periods\(^\text{82}\) and indexing,\(^\text{83}\) among other things.

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\(^{82}\) 19 C.F.R. § 163.4.
\(^{83}\) 19 C.F.R. § 163.5.
C. Compliance Date

We support FDA’s proposal that any compliance date would be 18 months after publication of the final rule to allow importers time to come into compliance. Thereafter, we request that FDA grant an informed compliance period for 12 months during which importers are expected to comply gradually without the threat of full enforcement and associated penalties. This time is needed so that the agency and industry can better understand how the several new FSMA regulations will work together. Even beyond the extended compliance date of 18 months after publication of the final FSVP regulations, GMA believes that both industry and FDA could 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. During this adjustment period of informed compliance, FDA and industry should be communicating regularly about what is working and what needs to be adjusted.

FDA can use this opportunity to collect more feedback from industry and issue and improve guidance accordingly, while industry can ensure that they are complying with the regulations as FDA intended. In order to maximize the mutual benefits of an informed compliance period, GMA proposes that FDA and industry provide periodic status updates and metrics throughout the period. This informed compliance period is similar to what the Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) did, to great benefit, before fully enforcing provisions of the Lacey Act.84

D. Comparability/Systems Assessment

GMA congratulates the Agency on their recent food safety compatibility arrangement with New Zealand. However, at the same time we are stoutly disappointed that FDA has only achieved such an agreement with solely one country worldwide. We strongly encourage FDA to rapidly pursue similar arrangements with our many global partners. In contrast, FSIS has determined that 34 countries have some level of food safety equivalency (comparable to FSIS food safety programs) and are able to import some FSIS-regulated products into the United States.85 Such an objective on the part of FDA should be part of an overall strategy for strengthening the global food safety net through closer collaboration with regulators around the world. These relationships would lessen the expenditure of precious Agency and industry resources that will be necessary to comply with and audit the proposed FSVP mandates.

Expansion of such compatibility arrangements serve to fulfill the requirements of FSMA whereby FDA is mandated to strengthen its import tool kit beyond border screening to include stronger importer accountability for verifying the safety of food imports, a much strengthened system of private audits, which could be performed by government agencies, more FDA inspections overseas, and importantly, greater collaboration with foreign regulatory authorities. We further propose that the Agency fast-track such an arrangement with Canada, a country who has been a major US trading partner for centuries, shares a 4,500 mile border with the United


States, and apparently has food safety programs similar to those we employ domestically. Canada is the only country that currently is allowed to import products from all the categories evaluated by FSIS in their equivalency process: meat, pork, poultry, eggs, lamb and goat.

GMA recognizes that there are major differences in the strength of foreign food safety regulatory systems. Through both GMA’s and our member’s involvement in programs like Codex, GFSI, APEC-PTIN, and the Trans-Pacific Partnership over the years, we have been able to explore various food safety policies and programs in place in other countries designed to provide assurances of safety of individual products. Accordingly, we can recognize that pursuing compatibility is not an easy process. Nevertheless, the expenditure of resources in this area will have a rapid payback considering the resources expended by FDA and industry to comply with proposed FSVP requirements for goods imported from countries without compatibility; currently every country in the world except New Zealand.

One practical result of this arrangement is enhanced information exchanges available to avoid duplication of efforts. With assurance about each other’s food safety competency and commitment, both are more likely to focus their resources on higher risks. For example, if the two food-exporting countries decide their food safety programs and practices provide a comparable level of food safety assurance, they can take this into account as appropriate in determining the type and frequency of inspections to conduct of foreign manufacturing establishments and of imported food shipments.

E. FSVP Inspections

GMA commends FDA on its goal of modernizing the way the Agency conducts inspections under FSMA, shifting its approach to ensuring consistent implementation of FSMA’s modern prevention measures rather than being narrowly focused on identifying legal violations. As part of this transformation, we encourage FDA to pay particular attention to developing a thoughtful and effective approach to inspecting and enforcing the FSVP requirements. Supplier verification will require a unique approach for inspections, as many importers do not operate food factories and are not currently part of the Agency’s inspection inventory.

Because most supplier verification programs are managed on the corporate level, we encourage FDA to conduct targeted inspections at corporate headquarters that focus only on the importer’s FSVP and their supplier verification activities under their preventive controls program. This would enable FDA to inspect supplier verification programs using investigators with specialized experience in this area (i.e., a dedicated cadre of supplier verification inspectors that have the same qualifications required of “qualified individuals”). GMA welcomes the opportunity to work with FDA to develop such an inspection program.86

During inspections, FDA should focus efforts on ensuring a company has a documented, risk-based FSVP that is consistently implemented. The goal of FSVP inspections for supplier verification should be to ensure importers have a well-functioning system in place. Importers, not FDA investigators, are best situated to assess the risks presented by their suppliers and

86 We also encourage reviewing GFSI’s program materials regarding inspections when developing an inspection protocol, to understand how they recommend supplier verification programs be inspected and assessed.
supply chains. Thus, when FDA conducts an inspection of an FSVP, the Agency should ensure
the importer has developed and implemented an appropriate program but should only scrutinize
the specific rationales or reasoning underlying the program when there is good cause for doing
so. Certainly we agree that it would be appropriate for FDA to take action if a program is clearly
deficient. However, FDA should not routinely focus its limited inspection resources on
questioning the specific verification activities applied for a given supplier if the importer being
inspected has a robust FSVP in place.

We believe that the regulations we propose are enforceable if FDA takes the following
approach to FSVP inspections:

- The first question asked should always be “Do you have qualified individuals?” and
  “Are individuals qualified to evaluate ingredient hazard and supplier risks?.” Interviews
  with these individuals will be key to assess whether they have the appropriate level of
  knowledge and experience to develop and implement an FSVP. This is why FDA’s
  inspectors themselves need to also be qualified individuals. Examples of enforcement
  red flags may be where a company simply uses its sourcing or procurement personnel,
  who lack a food safety background, to engage in FSVP activities. On the other hand,
  individuals or consultants with clear food safety background, experience, should be
  readily identifiable to the FDA’s trained inspectors.

- Second, FDA should assess the evaluation of a particular supplier, asking questions like
  “What supplier risk factors were evaluated?,” “Was this appropriate for the supplier?,”
  “Are there risks you ignored or disregarded?,” and “Did you consider appropriate risks
  presented both by the ingredient and the supplier?”

- Third, FDA’s inspectors should consider whether the evaluation of supplier risk and
  ingredient hazards dictated the appropriate level of supplier verification activities. For
  example, an importer may conclude that an ingredient presents a “6 of 10” risk on their
  ingredient risk scale. However, based on the specific supplier’s strong food safety
  programs and performance track record, the importer may conclude that this places the
  specific supplier’s risk at “3 of 10” on the supplier scale. This would mean that the
  supplier is medium risk, and will be audited less frequently than a supplier of the same
  ingredient that presents a higher supplier risk.

- Fourth, FDA should consider whether the importer conducted the supplier verification
  activities dictated by the assessment of risk. Is there evidence of completion of auditing
  activities, such as certificates on file? Are corrective actions of significant deficiencies
documented? Are there COAs on file if the importer’s program indicates that testing
  is needed at a particular frequency?

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87 As discussed above, the agency should be able to review (1) documentation that demonstrates an audit was conducted
(i.e., the date(s) of the audit and name(s) of auditor(s)), and (2) documentation that demonstrates any corrective actions in
response to any significant deficiencies (i.e., issues that would trigger a Reportable Food Registry report) were completed.
Just as FSMA should provide companies with the flexibility to develop their food safety plans in the manner their experts determine is most effective to make safe food, the same should be true for supplier verification programs. FDA should ensure importers have programs in place and that the programs are consistently and effectively implemented. GMA appreciates that some importers, especially those that are smaller, may not yet have the same in-house expertise on supplier verification programs that GMA members have. We believe it is important that the qualified individual preparing or overseeing preparation and implementation of the FSVP possess the necessary expertise in supplier verification. Even with less experienced importers, we believe FDA should focus on whether the importer has a truly qualified individual overseeing the FSVP.

As discussed above, it is particularly important that FDA establish and maintain protections for the content of audit reports during inspections. Inspections should ensure audits have been conducted as required by an importer’s FSVP. Consistent with the Agency’s approach in the medical device regulations, we support a requirement to provide FDA with documentation of corrective actions for significant deficiencies observed during audits.

VII. Economic Analysis

GMA members fully support establishment of supplier verification requirements through FSVP. We believe that actions required in the rules must add value in improving food safety and have costs that justify net food safety benefits. However, we are concerned that the FSVP PRIA vastly underestimates cost implications of Option 1. FDA assumes 43,000 of the 200,000 foreign facilities would undergo Option 2 periodic audits and 47,000 would undergo Option 1 annual audits, estimating that Option 1 would result in 10% more audits at a cost of $460 million passed on to consumers. In contrast, we calculate a 30% increase in the number of audits under Option 1, which would be a $1.38 billion cost passed on to the consumers.

FDA assumes only a 10% increase in cost for companies to comply with the prescriptive Option 1, whereas GMA members indicate the costs would range from a 30-50% increase with no added food safety benefit. The estimated cost for a foreign audit is about $8,000 per audit, which includes internal resources, auditor cost, and travel. Based on the data collected from GMA members the added cost to the industry to adopt Option 1 would range from $1.3 - 2 billion annually. This would result in significant increased costs passed on to consumers without delivering commensurate food safety benefits.
For example, one of our large manufacturer members annually audits about 10% of their foreign suppliers. If they now had to conduct mandatory yearly onsite audits for more suppliers as required by Option 1, a conservative estimate is that this would result in three to five-times the current costs to increase annual audits to cover about 35% of their foreign suppliers. That would add $320,000 - $640,000 in costs for one company with no added food safety benefits. Our conclusions are summarized on the table that follows.

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<th>Option 1</th>
<th>Option 2</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRIA Annual Foreign Supplier Audits</td>
<td>47,679</td>
<td>43,364</td>
<td>4,315 or ~10% more audits for Option 1</td>
</tr>
<tr>
<td>PRIA FSVP Annualized Costs</td>
<td>$473M</td>
<td>$461M</td>
<td>$12M added cost to audit 10% more foreign suppliers</td>
</tr>
<tr>
<td>GMA Member Data: % of Foreign Suppliers required for an annual audits as proposed in FSVP</td>
<td>30-50%</td>
<td>10%</td>
<td>3-5 fold increase for Option 1</td>
</tr>
<tr>
<td>Increased Annualized Costs to Implement FSVP Option 1 or 2</td>
<td>$1.4 – 2.3B</td>
<td>~$460M</td>
<td>3-5 fold increase for Option 1</td>
</tr>
</tbody>
</table>

* * * * *

Thank you for considering these comments. We appreciate the opportunity to participate in the rulemaking process.
Appendix: Recommended Revisions for FSVP Codified Language

Note: The revisions below do not reflect the complete changes that GMA is recommending for the FSVP regulation, but rather only indicate revisions where we believe suggestions for codified language are particularly illustrative to reinforce our comments.

§ 1.500 What definitions apply to this subpart?

Affiliated party means, with respect to an entity, any other entity that (i) directly or indirectly controls or is controlled by, or is under common control with that entity, and (ii) is subject to the same food safety control framework, including but not limited to, adhering to the same corporate food safety policies, risk assessment processes, and corrective action procedures as the controlling entity. For purposes of this definition, “control” means (i) the direct or indirect ownership of more than fifty percent (50%) of the total voting security of every class or other evidences of ownership interest of the entity, or (ii) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity. For purposes of this definition “entity” means any individual, general partnership, limited partnership, limited liability company, corporation, or joint venture.

Foreign supplier means, for an article of food, the immediate previous source (i.e., the person from whom you received the food), 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.

§ 1.501 To what foods do the regulations in this subpart apply?

…

(f) Exemption for certain raw agricultural commodities. The regulations in this subpart do not apply to commingled raw agricultural commodities, except for raw agricultural commodities that are determined to be subject to the Standards for Produce Safety promulgated under 21 U.S.C. § 419 and implemented in part 112 of this chapter;

(g) Food contact substances. The regulations in this subpart do not apply to food contact substances as defined in 21 U.S.C. § 348(h)(6) or pesticides as defined in 7 U.S.C. § 136(u); and

(h) Imports from affiliated parties of the importer. The regulations in this subpart do not apply to food imported from a foreign supplier that is an affiliated party of the importer.

§ 1.504 What review of a food and foreign supplier’s compliance status must I conduct?

Before importing a food from a foreign supplier, you must review the compliance status of the food and the foreign supplier, including whether they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. You must document this review. You must continue to monitor and document the compliance status as long as you import the food from the foreign supplier.
§ 1.505 What hazard and risk analysis must I conduct?

(a) Requirement of a hazard and risk analysis. Except as permitted under paragraphs (d) and (e) of this section, for each food you import, you must determine the known or reasonably foreseeable hazards, if any, that are presented by reasonably likely to occur with the food and the known or reasonably foreseeable risks, if any, that are presented by the foreign supplier and, for each, the significance of these hazards and risks. For each food you import, you must determine appropriate verification activities in accordance with §1.506.

(b) Potential hazards and risks.

(1) Food hazards. Your evaluation of the hazards that are known or reasonably foreseeable for reasonably likely to occur with each food you import must consider hazards that may occur naturally or may be unintentionally introduced, including the following, as appropriate and necessary:
   (i) Biological hazards, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance;
   (ii) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, radiological hazards, and food allergens; and
   (iii) Physical hazards; and
   (iv) Radiological hazards.

(2) Supplier risks. Your evaluation of the known or reasonably foreseeable risks that are presented by the foreign supplier must consider the following factors and any other relevant factors, as appropriate and necessary to assess supplier risk:
   (i) Foreign supplier’s performance history (including audit performance) and length of relationship with importer;
   (ii) The U.S. regulatory compliance status of the foreign supplier;
   (iii) Regulatory oversight of foreign supplier in country of origin;
   (iv) Depth of importer’s knowledge about foreign supplier’s food safety programs and culture;
   (v) Recent management changes for foreign supplier; and
   (vi) Whether supplier operates as a contract manufacturer for the importer.

(c) Hazard evaluation. In evaluating the significance of the hazards and risks set forth in paragraph (b) of this section, you must consider the effect of the following on the safety of the finished food for the intended consumer:
   (1) The ingredients of the food;
   (2) The condition, function, and design of the foreign supplier’s establishment and equipment;
   (3) Transportation practices;
   (4) Harvesting, raising, manufacturing, processing, and packing procedures, as applicable;
   (5) Packaging and labeling activities;
   (6) Storage and distribution;
   (7) Intended or reasonably expected foreseeable use;
   (8) Sanitation, including employee hygiene; and
   (9) Any other relevant factors.

(d) Review of hazard analysis developed by foreign supplier. If your foreign supplier has conducted a hazard analysis for the food, you may identify the hazards that are known or
reasonably foreseeable reasonably likely to occur for a particular food by reviewing and evaluating the hazard analysis conducted by the foreign supplier. You must document the determination you make based on this review and evaluation. An evaluation of supplier risks under paragraph (b)(2) is still required.

(e) Microbiological hazards in raw agricultural commodities that are fruits or vegetables. If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to conduct a hazard analysis regarding microbiological hazards that might be known or reasonably foreseeable reasonably likely to occur with such food.

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) List of foreign suppliers. Upon FDA request, you must provide maintain a written listing of foreign suppliers from which you are importing food and that you are relying on to control known or reasonably foreseeable food safety hazards.

(b) Foreign supplier verification procedures. You must establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods you import.

(c) Purpose of supplier verification activities. Except with respect to verification activities specified in paragraph (h) of this section concerning raw agricultural commodities that are fruits or vegetables and that are subject to part 112 of this chapter, you must conduct the foreign supplier verification activities that are necessary to provide adequate assurances that the imported food is produced in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standard for produce safety), if either is applicable, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act hazards you have identified as reasonably likely to occur are adequately controlled.

(d) (1) Required supplier verification activities. You must determine and document which the supplier verification activity or activities listed in paragraphs (d)(2)(i) through (iv) of this section are appropriate and necessary for each imported food based your food hazard and supplier risk analysis and evaluation conducted in accordance with § 1.505 and considering the purpose of supplier verification activities under paragraph (c) of this section. You must determine and document how frequently the verification activities should be conducted based on these same factors.

...[Option 1/Option 2 omissions not included for clarity]...

(i) Periodic onsite auditing. You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier at intervals you determine to be appropriate to achieve the purpose of supplier verification activities under paragraph (c) this section.

(ii) Periodic or lot-by-lot sampling and testing of the food. You conduct (and document) or obtain documentation (such as a certificate of analysis containing the results of the testing) from your foreign supplier of lot-by-lot or periodic sampling and testing of the food for any relevant identified hazard.
(iii) **Periodic review of the foreign supplier’s food safety records.** You periodically review (and document) or obtain documentation of a review of your foreign supplier’s food safety records (such as records of your foreign supplier’s audit of its supplier’s hazard control activities).

(iv) **Other appropriate procedure.** You use any other procedure that you have established as being appropriate based on the risk associated with the food and supplier hazard. You must document your use of any such procedure.

(2) **Requirements of onsite auditing.** (i) An onsite audit conducted under this section must consider the FDA food safety regulations, if any, that apply to the food and foreign supplier and must include a review of the foreign supplier’s written food safety plan, if any, for the hazard being audited and the supplier’s implementation of such plan.

(ii) You must document the date on which an onsite audit under this section is conducted and any corrective actions taken in response to significant deficiencies identified during the audit. You are not required to make any other documentation regarding the audit, including written reports, available to FDA except as provided by 21 C.F.R. § 1.361.

(3) **Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.** Instead of an onsite audit conducted under paragraph (d) or (e) (g) or (h) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted and the supplier provides the importer with a copy of the complete Establishment Inspection Report (or foreign equivalent) and any other information requested by the supplier as necessary for their verification. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(4) **Review of results of verification activities.** You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (d) or (e) (g) or (h) of this section. If the results show that the supplier’s performance is not adequate, you must reassess the effectiveness of your FSVP under § 1.508 hazards identified as reasonably likely to occur with a food are not adequately controlled, you must take appropriate action in accordance with § 1.507(c).

(5) **Independence of qualified individuals conducting verification activities.** A qualified individual who conducts any of the verification activities set forth in paragraphs (d)(1) and (e) (g)(1) and (h) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.

(e) **Importers of certain produce.** For a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter, in addition to the other requirements of this section, before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, you must conduct one or more of the verification activities listed in paragraphs (dg)(1)(i) through (iv) of this section to
provide adequate assurances that your foreign supplier is producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112 of this chapter. An audit conducted under this paragraph is subject to paragraphs (dg)(2) through (5) of this section. You may conduct an activity under this paragraph in conjunction with an activity that you conduct in accordance with paragraph (dg)(1)(i) through (iv) of this section.

§ 1.508 How must I reassess the effectiveness of my FSVP?

(a) Timing. (1) Except as specified in paragraph (a)(2) of this section, for each food you import, you must conduct a reassessment of your FSVP for the food, as described in paragraph (b) of this section, within 3 years of establishing the FSVP and within 3 years of the last reassessment.

(2) You must promptly reassess the effectiveness of your FSVP for a food you import when you become aware of new information about potential hazards associated with the food or potential risks associated with the supplier, or if the results of your verification activities show that the supplier’s performance is not adequate.

(b) Reassessment and implementation of changes. In conducting a reassessment of your FSVP as required by paragraph (a) of this section, you must update your hazard and risk analysis for the food in accordance with § 1.505. If the hazards and risks you previously identified as reasonably likely to occur change as a result of the reassessment, you must promptly determine whether the verification activities you conduct under § 1.506 or § 1.511(c) need to be changed to comply with that section, and you must promptly implement any such changes. You must document each reassessment you conduct and any resulting changes to your FSVP.