January 27, 2014

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

Re: Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to issue Certifications (Docket No. FDA 2011-N-0146)

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments to the proposed rule entitled, “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to issue Certifications” (Docket No. 2011-N-0146/RIN 0910-AG66). In addition to this executive summary, PMA submits the attached document that provides specific, detailed comments on the proposal. PMA is the largest trade association representing companies in the fresh fruits and vegetables industry globally. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

The overarching objective for PMA is to increase the consumption of fresh fruits and vegetables on a global basis. PMA serves its members by providing a forum to make business connections and by providing them with the information they need to make decisions that will enhance their businesses and deliver fresh fruits and vegetables to consumers. It is in this role of educator that PMA’s food safety and technology efforts are focused. During the initial discussions on the Food Safety Modernization Act (FSMA), PMA provided industry expertise to congressional staff and FDA to help inform them of current science and industry practices. PMA is also a strong supporter of the development of fresh produce-based science as indicated by the association’s founding support of the Center for Produce Safety (CPS). CPS is a unique research foundation focused exclusively on produce-related food safety research in collaboration with
industry and government. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations benefit from CPS research.

In developing these comments to the proposed third-party accreditation rule, PMA staff has relied on numerous touch points with its members to gather feedback on those issues that resonated with them. We also engaged our Produce Safety, Science and Technology volunteer committee on several occasions to get their input and guidance. This committee is composed of industry experts from around the industry; small producers to very large, technology vendors, growers, processors, retailers and foodservice representatives. Their insights have proven to be invaluable in sorting through this proposed rule and developing comments based on their collective experiences with third-party auditing both domestically and internationally. We have also reached out to industry and regional association groups to gain their perspectives. We have participated as speakers in regional forums and events on food safety regulations and have met individually as well to discuss the impacts of this proposal.

Executive Summary

PMA is supportive of the FDA’s work to improve produce food safety as required by the Food Safety Modernization Act (FSMA). In previously submitted comments to the FDA on the proposed “Produce Safety” and “Preventive Controls for Human Foods” rules, PMA has indicated its support for hazard- and science-based standards for the produce industry. PMA understands the importance of these rules in preventing produce-related foodborne illnesses and is committed to improving the safety of fresh produce.

FDA states that the purpose of the proposed rule is to address the competence and independence of third-party auditors or certification bodies that will be authorized to perform foreign food safety audits and to issue certifications in two specific instances: (1) if FDA makes a determination that products from a specific country or region represent a serious public health risk to consumers in the U.S., or (2) if a company wishes to participate in the Voluntary Qualified Importer Program (VQIP). The proposed rule on “accreditation of third-party auditors/certification bodies to conduct food safety audits and to issue certifications” describes a system where FDA can recognize established accreditation bodies operating around the world based on the accreditation body’s competence and capability to conduct their oversight of third party auditors/certification bodies according to the requirements mandated by FDA. In situations where a credible accreditation body cannot be identified, FDA reserves the
option to act as a direct accreditor of third-party auditors/certification bodies. Similarly, FDA also describes rules that govern the administration and operation of third-party auditors/certification bodies to insure that food safety audits are conducted rigorously, reliably and without any potential conflicts of interest.

Food safety audits have been a focal point of industry conversation, frustration and proactive engagement for nearly 20 years. Food safety audits and the anxiety and re-affirmation they bring have essentially become a way of life for a large proportion of the produce industry. In a way, food safety auditing is where the rubber meets the road, where individuals all along the supply chain from farmer to harvester, processor to distributor, and retailer to foodservice buyer are engaged and submit to an evaluation of their food safety systems. The industry has wrestled with what standard they should be audited against and whether or not the level of rigor was appropriate for their specific commodity or production environment from the very beginning. But in reality the biggest source of frustration with food safety auditing for producers and buyers has been with the process itself: how the audit is conducted, the competency of the auditor, the scheduling of audits, record keeping, corrective actions communications, overall costs and from a supplier’s perspective, general acceptability of a specific audit to the buying community.

In the end, large segments of the produce industry have adopted third-party food safety auditing as an integral component of good business practices and have used this tool to improve corporate food safety programs. PMA members are pleased that FDA has chosen to build upon the globally recognized protocols for accreditation of third parties/certification bodies and for developing requirements that closely parallel those described by internationally recognized International Organization for Standardization (ISO) standards (17011 and 17021), Global Food Safety Initiative (GFSI) benchmarking guidance and other recognized entities. It is important that FDA recognize that our produce supply is global and as such, the practices and procedures we implement for auditing food safety be not only acceptable in the U.S., but also have firm grounding around the world. FDA’s utilization of internationally recognized frameworks should not only help the industry leverage existing infrastructure, but also facilitate increased confidence that foreign supplier auditing will be conducted in a rigorous and reliably consistent manner that reflects the food safety status of the growing, packing or processing operation.
This proposal on accredited third-party auditing uncovers several critical issues where PMA has focused its comments. Among these are:

- **How will FDA determine when an accredited third-party audit will be required?** The precise circumstances and decision points for how and when FDA will determine that specific products from a foreign country or region will require a third-party audit in order to be imported into the U.S. is important to understand and more clarification is required.

- **VQIP and accredited third party audits.** As these audits are proposed as a qualifying component of the Voluntary Qualified Importer program (VQIP), the industry eagerly awaits an opportunity to review the specifics of VQIP. This would aid FDA and the industry in determining or assessing accreditation body/certification body capacity issues around the world.

- **Transparency and balance.** We also need to further explore how FDA will balance the need for an open and transparent system for accreditation of third-party auditors/certification bodies with the equally important need to protect the proprietary business information of the eligible entities. This is a vital concern as the system needs to provide enough protection and value to participants to encourage companies to use third-party audits as a tool to monitor and communicate their food safety capabilities.

- **Capacity at FDA.** It will also be important to gain a better understanding for how FDA will develop the internal capacity to manage the large and complex process of approving and monitoring accreditation bodies and dealing with the data inputs from audits reporting potential public health risks and assessing how to use that data to safeguard public health.

- **English only?** The proposed policy of FDA accepting English-only documentation seems to be unrealistic in light of the global nature of the produce industry. It may also be an impediment to those exporters that want to build successful food safety programs and participate in programs like VQIP.

- **Unannounced audits.** The concept of unannounced audits is important for the credibility of the program and FDA has outlined a process that will insure audits are conducted within the framework of normal business hours and that the food safety documentation can be appropriately accessed and evaluated.
• **Importance of consultative audits.** It will be important to ensure that the food safety tool of “consultative” audits is unencumbered by a requirement to report observations directly to FDA. Consultative audits are important to producers to gauge readiness for subsequent third-party audits and to identify areas where improvements are warranted.

• **Ramifications of direct reports to FDA by accreditation and certification bodies.** It is understandable that observations of conditions that could seriously affect public health made by third-party auditors would be reported to FDA. However, careful consideration needs to be given to more fully developing and describing the process for how this is to be accomplished, the lines of communication that need to be opened with the audited entity and the recourse options for facilities and operations.

• **Domestic food safety audits.** Last, as this process moves forward, the industry is anxious to engage the agency to determine what impact this system of limited foreign accreditation and certification might have on universal accredited third-party auditing for domestic fruit and vegetable production. There are several areas of concern that require comprehensive evaluation around need, benefit, cost and capacity that must be considered.

In closing, PMA and its members look forward to continuing to work with FDA to create clarity around these issues, and we will work with our volunteer committees and other interested parties to construct positive commentary to assist the agency in shaping and finalizing the rule.

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of the proposed rules. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on the rules. Attached are those comments.

Thank you for the opportunity.

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“Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications”

Organization of comments

The proposed rule for “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications” is a comprehensive document broken into subject areas that include a general overview, definitions, proposed rules for accreditation bodies and proposed rules for third-party auditors/certification bodies. Several areas covered for accreditation bodies are then repeated when the rules turn to certification bodies as many of the issues have equal significance for both types of organizations. For example, conflict of interest, term durations, record keeping and reporting requirements are among those areas of focus that pertain to both types of organizations. We have commented where FDA has posed questions to the industry (and in other areas where no specific questions were included) and cross-reference comments made for both accreditation and certification bodies. To assist both FDA and our PMA membership in traversing the comments made here, we have organized them into specific categories and have also provided the titles (gray print) and relevant passages or paraphrased segments (blue print) from the proposed rules to provide context to our comments. The general categories we have organized around are as follows:

I. General and overarching points of consideration
II. General provisions – scope of coverage
III. Recognition of accreditation bodies
IV. Requirements for recognizing accreditation bodies
V. Procedures for recognition of accreditation bodies
VI. Accreditation of third-party auditors/certification bodies
VII. Requirements for accredited auditors/certification bodies
VIII. Procedure for accreditation of third-party auditors/certification bodies
IX. Additional procedures for direct accreditation of third party auditors/certification bodies
X. General requirements
The proposed rule covers much more than produce and while PMA believes these areas are of critical importance to the overall food industry, we have limited our comments and suggestions to produce and fresh cut or processed fresh produce. We have also not just focused on areas where we disagree or have alternative suggestions for FDA as we feel it is equally important to provide affirmation where we are in agreement with the agency.
I. General and overarching points of consideration

In the “Introduction” and “Background” sections of the proposed rule on “Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications,” FDA raises several general or overarching questions and seeks comment to help refine the proposal. These general areas and PMA’s comments are as follows:

U.S. Government Policies on Consensus Standards and Conformity Assessment
The current federal conformity assessment guidance provides for federal agencies to use, where appropriate, relevant guides or standards for conformity assessment practices from domestic and international standardizing bodies such as the Codex Alimentarius Commission (Codex), the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), and the American National Standards Institute (ANSI). The guidance also notes that each agency retains the responsibility and authority, to select the conformity assessment activities and procedures (e.g., guides and standards) that will best meet its legislative mandates and programmatic objectives (15 CFR part 287).

In developing the proposed rule, we considered several voluntary consensus standards, specifically ISO/IEC 17000:2004… We will address elements of ISO/IEC 17011:2004 that are relevant to this rule in our discussion of the proposed requirements for accreditation bodies in section IV.A.2 through IV.A.4.

In addition, we considered other ISO/IEC 17021: 2011…We also considered ISO/IEC Guide 65: 1996..These standards are among the relevant information we used in developing this proposed rule. We do not propose to incorporate these standards by reference into our regulations, because they contain additional requirements that are not relevant to our program and might unnecessarily create disincentives to participation.

Under the guidance at 15 CFR 287.4(b), we seek comment on the rationale for the conformity assessment decisions we have made in developing this proposal. In particular, we seek comment on whether the voluntary consensus standards we cite are the appropriate standards upon which to base this rulemaking. If alternative standards are suggested, we request that copies of any such standards be submitted along with the comment(s).

PMA Comment: PMA agrees with the current federal guidance that “each agency should coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary
duplication.” The application of internationally accepted audit standards in developing the framework for the proposed rule is also strongly supported by PMA, particularly the use of CODEX/WHO, ISO and ANSI as frameworks for the FDA’s program. These standards describe key aspects of accreditation bodies (AB’s) and certification bodies (CB’s), e.g., legal authority, competency, management practices, impartiality, quality assurance and record keeping practices. Certainly elements of these same standards have been employed in developing Global Food Safety Initiative (GFSI) benchmarking documents used to establish several standards currently employed within the produce industry.

**Voluntary Qualified Importer Program (VQIP)**

Facility certifications (as described in sections 806(a) and 808(c)(2) of the FD&C Act) will be used by FDA to help determine whether a facility is eligible to be a facility from which food may be offered for import under VQIP. The criteria and procedures for VQIP participation are outside the scope of this rulemaking. FDA plans to issue guidance on VQIP and will solicit public comment on VQIP at that time.

**PMA Comment:** PMA supports the concept of the Voluntary Qualified Importer Program (VQIP). In PMA testimony on March 29, 2011, for the Food Safety Modernization Act, we stated, “Because produce is perishable, the Voluntary Qualified Importer Program is of great importance to produce suppliers, who will welcome reasonable measures to speed border crossings. This will help relieve bottlenecks at the border, allowing FDA to better focus its resources. However, this will require having the third-party certification rules in place to work. FDA must resist the temptation to save this program for later and implement it as quickly as possible as it will provide immediate benefits to industry and FDA.” VQIP represents an opportunity for U.S. companies and others to reduce import delays for highly perishable products and PMA urges FDA to issue guidance on VQIP and seek public comment as soon as possible. However, it must also be recognized that since one of the key objectives of the Third-Party Accreditation rule is to lay out the requirements for audits and certifications that will be required to qualify for VQIP, it would be useful for the produce industry to be able to gain access to FDA’s best thinking on VQIP to see how this will dovetail with the current proposals. Absent details on VQIP, companies will find it difficult to plan or even assess how this current proposed rule will affect them. PMA encourages the FDA to issue details on VQIP participation and subsequent guidance as soon as possible.

**Import Certifications for Food: when will they be used?**
FDA will use certifications issued by accredited third-party auditors/certification bodies in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports… Section 801(q)(3) of the FD&C Act states the food certifications or other assurances used for purposes of section 801(a) of the FD&C Act may be issued by third-party auditors accredited under section 808 of the FD&C Act or by the government of the country from which such food originated, if we so designate (21 U.S.C. 381(q)(3)). The certifications or other assurances may take the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as we may specify.

**PMA Comment:** Certifications are required for imported food that “FDA has determined poses a food safety risk.” PMA supports FDA activities to ensure that foods that represent a public health risk are prevented from entering the U.S. However, it is important for the industry to understand how FDA will make the determination that a specific product poses a food safety risk. FDA describes some criteria that would influence their determination including: known food safety risks associated with a food, known food safety risks associated with a country, territory or region of origin of the food and any science- or risk-based finding FDA might make that determines the food does not meet the requirements of the FD&C Act. FDA has stated that foods entering the U.S. must be produced according to the food safety requirements as described in the Produce Safety rule and Preventive Controls for Human Foods rule (once finalized). What process will FDA use to make the determination that an article of food does not meet these criteria? Will FDA make this designation for an entire region (as indicated) or on a facility or operation basis? If FDA requires a certification in order for a product to be granted entry into the U.S., will all producers of that product in the specified region also be required to become certified? Once a determination is made that a product from a specified region must be certified for export to the U.S., what is the process for demonstrating that effective corrective actions have been implemented or that preventive controls are being used in specific operations such that certification might no longer be warranted? Also, further clarification is needed for “other assurances” that may be provided instead of food certifications. In what cases would “other assurances” be permitted and when would they not be permitted? It would benefit the produce industry if the FDA would provide a complete list of “other assurances” and the procedures for their use.
Third-Party Auditor Competence and Capacity

FDA understands from public comments and stakeholder meetings that industry and the conformity assessment community have concerns about access to sufficient numbers of qualified third-party auditors/certification bodies under current conditions. We also understand that some industry leaders have developed various strategies and plans for increasing auditor capacity. We request comments and information on the progress of these efforts and the impact the establishment of our program will have on accelerating these efforts. Given that this program is for food and facility certifications only for purposes of mandatory certification and VQIP eligibility under sections 801(q) and 806 of the FD&C Act (respectively), what effect, if any, do stakeholders anticipate this program will have on current capacity issues?

PMA Comment: PMA supports FDA’s concept of using private third-party audits to augment regulatory inspections. However, it is difficult to assess questions of auditor capacity at this stage without knowing how many certification audits will ultimately be needed. It is understood that FDA’s intention within the Foreign Supplier Verification Program (FSVP) to require third-party certification audits when foreign-produced foods are thought to be a potential threat to public health or for eligibility for the VQIP program is also a mechanism to encourage foreign suppliers to use third-party food safety audits as a tool to improve the safety of the products. FDA openly states that they hope to develop a program that will ultimately increase the use of third-party audits by foreign producers and/or importers.

At this early stage, it is difficult to determine whether the supply of available, qualified auditors will meet the FDA’s and industry’s needs to implement the finalized rule. Without understanding the process FDA will use to determine what products and which production regions might lead them to declare that certification audits are required for import into the U.S. in order to protect public health or the ramp up and scope of the projected VQIP program, it is difficult to be precise in these comments. However, we do know that while there are a number of very qualified food safety auditors working today both domestically and in production areas around the world, there have been issues around consistent auditing performance. Produce operators at the field, packing, cooling and processing levels have experienced third-party and regulatory audits where the auditor’s performance was less than ideal and the individual lacks experience in produce industry operations (though they may be experienced in other food industry segments). If this occurs during the implementation of this program, audited parties and the very operations that FDA would like to see begin using these tools on a more
regular, if not voluntary basis, will become disenchanted. More importantly, should FDA find reason to place a specific production region in a situation that requires certification audits, a deficit of qualified food safety auditors could severely impact execution of those audits and unfairly hamper fruit and vegetable exports to the U.S. from that specific area.

PMA suggests prior to finalizing either the FSVP or Third-Party Accreditation rules, FDA gain a more detailed understanding of potential pool of third-party auditors/certification bodies that might be available and trained on a country by country basis over the next five to 10 years (or during the ramp up and implementation of the proposed programs). More importantly, FDA should more closely examine the capacity of accreditation bodies to accredit certification bodies and certification bodies to recruit, develop educational programs and train auditors per the requirements laid out in this proposal with relevant experience in the food sector they will work in. FDA may also benefit from a food industry by product sector survey to understand how many companies might apply for VQIP status.

Lastly, in regard to capacity, FDA is proposing that in instances where, after two years of evaluation, and no qualified accreditation bodies can be identified then FDA will directly accredit CB’s to participate in the audit/certification program. It is unclear what capacity FDA has to undertake this responsibility. In which areas of the world, does FDA anticipate having to step into the accreditation role? What capacity does FDA have to make this determination and to carry out the accreditation process as outlined in this proposal?

**Balance: Consumer Confidence and Transparency**

As an initial matter, FDA notes that they are bound to implement FSMA as enacted and to comply with all other applicable disclosure laws (e.g., the Freedom of Information Act (FOIA) (5 U.S.C. 552). Within that legal framework, we have balanced the following competing public interests: (1) providing as much information to the public as possible about audits of foreign food entities and the performance of accredited auditors/certification bodies, so that individuals may assess the performance and credibility of the accredited third-party audits and certification program; (2) protecting the proprietary interests of food entities related to their trade secrets and confidential commercial information to the extent allowable by statute, as well concerns about public release of sensitive information that would not otherwise be publicly available; and (3) protecting the public health by being able to attract sufficient numbers of foreign food entities, third-party auditors/certification bodies, and accreditation bodies to make the
program cost-effective and otherwise successful. To gain credibility with consumers and address industry views on sensitive information, this proposed rule seeks to balance disclosure and confidentiality concerns. It reflects FDA’s views on how best to strike the balance between these and other competing interests. FDA believes this proposal reflects the intent of section 808 of the FD&C Act and the purpose of the law, offering a practical, flexible, and effective approach to the accredited third-party audits and certification program.

FDA seeks comment on the framework this proposed rule would create for recognition of accreditation bodies and accreditation of third-party auditors/certification bodies, how it aligns with existing voluntary industry programs, and what expectations consumers have for the ability of this program to help us ensure the safety of imported food.

PMA Comment: PMA appreciates that FDA has to find a balance between providing sufficient information to the public about audits of foreign food entities and the performance of accredited auditors/certification bodies, so that: (1) individuals may assess the performance and credibility of the accredited third-party audits and certification programs; (2) the proprietary interests of food production operations are protected in the context of their trade secrets and confidential commercial information (to the extent allowable by statute) as well as concerns about public release of sensitive information that would not otherwise be publicly available; and (3) public health is better protected by attracting sufficient numbers of foreign food entities, third-party auditors/certification bodies, and accreditation bodies to make the program cost-effective and otherwise successful. Recognizing that consumers want to be able to access relevant food safety information about their food, PMA supports FDA’s efforts at transparency in the third-party accreditation and food safety auditing rule and its focal points of use when FDA determines a country or region does not meet U.S. food safety standards or a company chooses to engage in the proposed VQIP. However, simply providing access to audits or audit scores is not enough. PMA encourages FDA to consider developing communication-messaging strategies to help consumers view the data within the context of food production. This communication should take place at two levels: (1) properly setting program expectations with consumers and (2) providing proper context for consumers to understand what the data mean. In setting program expectations, it is important for FDA, the industry and consumers to understand what value accreditation of third-party auditors is expected to bring regarding the safety of imported fruits and vegetables. Can the outcome of the implementation of this rule be quantified? What role do audits play in improving food safety versus other tools that might be employed by growers, packers and processors?
FDA states that transparency is a critical element of this proposal and that consumer
groups have offered comments at hearings and elsewhere that public disclosure of audit
reports is needed in order to gain consumer trust. The question remains as to the
extent and formats of the third-party audit data FDA intends to make public and what
might be held confidential. While PMA supports transparency, it is important to
understand that it is critically important to provide a frame of reference so that
consumers have a basis for understanding what the audit data means and can then
proceed to make informed decisions. On a more granular level, food safety standards
are used to develop question sets in the development of food safety audits that can be
quite complex. Experience also tells us that not all questions are as critical in terms of
threats to public health as others. For example, how will consumers interpret a
deduction on a third-party food safety audit for failure to store maintenance tools
properly versus a deduction for failure to maintain operate within expressed wash-water
parameters for pH control? While both are important aspects of operational food safety
programs and familiar to trained food safety professionals, failure to operate within
expressed wash-water parameters that affect the disinfectant properties of the wash
system would certainly be viewed as a higher priority, more directly impactful risk
concern by those who understand fruit and vegetable operations. Yet, how would a
consumer know this and be able to take actions based on this information?

Interestingly, it is this inability to properly interpret food safety audit data and understand
its context that has led many within the produce industry to be protective of audit data
(along with issues of proprietary protection; see below). To be sure, audit results and
even the raw data are frequently shared between producer and buyer within the
produce industry, but even that exchange is closely monitored. Part of the issue is a
misconception across the industry and more generally by most people about the value
of food safety audits. So much emphasis is placed on whether the audited entity
“passes” or “fails” the audit, that we lose track of the fact that the audit is only a tool to
measure compliance of the operation against their food safety plan. Equally important
is how the audited entity uses the audit to improve the food safety activities of the
operation, i.e., corrective actions. So while many in the industry are fearful of sharing
audit details between suppliers and buyers because a certain score or area of non-
compliance might be used to limit sales opportunities, the real value of the audit is as a
communications tool where the audited operation can share the level of compliance
they achieved during the audit with a buyer and further communicate their commitment
to food safety by sharing the corrective actions enacted as a result of the audit. In
creating messaging around food safety audits, FDA and others would be best served by
placing audits in perspective; they are but a tool that can be used to communicate compliance. We have certainly witnessed operations (including operations with government inspections, globally benchmarked audits and private third-party audits) with exemplary food safety audit scores that suffered subsequent breaches in food safety execution that contributed to recalls and illness outbreaks. Audits and certifications are not declarations or guarantees that products are safe, and FDA and the industry need to feature this reality in communications strategies aimed to assist consumer groups and consumers in using any audit data that might be available for review as a result of this proposed rule.

It is also important for industry to gain a better understanding of how FDA intends on collecting audit data, updated the data and presenting that data to consumers. What type of audit data will FDA require? Currently, FDA only notes deficiencies (FDA form 483); will this continue to be the reporting format required of accredited certification bodies/third-party auditors? Often an audit is really composed of the audit itself, auditor notes, notes taken by the person responsible for the operation, perhaps appended documents dealing with the operations procedures, test results of various kinds, personnel training records, etc., and corrective actions documents. Even with the seemingly limited scope of this proposed rule where third-party audits would be used only for foreign suppliers in countries or regions where FDA determines that products may pose a public health risk in the U.S. or for companies that choose to participate in VQIP, the potential number of audits, and therefore data that would need to be received, processed, reviewed and posted could be substantial over time. As audits are generally conducted at least once per production season, data will accumulate and need to be located or linked to previous data from the same operation in order to maximize its usefulness. This requires the development of a dynamic database and resources to update and maintain it. It is not clear how FDA intends to develop and maintain this system.

While PMA supports transparency and views audits as a communications vehicle to demonstrate compliance with an operations food safety plan and efforts made to improve performance, FDA and others need to recognize that within the context of an audit and the documentation that might accompany an audit, businesses do have a need to protect proprietary information that might compromise their ability to carry out business functions. Examples of the types of information that business may want to hold proprietary are sales lists, supplier lists, equipment designs and specific information about product attributes. The produce industry is a highly competitive
industry and these areas can be critical to maintaining competitive advantage. It will be important for FDA to recognize this issue and develop mechanisms to protect proprietary information while meeting the balance of supplying data to support food safety status. Industry and FDA should not underestimate the difficulty in sorting this issue out as effective management of information that protects proprietary information will require detailed review of documentation and a process that ensures consistent application of data standards. It will require knowledge of industry practices and an understanding of those elements that are truly important to protect. What considerations has FDA taken to keep confidential business information proprietary and will FDA take steps to protect information provided by certification bodies to FDA from FOIA?

FDA also states in the “Background” that section 808 (c)(5)(C) of the FD&C Act directs them to issue implementing regulations and that one aspect of these regulations is to require that “audits be unannounced.” This issue is included here in these comments because it speaks to FDA’s desire to provide transparency in the process of using third-party audits and certification to address potential food safety issues where they have determined there is need for public health concerns or expedited importation of food is permitted via VQIP. PMA believes that making the audits unannounced adds value to the activity as a tool for the audited entity and the buyer, regulator or even the consumer. The “unannounced” aspect of the audit protects against operations specifically “preparing” for the audit so that the operation does not really reflect daily activities at the time of the audit. It gives the audited entity a much more realistic view of their compliance status and a fair baseline from which they measure program improvements. The industry has seen a gradual move to unannounced audits over the last few years in some sectors, e.g., many who already used some of the GFSI benchmarked standards are familiar with unannounced audits and certainly the signatories to the California Leafy Greens Marketing Agreement covering leafy greens production. In both instances, the audited parties have adapted to unannounced audits and are subject to them as part of “doing business.” More broadly, all FDA regulatory inspections are unannounced and all sectors of the produce industry are subject to those requirements. FDA has provided reasonable measures to obtain the audited entity’s operational schedule to help insure the audit can be performed during normal hours of operation and related documents can be made available (see comments to §1.651). As FDA looks to build confidence with consumers and consumer groups, unannounced audits can be an important characteristic of the process.
Trade Impacts

FDA also requests stakeholder input on any possible trade impacts of the program, once established. What effect might this program have on the existing issues with auditor capacity? Will it affect foreign or domestic food firms’ ability to provide certifications to their customers? If so, are foreign and domestic firms likely to be affected in the same manner and to the same degree? If not, what are the likely impacts to each? Are there particular types of food firms or food products, or certain areas of the world in which capacity issues are more likely to be prevalent and to what degree?

PMA Comment: One of the basic tenets of the FSMA mandated Produce Safety and Preventive Controls for Human Foods proposed rules was that all foods, both domestic and imported would be required to be produced using the same food safety rigor. Therefore the basic risk- and science-based requirements placed on foreign entities are comparable to the ones placed on domestic entities. Still, the FDA has not proposed requiring third-party audits for domestic producers while they are proposing a requirement for certification audits of foreign facilities under specific circumstances. This important difference may encourage some countries to take retaliatory action particularly in countries with limited food safety oversight capabilities. The issue might be amplified by the lack of clarity around how FDA will make the determination that a food or a specific region or country might not be able to produce that food according to the production food safety standards in place in the U.S. It is important for FDA to more fully describe that process, the criteria to be used, and the public health science used to guide their decisions and remedial actions that might be taken by the producers, regions or countries affected.

As we have already commented, without knowing just how many audits will be required as this rule becomes final, it is difficult to be specific about questions of auditor capacity. Presumably, it is more likely that FDA might declare the need for third-party certification audits in regions or countries that do not have a food safety infrastructure already in place. Given this assumption, the auditing capacity and competency in those regions will likely not be sufficient to handle the workload should FDA require third-party audits as a prerequisite for export to the U.S. Capacity will also be a function of timing; if FDA determines that several regions within a country or a number of countries on a continent need to provide third-party certifications immediately after this proposal is finalized, the pool of qualified auditors in that region would likely not be capable of handling the immediacy of the need in order to permit export of unaffected products. Setting up the certification system will take time as will a determination of eligible entities. To facilitate
roll-out of the proposed rule, PMA encourages the FDA to develop country-specific implementation plans that include staged roll-outs that occur upon completion of predetermined milestones. Staged roll-outs provide the opportunity to test the capabilities of the accreditation bodies and accredited third-party auditors/certification bodies in a manner that issues can be identified and addressed. During this stage, issues with auditor availability and competency can also be addressed. After the initial roll-out is functioning, the country operation can be scaled up.

II. General Provisions – Scope of Coverage

Definitions and Scope (§1.600(a))

Proposed §1.600(a) contains definitions for several terms used in this rule. FDA proposes relying on existing statutory and regulatory definitions. Where necessary to provide clarity to this rule, FDA has developed some additional definitions that align with existing law and regulations, as well as current practices of the international community, accreditation and certification bodies and the food industry.

PMA Comment: Though many of these definitions are not identified by FDA as subjects they specifically request comment on, PMA is in general agreement with FDA on these definitions; e.g., accreditation, accreditation body, audit, audit agent, certification body, consultative audit, direct accreditation, facility, etc. FDA specifically asked the industry for input on the following:

“Eligible entity” - FDA defines an eligible entity as a foreign entity that chooses to be subjected to a food safety audit by an accredited auditor/certification body. Eligible entities include foreign facilities subject to the registration requirements of 21 CFR part 1, subpart H. FDA seeks comment on whether to provide examples of specific types of entities that may meet the definition of eligible entity. For example, are foreign cooperatives that aggregate product, such as fruits or vegetables, the types of entities that should be able to seek audits and certification under this program? We note that the National Organic Program (NOP) administered by the U.S. Department of Agriculture’s (USDA’s) Agricultural Marketing Service (AMS), allows producers who are located in geographic proximity, who are organized under a single management and marketing system and whose farms are “uniform in most ways” to be certified as a group. We seek comment on whether these NOP criteria are relevant in determining whether a foreign cooperative is an “eligible entity” under this proposed rule. Are there
other types of foreign entities or facilities that should be eligible to seek audits and certification under the FDA program?

**PMA Comment:** PMA supports FDA’s definition of an “eligible entity.” PMA is also supportive of the USDA NOP program, which permits producers located in geographic proximity, organized under a single management and marketing system and whose farms are “uniform in most ways” to be certified as a group. PMA believes the NOP program is a relevant example of where growers can be grouped together based on specific criteria to earn certification. It seems reasonable that foreign cooperatives that meet the same definitions used by the NOP where those entities in geographic proximity organized under a single management and marketing system and whose operations are “uniform in most ways” should be considered as eligible entities and could be audited and certified by a recognized third-party/certification body. Indeed, many commodities, e.g., asparagus, papaya and mangoes, are produced by small growers who have very small productions but who take their product to packing sheds and cooling operations to be packed with RACs from other growers. On their own, it might be difficult for these types of growing operations to seek and earn a third-party audit certification, but taken as a group as defined by the NOP criteria, the task would likely be more manageable.

**“Facility certification and food certification”** – FDA seeks comment on our proposed definitions of “facility certification” and “food certification” and on whether the scope of these definitions is sufficiently broad to fulfill the objectives of section 808 of the FD&C Act. In addition, we seek comment on whether to allow groups meeting the NOP criteria (i.e., having multiple sites operating under a single management system and whose farms are “uniform in most ways,” to be issued (group) food certifications, facility certifications, or both.

**PMA Comment:** PMA believes that the proposed definitions for “facility certification” and “food certification” are sufficiently broad to fulfill the objectives set out in section 808 of the FD&C Act. Using the proposed definitions, entities like foreign cooperatives or groups meeting the criteria currently in place and established by the USDA NOP would be eligible as a group to receive both food and facility certifications subject to ISO requirements for awarding those certifications.

**“Consultative audit”** – means an audit of an eligible entity: (1) to determine whether such entity is in compliance with applicable requirements of the FD&C Act and industry standards and practices and (2) the results of which are for **internal purposes only**
and cannot be used to determine eligibility for a food or facility certification issued under this subpart or in meeting the requirements for an onsite audit of a foreign supplier …

PMA Comment: PMA is offering a comment here because the concept of a consultative audit is important in the produce industry. Specifically, we wish to comment on Table 1 of the proposed rule, which indicates that the audit report does not need to be submitted to FDA. PMA supports this view as it is important for operations all along the produce supply chain to be able to use consultative audits to measure themselves and determine what improvements they might need to make in order to fine tune their organizational food safety programs and eventually earn food safety certification. It is appropriate to keep consultative audits for internal use only so that entities that might seek an audit to qualify for VQIP can “test the water” so to speak and use the output to improve their programs. This is consistent with one of FDA’s objectives in building a system that encourages operational entities to use third-party audits.

Who is subject to the proposed rule? (§1.601)

As described in the “Summary of Major Provisions of the Proposed Rule,” this rule would apply only to entities that voluntarily participate in FDA’s accredited third-party audits and certification program, which would be the following: (1) accreditation bodies seeking recognition, or recognized, under this program; (2) third-party auditors/certification bodies (including audit agents) that seek accreditation, or are accredited under this program; and (3) eligible entities that seek food safety audits from, or that are audited or certified by, accredited auditors/certification bodies under this program, except for an eligible entity that meets the criteria for exemption under section 116 of FSMA. FDA invites comment on the scope of this proposed rule, including comments on its anticipated effects on accreditation bodies and third-party auditors/certification bodies already performing these activities, or that may be interested in doing so. FDA also seeks comment on its anticipated effect on foreign food facilities and other eligible entities that are currently audited by third-party auditors/certification bodies.

PMA Comment: The scope of the proposed rule seems appropriate and is well characterized within the body of the rule. There is no doubt that if these rules are finalized, there will be a significant impact of existing accreditation bodies and third-party auditors/certification bodies. These rules are not being promulgated in a vacuum; there are currently accreditation bodies and third-party auditors operating around the
world that are going to be faced with the reality that they may need to alter their basic operational practices or fine tune procedures in order to accredit, audit or issue certificates under the conditions set forth by the rule. As FDA has developed this proposal based on existing, internationally recognized standards, the gap might not be very great for those accreditation or certification bodies that are already compliant with these standards. One suspects that accreditation bodies might have an easier path to becoming compliant under FDA’s proposal than perhaps some certification bodies/third-party auditors that have operated as independent businesses and may not have been focused on some of the administrative and operational aspects described in the FDA proposals. In any event, accreditation bodies and third-party auditors/certification bodies will need to make a business decision; i.e., is the market for performing audits under the rules laid out by FDA sufficient to warrant the investment in training, personnel and infrastructure to pursue recognition by FDA. These decisions will ultimately affect capacity of available accreditation bodies and subsequent third-party auditors/certification bodies to operate in specific regions of the world.

III. Recognition of Accreditation Bodies

Who is eligible for recognition? (Proposed § 1.610)

FDA invites comments and examples (in particular, examples from regulatory programs) in support of, or opposition to, using an accreditation body’s status as a signatory to an IAF MLA as the sole criterion for recognition or as a factor weighing in favor of an application for recognition under the accredited third-party audits and certification program.

PMA Comment: PMA supports using an accreditation body’s status as a signatory to an IAF MLA as a factor weighing in favor of an application for recognition under the accredited third-party audits and certification program. The IAF multilateral recognition arrangement requires signatories to conform to ISO/IEC 17011:2004, which is also a GFSI requirement for food safety scheme owners. PMA supports the concept of documented compliance to ISO/IEC 17011:2004 as a key qualifying determinate in recognition of an accreditation body.

Using IAF MLA signatory status as sole criterion for recognition should be further investigated by FDA. It is not clear that how many producing countries exporting produce to the U.S. have signatory IAF MLA members representing them.
What legal authority must an accreditation body have to qualify for recognition? (Proposed §1.611)

Proposed §1.611 would allow both governmental bodies, with accreditation authority inherent in their roles as public officials, and private bodies, who have authority under contracts with third-party auditors/certification bodies, to qualify for recognition if they have the sufficient authority to conduct accreditation activities. This include adequate authority to access records; to conduct onsite performance assessments, reassessments, and surveillance; and to grant, modify and remove accreditation status.

FDA invites comment on our proposal to require accreditation bodies to have demonstrable evidence to support a conclusion that they would have adequate legal authority to meet our requirements (e.g., authority to withdraw accreditation for cause), if recognized. We also seek examples of other types of evidence that might demonstrate the scope of an applicant’s legal authority. For comments opposing this requirement, we request comment on what, if any, requirements we should put in place to ensure that an accreditation body applying to us for recognition would be equipped, upon recognition, to perform the obligations required under the program.

PMA Comment: PMA agrees with the FDA that accreditation bodies must have demonstrable evidence to support the conclusion that they would have adequate legal authority to meet the FDA’s requirements. Proposed §1.611(b) further stipulates that accreditation bodies should be able to demonstrate that they have adequate legal authority to assess third-party auditors/certification bodies for accreditation, perform self-assessments, submit reports and notifications to FDA, implement procedures to protect against conflicts of interest, establish and maintain records and follow the applicable procedural requirements of the FDA program. These requirements are reasonable and logical.

IV. Requirements for Recognized Accreditation Bodies

How must a recognized accreditation body assess third-party auditors/certification bodies seeking accreditation? (Proposed §1.620 through §1.625)

Proposed §1.620 describes several requirements for how an accreditation body must assess third-party auditors/certification bodies seeking accreditation. The proposals
under this section deal with recognition of foreign governments/agencies to qualify as accreditation bodies, requirements for accreditation bodies to assess third-parties/certification bodies using FDA’s model accreditation standards, requirements on observations the accreditation body must make in order to accredit a third-party auditor/certification body, maintenance of records, etc. PMA has focused on the following:

Proposed § 1.620(b) – Conditions of accreditation: A third-party auditor/certification body would have to comply with the requirement in section 808(c)(4)(A) of the FD&C Act to notify FDA immediately upon discovering, during a food safety audit, a condition that could cause or contribute to a serious risk to the public health, as a condition of its accreditation. Having timely notification of such risks directly affects FDA’s ability to respond rapidly to protect the public health. FDA believes this notification requirement is of such a critical nature that, we are proposing to require compliance as a condition of accreditation. FDA seeks comment on our tentative conclusion to require compliance with section 808(c)(4)(A) of the FD&C Act a condition of accreditation.

PMA Comment: PMA supports having third-party auditor/certification bodies notify the FDA immediately upon discovering a condition that is a threat of serious adverse health consequences or death to humans or animals during a food safety audit. The produce industry is committed to producing safe food and as such, any food that might be compromised should be removed from commerce and corrective actions taken to prevent reoccurrence. A well understood, documented system to report situations where public health might be compromised by a specific product from a specified operation would benefit the produce industry by removing some of the uncertainty commonly experienced when we are in the early stages of a product recall. However, the decision on what constitutes “a condition that could cause or contribute to a serious risk to public health” needs to be better understood by the industry. FDA needs to define what those conditions might be and the process, science and historical evidence for making that determination. Clearly, FDA’s best thoughts on this subject are already contained within the proposed “Produce Safety” and “Preventive Controls for Human Foods” rules. However, those proposals identify potential risk factors which if left unmanaged can lead to contamination and perhaps illness. PMA certainly supports FDA’s efforts in developing these proposals and we have made extensive comment on critical aspects of these documents. Identification of actual conditions that would precipitate a notification to FDA seemingly represents a different level of rigor. This is a daunting task; short of a pathogen contaminated sample of a product in hand, determination of a verifiable public health risk is difficult.
So much of determining potential contamination hazards is dependent on specific growing, harvesting, packing, cooling, storage and processing operational practices. Regionalized production practices, crop characteristics and intended use are also factors in determining potential contamination hazards and subsequently public health risks. It is often interesting and frustrating to read FDA investigative reports following a foodborne illness event where conditions in the field or packing facility are described. Observations are included and cited as potential contributing factors to potential contamination even though those same observations could be made at hundreds or perhaps thousands of production operations around the world. For example, water on floors of packing houses, cracks in concrete floors, animals in proximity to fields and other observations of a similar nature are reported yet these conditions are common to many fruit or vegetable production operations. Without linking data that show contamination actually resulted from these observed potential risk factors, we really do not know that they played a role in the subsequent event. Similarly, there are many incidences with current third-party auditing along the supply chain, where well-intentioned but perhaps poorly trained auditors identify an issue during an audit and call it out even though the science or operational facts do not support their position. Even though auditor training is a requirement of this program, we can reasonable anticipate that there will be variability between auditors (we see this today in regulatory audits and audits conducted against benchmarked schemes) and how does the industry protect against misinterpretation by the auditor of the actual risk?

Therefore, FDA needs to be very clear in what constitutes conditions that they would see as cause for an accreditation body or certification body to report to FDA. FDA needs to clarify for auditors/certification bodies examples of what constitutes a threat of serious adverse health consequences. Training and actual produce industry experiences are going to be key elements of making the system workable for both regulatory as well as third-party audits. In the end, the audit and the inspection process by themselves will not be sufficient to make a determination of whether public health might be compromised. The audit and observations need to be placed within a framework of the known science, hazard analysis, the food safety program of the operation, the product, regional production practices and ultimately the products’ intended use. The data must be given context in order to be used to make the determination of public risk or safety. Additionally, FDA should consider aligning this process with existing requirements associated with product recalls and the Reportable Food Registry.
What reports and notifications must a recognized accreditation body submit to FDA? (Proposed § 1.623)

FDA invites comment on our proposal to require submissions in English and to require translation or interpretation services as necessary. For comments in opposition, we seek input on how FDA might address translation and interpretation issues in a manner that is not overly burdensome or infeasible for the Agency and for submitters. How can FDA mitigate indirect effects on others submitting applications or requests? For example, is there a limit on the amount of time or resources FDA should spend translating and processing an application submitted in a foreign language? Are there other factors we should consider in deciding whether to require submissions in English and translation and interpretation services where necessary?

PMA Comment: §1.623 describes several requirements for reports and notifications that must be submitted to FDA by accreditation bodies. Reports or notifications are triggered: (§1.623(a)) within 45 days after completion of required annual assessments of accredited auditors/certification bodies, (§1.623(b)) within 45 days of completion of their annual self-assessments, (§1.623(c)) immediately when the accreditation body grants accreditation to an auditor/certification body or when they withdraw, suspend or reduce the scope of an accreditation, (§1.623(d)) within 30 days after denying accreditation to an auditor/certification body and (§1.623(d)(2) within 30 days if the accreditation body makes significant changes that would affect compliance with recognition requirements. PMA supports the requirements laid out by FDA and agrees with FDA that setting timelines will enhance FDA’s ability to monitor the program.

FDA also states that the reports and notifications described in §1.623 (and elsewhere in the proposed rule) be submitted to FDA in English. Further, FDA proposes that when applications or requests require interpretation or translation services, these services be provided by the submitter. The immediate answer to FDA’s request on whether it is appropriate to submit documents in English or provide translation services is that these documents are being prepared for consideration by the U.S. FDA to permit import into the U.S. where English is the language in which business is transacted. However, the produce industry is a global industry and consumers depend on a year-round supply of fresh fruits and vegetables, which demands the participation of global producers where English might not be the language of commerce. PMA recognizes that FDA has limited resources and it is vital in monitoring this program for FDA to be able to understand the required documentation that supports this program so that appropriate decisions can be
made to uphold the integrity of the third-party auditing program and protect public health. However, PMA suggests that FDA explore technical translation and recognition software that might permit at least some documentation to be submitted in a specified list of foreign languages. If the documentation is developed with an eye towards standardization and the need to permit or facilitate translation, technology might permit document submission in more than just English. FDA states one of their objectives is to create a system where operations increase their use of third-party audits to help improve food safety performance. Certainly exploring alternative options to the “English-only” requirements would help FDA achieve this objective by making data and document submission by accreditation bodies and third-party auditors/certification bodies easier and by extension making it more practical for audited entities. It is reasonable that FDA might initiate the program, after these proposals are finalized, with English-only documents but move to broaden the permissible language spectrum shortly thereafter based on their analysis of regions or countries where they begin requiring third-party audits to gain entrance to the U.S. markets or where the greatest interest is shown by industry to participate in the VQIP.

How must a recognized accreditation body protection against conflicts of interest? (§1.624)

*FDA seeks comment on whether to define de minimis value according to the limits established for U.S. Government employees for accepting gifts or gratuities.*

*While FDA does not believe that information on timing of payment of fees would be protected from disclosure under existing disclosure laws, they seek comment on this matter.*

*FDA seeks comment on the tentative conclusions identified here, namely that they should require recognized accreditation bodies to: (1) Have a written program to safeguard against conflicts of interest; (2) include the interest of any affiliate, parent, or subsidiary of a third-party auditor/certification body within the scope of interests covered by the accreditation body’s conflict of interest program; (3) impute the interests of immediate family members of an officer, employee, or other agent to such officer, employee, or other agent; and (4) maintain on its Web site a list of its accredited auditors/certification bodies, including duration and scope of each such accreditation, and information about the timing of payments by each such auditor/certification body. For interested parties recommending alternative approaches regarding public disclosure*
of payments, FDA requests that such comments be accompanied by any examples or other information to describe or support the recommended approaches.

FDA also seeks comment on whether there are conflicts other than financial interests of recognized accreditation bodies that should be addressed in these regulations. For any comment recommending that we address other types of conflicts, FDA seeks recommended measures to address such conflicts, any documents or references that are available to support the recommendation, and input on whether similar measures should apply to accredited auditors/certification bodies under this program.

**PMA Comment:** PMA agrees with the FDA’s statement that, “nothing short of rigorous safeguards will offer the transparency and credibility we believe necessary for our oversight of, and consumer confidence in this accredited third-party audits and certification program.” PMA suggests that rigorous safeguards to protect transparency and credibility are equally important to those that will operate businesses that will be subject to third-party audits. If the audited entities lose confidence that the system is balanced and properly managed, then they will ultimately fail and businesses will not opt to participate in the VQIP program and the spectrum of growers required to use third-party audits to facilitate export to the U.S. will diminish. Protection against accreditation body conflict of interest is an essential safeguard for this program. Maintaining a list of accredited auditors/certification bodies would indeed be very useful to the produce industry and consumers alike. PMA certainly understands FDA’s concerns over financial payment schedules, but also recognizes that certain aspects of business operations need to be held proprietary. Perhaps FDA could consider requiring accreditation bodies to keep records of financial transactions and make those records available to FDA should FDA have reason to examine them.

**What record requirements must a recognized accreditation body meet? (§1.625)**

We have tentatively concluded that the records identified and the records maintenance and access requirements in proposed §1.625 are necessary for us to adequately monitor recognized accreditation bodies, as directed by section 808(f) of the FD&C Act. We understand that accreditation bodies frequently include confidentiality provisions in standard contracts with third-party auditors/certification bodies. Many of those contract provisions may, in the past, have prevented disclosure of these records to us. If so, the requirements of proposed §1.625, would require revisions to such contracts (and perhaps other documents) establishing and limiting the scope of an accreditation body’s authority to grant us records access. We believe that such access is necessary for us to
conduct the monitoring required by section 808(f) of the FD&C Act and to otherwise exercise adequate oversight of the accredited third-party audits and certification program. We seek comment on this tentative conclusion and on the specific requirements we propose in this section.

PMA Comment: PMA agrees with FDA that it can be important for the agency to have access to an accreditation bodies records as defined under §1.625. As has already been discussed, maintaining the integrity of the food safety auditing system is of paramount importance to those being audited and to consumers who rely on the fruits and vegetables they purchase being safe. §1.625 also requires accreditation bodies to maintain their records for five years and that these records are in English. PMA agrees with FDA on the five-year timeframe as the purpose is to be able to look at performance over a reasonable time window and make decisions on renewal of recognition of the accreditation body by FDA. Again, we have already commented on the “English-only” mandate and find this to be unacceptable. The produce industry is a global industry sourcing products daily from all over the world and as such FDA needs to be able to accept records in languages besides English: perhaps identifying three of four additional languages commonly used in fruit and vegetable production regions that export to the U.S. and add them to the requirement.

§1.625(b) requires a recognized accreditation body to make records available to FDA for inspection and §1.625(c) prohibits a recognized accreditation body from preventing or interfering with FDA’s access to its accredited auditors/certification bodies and the records of the auditors/certification bodies. FDA calls out the fact that many accreditation bodies have confidentiality agreements in place with third-party auditors/certification bodies written in as part of their standard business contracts and this confidentiality clause has been used to block FDA access to records in the past. FDA proposes that these contracts be rewritten to limit the scope of an accreditation body’s ability to limit access to records by the FDA. This is a difficult question in that FDA maintains that they need access to records to exercise adequate oversight of the accreditation and certification program and oversight is a critical aspect of this program. Yet documents that may be part of an audit/inspection process may contain critical business information that authentically merits some level of proprietary protection in order to protect the audited entity, the certification body and the accredditor. PMA encourages FDA to explore ways in which proprietary information can be protected while still providing the agency access to information that permits them to properly manage the system and provide the basis for credibility and transparency needed.
Perhaps there is a tiered way to provide documentation to FDA that might still meet the needs of providing oversight and protect the public. For example, perhaps accreditation bodies could provide “summary reports” that identify specific companies that are accredited by the accreditation body and results of certification body audits to facilitate oversight, but could these reports be constructed so that proprietary information is omitted? In the vast majority of cases, business information can be protected. Of course, if there are observations of conditions that pose a credible threat to public health, then FDA would need access to all records to support causative investigations.

V. Procedures for Recognition of Accreditation Bodies

How do I apply to FDA for recognition or renewal of recognition? (§ 1.630)

We tentatively conclude that the application procedures in proposed §1.630 are reasonable requirements for accreditation bodies to meet. We believe that an accreditation body having the competency and capacity to qualify for recognition under the criteria in proposed §1.610 would be similarly capable of meeting the application requirements in proposed §1.630. Requirements for electronic, English language communications are necessary for us to make well-informed and timely decisions on applications and to conduct appropriate oversight of accreditation bodies, once recognized. We seek comment on these conclusions and the proposed requirements of §1.630.

PMA Comment: §1.630 speaks specifically to accreditation body applications to FDA for recognition and renewal. As detailed in our comments to §1.623 regarding English-only documentation on reports of self-assessments and other administrative activities, PMA strongly urged FDA to consider acceptance of other languages common to the major production areas exporting product to the U.S. during the course of a year. The basis for this comment was the global nature of produce supply to the U.S. and the objective of being inclusive and encouraging supply chain participation in third-party auditing programs as tools to improve food safety. It is our assumption under §1.623 that some of the documentation would include materials directly from the certification body and the audited entity and that it might be difficult for them; especially the audited entity to provide food safety documentation in English. Indeed, it might not even be desirable to translate food safety documentation from a native language to English and key information could be lost in the translation process if the translation is done by a
person not familiar with the specific practices of the audited operation. For §1.630, the application and renewal information is specifically defined and FDA makes a reasonable argument that any accreditation body with the capabilities of meeting the criteria outlined in the proposed rule and in other similar international standards should have the ability to provide English language application/renewal documents. PMA encourages FDA to consider broadening their language requirements to more accurately reflect the major production areas that export to the U.S. Perhaps the agency could develop a phased timeframe where initially as the program gets up and running applications would be in English, but more flexibility would be built in over time so that applications/renewal documents as well as other documents described in this proposal would be permitted in other languages.

**Duration of recognition (§ 1.632), revocation of recognition (§1.634) and reinstatement (§1.636)**

FDA poses a number of questions regarding procedures for accreditation bodies in addition to the English language requirements just discussed. These deal with application reviews, duration of recognition, monitoring accreditation bodies, revocation of recognition and the process for reinstatement. More specifically:

*FDA seeks comment on proposed §1.632 and the factors we considered in developing it. FDA does not claim to have compiled an exhaustive list of government programs for approving accreditation bodies and are interested in comments offering other examples that are relevant to the type of program we are establishing. To the extent that an alternative term of recognition is suggested, FDA seeks any information that can be provided in support of such alternative.*

*FDA solicits comment on our tentative conclusions regarding possible grounds for revocation (§1.634), particularly revocation for cause. FDA seeks examples that commenters believe do or do not represent good cause for revocation. We also solicit input on our proposal to use the informal hearing procedures set out in part 16 for challenges to a revocation decision.*

*FDA believes that a new application would be an appropriate requirement for an accreditation body that had been previously shown not to be in compliance with the requirements of this rule, and any conditions we imposed on its recognition. FDA seeks comment on this tentative conclusion and on the requirements we propose in § 1.636 for reinstatement of recognition.*
**PMA Comment:** PMA supports FDA’s rationale for duration of recognition (§1.632) of up to five years with shorter durations awarded early in the program for accreditation bodies with little experience in accrediting certification bodies/third-party auditors. FDA states they can revisit the duration as they and presumably the accreditation bodies gain experience with the program.

§1.634 describes conditions or issues that would cause FDA to revoke recognition from an accreditation body. Among these circumstances would be an accreditation body’s refusal to permit FDA access to records, assessments or investigations or to conduct audits, assessments or investigations (§1.634(a)(1)); failure to take timely and necessary corrective actions (§1.634(a)(2)(i)), fails to take actions on deficiencies uncovered in self-assessments (§1.634(a)(2)(ii) and fails to implement corrective actions offered by FDA (§1.634(a)(2)(iii)); if the accreditation body commits fraud and/or submits documents with false statements (§1.634(a)(3)); and if an accreditation body commits an act not covered by the previous regulations, e.g., failure to adequately support accreditation decisions.

PMA supports FDA conclusions under §1.634(d) where if an accreditation body’s recognition is revoked, the certification body’s/auditor’s would remain in effect provide the certification body/auditor conducts a self-assessment and reports its results to FDA within two months. This protects the certification body and the entities it performs audits on from undo harm as a result of the accreditation body failing to adhere to finalized rules. PMA also agrees that providing the certification body/third-party auditor one year to transition and become accredited with another accreditation body is a reasonable concept providing there is sufficient capacity. In many countries there may be only one accreditation body available and should that accreditation body lose recognition, certification bodies operating within the scope of that accreditation body may find re-accreditation difficult within a one-year timeframe. FDA admits itself that there may not be suitable accreditation bodies in some regions and that they may have to take on that role. Given that admission, we are concerned that re-accreditation may be a difficult process in some areas of the world and that capacity needs to be considered in setting timeframes.

PMA has the same concerns regarding §1.634(e) where the certifications earned by audited entities will remain in effect for the duration of their tenure if an accreditation body fails to remain eligible. PMA agrees with FDA that the audited entities should not be penalized, but we have concerns regarding capacity should the certification body have to become re-accredited within one year and then the impacts of that process on
scheduling certification audits. PMA has suggested elsewhere in these comments that FDA should assess accreditation capacity in key production regions around the world and use that baseline information to inform timeframes on re-accreditiation of certification bodies/third party auditors.

VI. Accreditation of Third-Party Auditors/Certification Bodies
This area of the proposal covers the requirements for third-party auditors/certification bodies. Many of the requirements are similar to those described for accreditation bodies but reframed within the context of the certification body/third-party auditor. PMA offer specific comments on the following:

Who is eligible for accreditation (§1.640) and what legal authority must a third-party auditor/certification body have to qualify for accreditation? (§ 1.641)

*FDA seeks comment on this tentative conclusion and our proposal to require third-party auditors/certification bodies to have demonstrable evidence to support a conclusion that they would be capable of meeting our requirements, if accredited. For comments opposing this requirement, we seek comment on what, if any, requirements we should put in place to ensure that a third-party auditor/certification body seeking accreditation would be equipped, upon accreditation, to perform the obligations required under the program.*

**PMA Comment:** PMA supports FDA’s assertion that certification bodies/third-party auditors should be able to demonstrate they have legal authority to operate and that they have the systems, programs and standards in place to capably determine that those seeking certifications meet FDA requirements for foods manufactured, processed, packed or held to import into the U.S.

What competency and capacity must a third-party auditor/certification body have to qualify for accreditation? (§1.642)

*The proposed rule would require third-party auditors/certification bodies seeking accreditation to demonstrate adequate resources to fully implement their auditing and certification programs.*

**PMA Comment:** PMA supports FDA’s contentions that certification bodies should be able to demonstrate that their auditors and audit agents have the competency, i.e.,
knowledge, skills and experience to perform credible audits. FDA promises to provide detail in the model accreditation standards as to what types of expertise and training are expected of auditors so we can only comment conceptually, and we look forward to seeing more specifics from FDA. FDA points out the importance of auditor competence in the proposed rule and draws the parallel emphasis placed on this issue in international standards for certification bodies. PMA encourages FDA’s continued reliance on existing international standards in this area.

What quality assurance procedures must a third-party auditor/certification body have in place to qualify for accreditation? (§1.644)

The proposed rule would require third-party auditors/certification bodies seeking accreditation to have quality assurance procedures in place. Proposal §1.644(a) requires a “written program for monitoring and assessing the performance of its officers, personnel and other agents. The program must include procedures for identifying areas for improvement and quickly executing corrective actions”.

PMA Comment: PMA supports FDA’s proposal on quality assurance programs for certification bodies. Despite rigorous efforts to standardize audits and their execution, so much of auditing comes down to individual auditor performance and capability. Complaints around frustrating experiences with auditors often come down to the individual’s execution of the audit and follow up after the audit is complete. Inclusion of a requirement for quality assurance that includes personal performance may help create more consistency in the process. Many leading auditing companies/certification bodies already have these procedures in place.

VII. Requirements for Accredited Auditors/Certification Bodies

How must an accredited auditor/certification body ensure its audit agents are competent and objective? (§1.650)

This section of the proposed rules (§1.650 to §1.658) deals with proposed requirements for third party auditors/certification bodies accredited by recognized accreditation bodies or FDA. FDA has asked for comments on specific areas:

FDA seeks comment on the requirements they propose to ensure that audit agents are competent and objective (§1.650) and on any other requirements necessary to achieve this objective. In particular, FDA seeks input on whether they should place other
requirements or limitations to help ensure auditor competency. Any recommendations that are based on common industry standards or practices should be so identified.

PMA Comment: §1.650 generally requires accredited third-party auditors/certification bodies to ensure that any audit agents are competent and objective. FDA goes on further in §1.650(a)(1) to require certification bodies to use audit agents that “have knowledge and experience to conduct food safety audits within the scope of its accreditation” and that “competency and independence must be determined by observation of the audit agent conducting a food safety audit using the requirements of the FD&C Act…” There are additional proposals guarding against conflict of interest between the auditing agent and audited entities and §1.650(a)(5) “requires audit agents to agree to notify their certification bodies immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health, cross-referencing proposed §1.656(c), which requires the accredited auditor/certification body to immediately notify FDA of such condition. Proposed §1.650(a)(5) reflects the language of section 808(c)(4)(A) and (c)(4)(B) of the FD&C Act, which requires notification based on conditions found during an audit and identifies “audits” as both consultative and regulatory audits. To ensure that roles and responsibilities of the audit agent and accredited auditor/certification body are clearly delineated, proposed §1.650(a)(3) places the audit agent under an obligation to report to its auditor/certification body immediately upon discovering a notifiable condition. Having been informed by its agent, the accredited auditor/certification body must then immediately notify FDA, under proposed §1.656(c).

PMA certainly supports FDA’s proposal that audit agents be knowledgeable and have the experience to perform food safety audits within the scope of the accreditation. PMA further acknowledges the importance of the audit agent being free of conflicts of interest. In addition, PMA supports FDA’s proposal that an audit agent has an obligation to report “conditions that could cause or contribute to a serious risk to public health” to the accredited certification body. The produce industry has a commitment to product safety and certainly identifying and correcting conditions that may be a source of product contamination is consistent with that requirement. However, we would raise the same concern here that was raised earlier in this comment document: how will FDA define conditions that pose a serious risk to public health? Is the FDA referring to SACHODA risk? Should an audit agent observe a condition that they determine might pose a threat to public health during a third-party audit and report it to FDA, what is the process that might be followed by the audited entity to gain notice of the report to FDA,
communicate with FDA (or the certification body), develop and implement corrective actions and communicate those to FDA? How will FDA communicate with the audited entity? PMA requests that FDA clarify the process to be followed should a “condition that poses a serious health risk” be observed and reported by an audit agent.

PMA also requests clarification as to whether FDA will require audit agents to report serious risks found during a consultative audit intended only for internal company use? Table 1 and the definition listed for “consultative audit” in §1.600 of this proposed rule indicates that an audit agent performing a consultative audit for internal, educational purposes of the audited entity would not be obligated to report results or observations of the consultation to FDA. Consultative audits are an important educational tool to enable operations to benchmark their status on the way to earning food safety certifications; especially for small- to mid-size operations with little experience in food safety auditing.

Last, §1.650(c) imposes statutory restrictions on audit agents conducting regulatory audits. More specifically, FDA proposes that an audit agent may not conduct a regulatory audit of an eligible entity if they have conducted a consultative or regulatory audit for the same operation within the previous 13 months. PMA supports this proposal as it provides protection against potential conflicts of interest.

How must an accredited auditor/certification body conduct a food safety audit of an eligible entity? (§1.651)

*FDA seeks comment on their proposed approach for “unannounced” audits, including whether it is feasible and appropriate. We also request information on current industry practice on arranging audits--e.g., does industry commonly provide an auditor/certification body information about its operating schedule? If not, what other means are used to ensure that the auditor/certification body visits a facility at the appropriate time to conduct the requested activities? For comments suggesting other approaches, FDA requests information on the practical implications of the recommended alternate approach(es).*

**PMA Comment**: Proposed §1.651 sets out requirements for planning and conducting audits. These include obtaining basic information from the eligible entity on the type of audit requested (so the certification body can determine which audit agent to use based on qualifications, potential conflicts of interest or previous interactions that might violate the 13-month period described in §1.650(c). This proposal also requires the
auditor/certification body to obtain from the eligible entity their operating schedule for the next 30 days so that the “unannounced” audit can be conducted during scheduled working hours. This requirement is also a feature of ISO/IEC 17021:2011 standards and other audit schemes known to the produce industry. Additionally, the eligible entity and the certification body are expected by FDA to enter into a contract whereby the third-party auditor/certification body would be granted access to documents needed to complete the audit. FDA proposes to require third-party auditors/certification bodies to “first review an eligible entity’s food safety management systems (e.g., records) before conducting an onsite safety audit at the facility.”

PMA believes unannounced food safety audits are feasible and appropriate. PMA supports FDA’s requirement for obtaining a 30-day operating schedule from the entity to be audited to insure that the audit is conducted during regular operations. PMA supports the concept of performing a review of the entity’s records prior to a physical inspection to permit familiarization by the auditor with the entity’s practices and programs. This facilitates the “unannounced” aspect of the audit as it provides access to records and permits FDA flexibility to conduct the audit within the entity’s expressed 30-day schedule and frees the operator from having to be sure those familiar with the records are available at all times. This is not too dissimilar from practices of the California Leafy Green Marketing Agreement where unannounced audits are focused on physical inspection and auditors have already conducted records reviews in previous announced audits.

What must an accredited auditor/certification body include in food safety audit reports? (Proposed §1.652)

FDA has tentatively concluded that the type of information that has relevance for reanalysis of hazards in a facility under the Preventive Controls proposed rule is the same type of information that has relevance for the conduct of a regulatory audit of a facility under this rule. FDA invites comment on this tentative conclusion. For comments that oppose this criterion, FDA seeks comment on whether any other information on facility changes has relevance for our oversight and, if so, we seek alternative language for proposed § 1.652(b)(9).

PMA Comment: PMA agrees that the type of information that has relevance for reanalysis of hazards in a facility under the Preventive Controls proposed rule is the same type of information that has relevance for the conduct of a regulatory audit of a facility under this rule. The use of a DUNS number to identify the business and serve
as a universal identifier is reasonable. PMA is supportive of the requirement under §1.652(a)(5) regarding consultative audits that assigns the audited entity the responsibility of analyzing the cause of non-conformances and the development of corrective actions to address them. PMA also supports the verification and documentation of the effectiveness of the corrective actions through document review or even additional audits.

§1.652(b) with §1.656 requires an accredited auditor/certification body to prepare a report of a regulatory audit and submit it electronically to FDA in English within 45 days after completion of the audit as mandated in section 808(c)(3) of the FD&C Act. PMA supports electronic submission of audit reports provided those reports are formatted to insure that they do not include information that would compromise proprietary business information. As documented elsewhere in these comments, PMA does not support the English-only requirement and encourages FDA to look into mechanisms to permit submissions in the key languages spoken in production areas that export to the U.S. The 45-day requirement for report preparation and submission is reasonable and would greatly benefit the produce industry. However, in discussing this requirement with PMA members, it became apparent that many reports and certifications earned by members under current GFSI schemes are not prepared and delivered within 45 days. In some instances audit reports and certificates take up to a year to receive owing to capacity issues. In effect, by the time the certificates are received, the audited entity has to be audited again for that production year. PMA encourages FDA to examine auditor capacity in foreign production regions exporting to the U.S. and weigh the 45-day requirement against that capacity and the actual duration of the production “season” for that region.

PMA is supportive of the report content as described in the proposal. This content includes: (1) a description of the processes and foods observed during the audit, (2) whether the audited entity uses microbiological testing as a verification tool, (3) information on recent recalls and (4) details of any recent changes in the activities conducted at the facility.

What reports and notifications must an accredited auditor/certification body submit? (§1.656)

Although Congress chose to incorporate SAHCODHA by referencing section 414 of the FD&C Act as authority for FDA to access records of consultative audits under section 808(c)(3)(C) of the FD&C Act, Congress did not use the SAHCODHA standard in
describing the types of conditions that could cause or contribute to a serious risk to the public health and that must be reported to FDA under section 808(c)(4)(A) of the FD&C Act. FDA believes Congress intended the standard for notification to be a different standard than SAHCODHA. FDA invites comment from interested parties interpreting the notification standard in section 808(c)(4)(A) of the FD&C Act and providing examples of circumstances that stakeholders believe do and do not rise to the level of a “condition that could cause or contribute to a serious risk to the public health.” FDA is particularly interested in receiving input on whether their existing Class I and Class II recall standards, taken together, might adequately address any condition covered by section 808(c)(4)(A) of the FD&C Act. An FDA Class I recall occurs in a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. An FDA Class II recall occurs in a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

PMA Comment: §1.656 lists a number of requirements for reporting by accredited third party auditors/certification bodies. We have already commented on the 45-day reporting requirement, English-only stipulations and the importance of self-assessments elsewhere. §1.656(c) requires an accredited auditor/certification body to immediately report to FDA when an auditor or auditor agent discovers during an audit “any condition that could cause or contribute to a serious risk to public health.” The proposal outlines the information that must be submitted, i.e., name and address of the facility, FDA registration number where applicable and the condition observed. FDA notes that section 808 of the FD&C Act does not define “serious risk to public health” nor does it provide examples of these conditions. FDA believes that Congress intended the standard for notification by the third-party auditor/certification body to be different than SAHCODHA (serious adverse health consequences or death to humans or animals). PMA supports FDA’s suggestion that current Class I and II recall standards be used as a basis for determining conditions that present a serious public health risk. However, what specifically will auditors be looking for to make that determination? A facility whose processes and products are intimately understood by the operator and employees are well positioned to detect issues that may compromise the safety of a product and subsequently determine a Class I or II recall is need to protect public health. A third-party auditor or audit agent exposed to the operation for a brief period of time may not have the contextual understanding or the data to make an accurate assertion of public health risk in all circumstances. PMA has raised this issue in several
areas in these comments and it is not clear how specifically these determinations are to be made by individual auditors.

§1.656(c) requires an accredited auditor to notify FDA immediately of a serious risk to public health and §1.656(d) further specifies that the notification be accomplished electronically and in English upon withdrawing certification from a facility, and §1.656(e)(1) stipulates that immediately after notification of FDA, the auditor must notify the eligible entity. PMA has already expressed concerns to FDA regarding the English-only requirements. PMA supports notification of the eligible entity and sees no reason why this cannot be accomplished simultaneously with the notification to FDA if all submissions are to be transacted electronically as proposed here. The eligible entity would seemingly be in a better position logistically to ensure the products in question were held away from commerce that FDA or the certification body making communications with them critical and requiring them to be immediate.

How must an accredited auditor/certification body protect against conflicts of interest? (§ 1.657)

Given the multinational nature and multiple corporate interests of many food companies, FDA has tentatively concluded it is important to extend the conflict of interest safeguards in proposed §1.657 to subsidiaries, affiliates, and parent organizations. FDA seeks comment on this tentative conclusion.

FDA seeks comment on these tentative conclusions and on the approach we propose in §1.657(a)(2), including whether this approach might unnecessarily limit the availability of competent audit agents to conduct audits under this program and whether removing the restriction relating to interests in affiliates, parents, or subsidiaries might create, or create the appearance of, bias.

Proposed §1.657(a)(3) prohibits officers, employees, or other agents of an accredited auditor/certification body from accepting any gift, gratuity, or item of value from the entity subject to audit. A gift, gratuity, or item of value would not include meals of a de minimis value provided on the premises where the audit or assessment is being conducted, recognizing that some facilities may be remotely located and allowing onsite meals is appropriate in the interest of efficiency. FDA seeks comment on whether to interpret de minimis value according to the limits for gifts or items of value applicable to U.S. Government employees. Proposed §1.657(a)(3) also allows for authorized officials,
employees, or agents to accept payments of fees for the audit and certification, as described in proposed §1.657(b).

FDA believes that imposing a similar requirement on the immediate family of the officers, employees, or other agents of an accredited auditor/certification body will help to ensure the credibility of the accredited third-party audits and certification program at every level. FDA seeks comment on this tentative conclusion.

FDA seeks comment on the tentative conclusions identified here—namely, FDA should require accredited certification bodies to: (1) have a written program to safeguard against conflicts of interest; (2) include the interest of any affiliate, parent, or subsidiary of a certification body within the scope of interests covered by its conflict of interest program; (3) impute the interests of immediate family members of an officer, employee, or other agent to such officer, employee, or other agent; and (4) to maintain on its Web site a list of its certified eligible entities, including duration and scope of each such certification, and disclosure of the date(s) on which an eligible entity paid the accredited auditor/certification body any fee or reimbursement associated with an audit or certification under this program.

PMA Comment: PMA supports FDA’s conclusion in §1.657 to require accredited certification bodies to: (1) have a written program to safeguard against conflicts of interest; (2) include the interest of any affiliate, parent, or subsidiary of a certification body within the scope of interests covered by its conflict of interest program; (3) impute the interests of immediate family members of an officer, employee, or other agent to such officer, employee, or other agent; and (4) to maintain on its website a list of its certified eligible entities, including duration and scope of each such certification. However, rigorous safeguards need to be balanced with privacy rights. Protection against certification body conflict of interest is an essential safeguard for this program. PMA agrees with the proposed requirements, with the exception of publicly disclosing payments on a certification body’s website. Financial disclosures should be between the certification body and the certified eligible entities. The FDA should have access to financial details only if there is cause. PMA does recommend authorized representatives accompany all required documentation with a signed conflict of interest statement.
What records requirements must an accredited auditor/certification body meet? (§1.658)

_FDA solicits comment on the English-language records requirement in proposed §1.658 and on whether other approaches might be similarly efficient and effective. For example, should FDA allow an accredited auditor/certification body to maintain its records in a language other than English, if the auditor/certification body would be required to make an English translation of its records available “promptly” upon a written FDA request? What should “promptly” mean in this context (e.g., 2 business days of the written request)? Would such an approach be as efficient and effective as the proposed English-language records requirement would be? For comments offering other approaches, FDA requests a detailed description of the alternative, an analysis of the impacts of the alternative on our ability to ensure the compliance of accredited auditors/certification bodies with applicable FDA requirements._

_PMA Comment: §1.658 establishes requirements for accredited third-party auditors/certification bodies to establish, control and retain records related to their auditing and certification activities. The requirements identify several types of records, e.g., audit reports, self-assessments, notifications, etc., and stipulate that they be stored electronically, in English and maintained for four years. PMA has commented on the English-only requirement and respectfully request FDA consider including other languages common to major production areas exporting products to the U.S. Otherwise, PMA supports electronic record storage and the four-year timeframe. §1.658(b) and (c) speak to FDA access to records. We have already commented on our understanding of FDA’s need to access records, but that proprietary information pertaining to business strategies, pricing, costs, suppliers, etc. needs to be protected._

VIII. Procedures for Accreditation of Third-Party Auditors/Certification Bodies

What is the duration of accreditation? (§1.661)

_§1.661 states that accreditation of a third party/certification body may be granted for a period of up to 4 years. FDA “has tentatively concluded that 4 years is an appropriate duration…” As FDA and the recognized accreditation bodies participating in the accredited third-party audits and certification program for food gain experience with the program, FDA may revisit this matter. For these reasons, we have tentatively concluded_
that accreditation should be granted for a period of no longer than 4 years. FDA seeks comment on this tentative conclusion.

**PMA Comment:** PMA agrees with FDA’s assessment.

**How will FDA monitor accredited auditors/certification bodies? (§1.662)**

FDA seeks comment on whether the criteria in proposed § 1.662(a) and (b) are appropriate for evaluating accredited auditors/certification bodies under this program. Additionally, FDA seeks recommendations for possible approaches they might use to monitor performance, such as conducting inspections of a certain number of eligible entities, shortly after the accredited auditor/certification body conducted a food safety audit of an eligible entity. For each such recommendation, FDA seeks comment on how the approach might affect: (1) the incentives for auditors/certification bodies to seek accreditation under the program, and (2) the degree of oversight needed to meet the objectives of section 808 of the FD&C Act.

**PMA Comment:** This proposed rule establishes requirements for FDA’s evaluation of the performance of accredited auditors/certification bodies that statutorily must be performed at least once every four years. §1.662(b) identifies the types of information FDA may use in these evaluations and §1.662(c) makes clear that FDA can conduct evaluations through evaluations of performance during the execution of an onsite audit. PMA supports the basic approach as outlined in §1.662(a) and (b).

**IX. Additional Procedures for Direct Accreditation of Third-Party Auditors/Certification Bodies**

§1.670 to §1.672 detail additional procedures proposed for direct accreditation (by FDA) of third-party auditors/certification bodies. These would be in addition to those already discussed in the document and apply when there are no recognized accreditation bodies available and FDA has made the decision to directly accredit third-party auditors/certification bodies. FDA questions on how to apply and duration of accreditation have already been addressed, and our perspective is not appreciably different even though FDA is the *de facto* accreditation body.
How will FDA review applications for direct accreditation and for renewal of direct accreditation? (§1.671)

We seek comment on the process and procedures required by proposed §1.671.

PMA Comment: §1.671 describes a process for reviewing and deciding on applications for direct accreditation under the provisions of the proposed rules. There are no timeframes for the review process owing to FDA’s lack of experience in accrediting third parties and uncertainty over resources and funding. PMA supports the concept of direct accreditation by FDA where suitable accreditation bodies are not available and the process FDA lays out in this proposed rule subject to the comments PMA has provided. PMA encourages timely communications with the applicants and supports the concept of a “queue” for completed applications only.

X. General Requirements

How will FDA make information about recognized accreditation bodies and accredited auditors/certification bodies available to the public? (§1.690)

Section 808(g) of the FD&C Act requires FDA to establish a publicly available registry of recognized accreditation bodies and accredited third party auditors/certification bodies. Proposed §1.690 provides that FDA will post on their website a registry of recognized accreditation bodies and third party auditors/certification bodies. FDA is seeking comment on our proposed public registry.

PMA Comment: PMA supports the public availability of information naming the recognized accreditation bodies and accredited auditors/certification bodies. This type of information is beneficial for companies seeking to import product into the U.S. and supply-chain companies that work with the auditors and certification bodies.

XI. Audits for Other Purposes

May importers use reports of regulatory audits by accredited auditors/certification bodies for purposes of subpart L of this part? (§1.698)

This proposed rule would allow importers to use certain information from accredited auditors/certification bodies in meeting the Foreign Supplier Verification Program (FSVP) requirements.
PMA Comment: PMA agrees that importers should be able to use regulatory audit reports as documentation to verify compliance to the FSVP.

Accredited third-party food safety audits for domestic facilities

*It is FDA’s intent that the program they establish for foreign food safety audits be solidly grounded in key principles set out in the statute and in the international standards and best practices that are currently used by leaders at the forefront of efforts to ensure auditor competency and objectivity. We realize that the same principles and standards that are features of a rigorous and credible program for audits of foreign firms would likewise hold great merit for audits of domestic food facilities. FDA seeks comment on the value of, and need for, a program established and administered by FDA for the use of accredited auditors/certification bodies to conduct domestic food safety audits. FDA seeks input on whether accreditation bodies, auditors/certification bodies, and domestic food facilities might be interested in such a program and the incentives FDA might offer to encourage participation.*

PMA Comment: The produce industry has certainly suffered from a lack of confidence by buyers, producers and perhaps consumers in food safety auditing systems both foreign and domestic over the last decade. Some of this uncertainty is driven by a lack of understanding by both suppliers and buyers of how auditing should be used and its value as a tool to measure compliance against a standard; i.e., auditing is not a substitute for performing a hazard analysis and developing/implementing an operation-specific food safety plan with measurable preventive controls. Equally important is that while there are some first rate certifying bodies/third-party auditors operating in the produce industry sector, there are others whose performance is less consistent and certainly there are individual auditors that while outliers, need better training. For these and other reasons, we have seen the increased reliance by some major buying groups on GFSI-benchmarked food safety standards and derivative audits. The attractiveness of these schemes to buying groups is centered on their reliance on accreditation of certification bodies/third-party auditors to bring more credibility and consistency to the audit process. Similar concerns from production groups in response to illness outbreaks, recurrent product recalls and redundant, multiple buyer-driven food safety audits has fueled commodity specific initiatives like the California and Arizona Leafy Greens Marketing Agreements, the California Cantaloupe Marketing Order and others that are reliant on government auditing to verify compliance to commodity specific food safety standards.
The trend towards benchmarked standards and government audited food safety programs also carries with it real concerns for the entire supply chain. The production side of the produce industry carries the largest percentage of the burden of the costs of food safety auditing and the administrative costs of accreditation, training and more capable personnel and the data systems to track the program means that these audits are significantly more expensive than the more common non-accredited food safety audits. Audit costs are typically the most prominent concern of growers, especially medium and smaller growers and the costs of auditing against current benchmarked schemes have certainly affected their adoption domestically. Indeed, these schemes have been far more readily adopted by the larger processors with more resources and scientific sophistication. In addition, sampling schemes where these processors are permitted to have only a sub-population of their suppliers food safety documentation evaluated by the auditor to verify their suppliers have documented food safety programs has helped ease the potential cost burden on individual growers.

There is also a question of capacity for accredited third-party auditors/certification bodies domestically. When discussing these proposals with PMA members who undergo accredited third-party audits currently, a common refrain was dissatisfaction with current levels of service. In response to a large buying group requiring a specific accredited audit scheme, suppliers often find it difficult to schedule audits and receive certifications owing to a deficit of accredited auditors/certifying bodies. The turnaround time certainly does not currently routinely fall within the 45 days discussed in these proposals.

The other major discussion point when considering the current landscape is the promise that a more reliable food safety audit system may eliminate the multiplicity of audits that some growers and processors face. While it might not in reality reduce the overall cost of the audit process, it may reduce the time required to perform these audits and administer the follow up actions. Indeed, FDA holds out this promise in the introductory sections of this proposal. It is interesting that the genesis of the GFSI in Europe was based around a philosophy that benchmarked audits would be more widely acceptable to buyers and that redundant audits might be eliminated. Certainly a “once audited, accepted everywhere” approach was a desired objective for growers and buyers. While GFSI schemes represent the next generation in audit rigor and are to be congratulated on their accomplishments, it is not clear that this objective has really meant success. Many European retailers still maintain their own proprietary audits and growers who supply these retailers must undergo these audits to be accepted as suppliers. Similarly,
there are buying groups in the U.S. that accept recognized food safety audits but require addenda to meet their specific needs. It seems likely that individual buying groups will always seek increased measures to protect their brand equity and their customers and proprietary audits and addenda are one tool available to them.

The concept of a domestic accredited third-party/certification body auditing system in produce modeled after the proposal presented by FDA for foreign suppliers is intellectually attractive. In order to move from concept to reality, however, there remain a number of key obstacles. As FDA considers future actions, the agency must better understand the economic impacts of such a system and engage the industry in this discussion. Specific consideration must be given to small- and medium-sized growers, harvesters, packers and processors in light of the increased costs of undergoing accredited third-party audits. Also, there must be an in-depth consideration of auditor capacity. As discussed already, the industry has already witnessed the ramifications when a single buyer rolls out a requirement for an accredited third-party audit. As these requirements have been largely focused on large national and regional processors and a proportion of their raw product suppliers, one can imagine the market interruptions should a domestic accredited third-party auditing program be implemented by FDA for the entire supply chain without an adequate ramp-up timeline. It is suggested that FDA comprehensively survey current domestic capacity for accredited third-party food safety auditing before proposing regulations. While it may be supposed that the market demand would eventually be met, the gap from program initiation to the point when the market is satisfied could prove frustrating and the industry would likely lose confidence in the system.

Last, it is not clear that the FDA has the capacity to manage a domestic system. As currently proposed the accredited third-party auditor program is limited in application to those companies that eventually participate in VQIP and produce coming from foreign countries or regions FDA deems a risk to public health. PMA has already expressed concerns that FDA has the capacity to act as a direct accreditor and oversee the accredited third-party auditor/certification program in these limited instances. These concerns are only heightened when one considers the incremental scale of a domestic program. Clearly, FDA needs to assess their capacities as part of any consideration of a domestic program.

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