FOOD MARKETING INSTITUTE

July 23, 2010

SUBMITTED ELECTRONICALLY

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

Re: Docket No. FDA-2010-N-0085; Preventive Controls for Fresh Produce

Dear Sir or Madam:

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the request from the Food and Drug Administration (FDA) for information regarding the development of safety standards for fresh produce and strategies to ensure compliance.[1] FMI commends the agency for seeking input from all industry sectors, including retail, and for working to develop meaningful and effective safety standards for fresh produce. As explained below, **FMI supports FDA's effort to establish a comprehensive produce safety regulation and believes that such a regulation must be mandatory for all produce production and packing in order to be effective.**

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

I. Executive Summary

FMI's members pride themselves on the efforts they take to ensure that produce sold to consumers in retail stores is safe. In the absence of comprehensive federal regulation in this area, retailers have adopted stringent standards for their produce suppliers, implemented compliance programs using third party certification and have worked diligently to educate suppliers as to good agricultural practices. We welcome FDA's regulation of produce safety, as it is the agency's responsibility to develop regulatory standards, inspect facilities, and take

[1] 75 Fed. Reg. 8086 (February 23, 2010).

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enforcement action if there are violations. The food industry, including retailers, has a responsibility to ensure that food products intended for human consumption are as safe as possible and meet applicable FDA requirements. A partnership between the public and private sectors will be most effective if FDA establishes the regulatory basis that will serve as the underpinnings of a comprehensive food safety management system to improve the safety of fresh produce.

Through their years of experience, our members have learned that no single approach to produce safety is effective for all growers. Flexibility is necessary because of the broad diversity of operations and types of produce. However, unless produce safety is mandated for growers of all domestic and imported fresh fruits and vegetables, it will be impossible to ensure confidence as to the safety of our produce supply. Produce safety cannot be ensured through a system built on exemptions.

We also believe that a produce safety regulation will only be effective if it is introduced to growers through broad education, outreach, and training efforts. Many of our members work cooperatively with state governments and universities to provide training to their suppliers, which has proven to be an effective means of ensuring that requirements are adequately communicated to growers. Our members also find value in periodic audits of suppliers to verify compliance. In fact, some members spend significant resources to partner with third parties to conduct thousands of on-farm food safety verification audits annually. FDA will also need to develop a means of compliance verification, which we believe should be effected through a system of agency enforcement with a secondary layer of third-party certifications providing input as a risk-assessment tool. Retailers need to ensure that they are purchasing the safest produce available, wherever it is from, so that consumers, in turn, can be assured that they are buying safe products.

II. Safety Standards for Fresh Produce

FMI believes that, at a minimum, produce safety standards must be mandatory for both domestic and international products and for producers of all sizes and commodities. The mandate should apply to local growers as well as larger operations, and regardless of conventional or organic production systems. Above this baseline, FDA should establish requirements based on variables such as commodity-type, risk inherent in the product or process, and producer volume. Retailers can control and maintain the safety of fresh produce in the store but they cannot prevent or eliminate pathogens which might originate on the farm. The safety of produce reaching consumers is primarily dependent on the safety of the product when it is grown, harvested and packed prior to being offered for retail sale.

A. FDA Should Establish Baseline Standards for All Produce Suppliers.

FDA should develop produce safety regulations that ensure safety for all produce, regardless of commodity type or producer size. However, preventive controls also must be

adequately tailored based on operation scale so that they are feasible for a wide range of large and small operations. To achieve both of these requirements, we recommend that FDA establish a baseline similar to existing Good Agricultural Practices (GAPs) that apply to all produce growers and packers regardless of size or method of production. Such a scalable produce food safety approach can take into consideration size, complexity, and small and local growers. The food industry as a whole has been collaborating on the harmonization of international standards for food safety including those for the production of fresh produce. FDA's efforts to develop baseline standards should take this work into account as it encompasses a substantial effort to identify baseline good agricultural practices.

FDA's baseline standards must be mandatory in order to be effective because exemptions will undermine the goals of safety and public confidence. However, in our members' experience with purchasing produce and educating farmers, there is no one-size-fits-all approach to produce safety. Rather, flexibility is required to address the diversity of produce commodities and growers. Instead of establishing a regulation mandating prescriptive production controls we recommend that FDA establish a regulation whereby produce growers are required to develop food safety management systems, including written food safety plans, applicable to their products and processes.

Food safety plans will be effective by focusing on hazards and identifying control procedures to mitigate risks. This approach allows each grower to develop procedures that are unique to their own situation. All produce growers should be required to have a food safety management system including a written food safety plan that, at a minimum, identifies potential hazards, production controls and corrective actions. We recognize that specific metrics may be appropriate for certain production controls, such as water and soil enhancements, especially when there is a scientific basis for the performance standard. However, demonstration of process control is warranted for most aspects of produce production. Because there are key areas of growing that need to be controlled for all types of produce, FDA should identify areas that need controls as part of the food safety management system, but should allow flexibility in determining how to meet these goals.

Any production controls established by FDA should not be overly prescriptive. For many aspects of agricultural production, there are numerous appropriate practices to achieve the goal of safe produce. These practices differ based on factors such as grower size, capability, geography and philosophy (e.g., organic). In addition, "good" practices may change with time based on new technology, research, and experience. Rather than being bound to a regulation that must be amended through the time consuming notice and comment rulemaking process, growers should be given flexibility to achieve produce safety through different approaches as techniques evolve and based on their own unique situations.

In addition, FDA's regulation should recognize that recordkeeping should not be a burden to farmers or become more important than implementing the food safety plan itself. We recognize, however, that some minimum amount of records is necessary to establish and allow

for verification of a food safety plan. The records that are required should be adequate to verify compliance with FDA's requirements. Retailers are concerned that if FDA's recordkeeping obligations are too onerous, some growers will be forced out of business. Retailers increasingly strive to purchase seasonal produce from small, local operations, which may be run by only one or two people. To ensure that consumers continue to have access to produce grown at small-scale operations, FDA's recordkeeping requirements need to be simple enough for these small farms to comply.

Additionally, retailers should not be responsible for ensuring the adequacy or accuracy of grower's records. Some retailers may voluntarily opt to verify if their suppliers are adhering to both regulatory requirements and retail specifications through independent, accredited third-party certification programs such as FMI's Safe Quality Food (SQF).[2] However, retailers should not be held accountable for carrying out regulatory inspections or verifying that suppliers meet Federal requirements for such things as recordkeeping. (The role of retailers in verification activities is discussed further in the section III.D.)

In order to be effective, FDA's regulation must apply both domestically and internationally. Consumer demand for year-round produce availability requires retailers to source globally. According to a recent report from the U.S. Government Accountability Office, 60% of the U.S. supply of fresh fruits and vegetables are imported.[3] FDA's regulation will be easily circumvented by increased international purchases if it does not equally apply to imported produce. Country of origin should never be an indication of safety.

B. FDA Should Establish Requirements Based on Sound Science and Risk.

Building on the baseline or fundamental requirements that would apply to all producers, FMI recommends that FDA consider developing specific regulatory requirements for certain producers based on risk. This approach would allow regulations to be scale appropriate, based on risk. Certain produce items have been identified by FDA as higher risk foods because of their association with food borne illness and/or outbreaks. However, regardless of the risk classification of these items, they can and should be equally safe to consume as any other produce item of lesser risk. Therefore, in these comments, we identify these so-called higher risk items as "priority" items.

For priority items that have a history of safety challenges, FDA should establish commodity-specific requirements similar to those currently in place for certain commodities in the form of guidance (e.g., tomatoes, leafy greens, melons). By establishing specific requirements for certain types of produce, safety will be assured regardless of the commodity, producer size or volume. For example, it may be appropriate to require a small producer of a

[2] Safe Quality Food Institute, *SQF Certification Program*, http://www.sqfi.com/ (July 5, 2010).
[3] U.S. Gen. Accountability Office, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (September 2009).

priority item to meet different safety standards than a medium-sized producer of non-priority items. A risk assessment takes into account the magnitude of exposure to a potential hazard. Therefore, growers producing high volumes of priority items may be identified as appropriate parties to apply different controls based on population exposure.

Although a robust food safety plan without FDA-defined metrics is sufficient to ensure safety for some commodities, experience dictates that prescriptive metrics may be warranted for priority items. This approach also would enable FDA to adapt requirements as new risks develop. FDA should conduct a priority ranking of commodities to determine which warrant specific measures. The agency may determine that produce it has identified as priority items in the past (e.g., tomatoes, leafy greens, melons) require safeguards beyond the baseline standards.

C. Environmental Sustainability Efforts Must Not Be Detrimental to Food Safety.

FDA specifically requested comments on coordination of produce food safety practices, sustainable and organic production methods, and environmental and conservation goals and practices. Although food safety is always the paramount goal for FMI's members, these issues also are important to us. Many retailers have implemented business practices and strategies to promote a sustainable environment and social responsibility, and they expect the same of their suppliers. However our members strongly believe that food safety cannot be jeopardized in pursuit of these other goals. Fortunately, there are many situations where food safety, environmental sustainability and social responsibility are not mutually exclusive, and in fact may compliment each other. For example, FMI's supplier certification program, SQF, has recently launched an Ethical Sourcing standard and guideline to help suppliers implement and assess their environmental and social programs. The Ethical Sourcing module can be a part of a comprehensive food safety and quality audit, or it can stand on its own as a measure of commitment to sustainable best practices.

We believe that sustainability practices should not, in and of themselves, be included in the FDA regulation. Where they are inexorably included, they should not result in negative consequences for food safety or public health.

With respect to organics, many of our members pride themselves on providing organic produce to consumers. Although we strongly believe that FDA's produce safety regulation should not be detrimental to the availability of organic produce or be prohibitive to the ability of organic growers to remain viable in the marketplace, organic growers cannot be an exception to the safety regulations. Consumers expect and should be assured that the regulations for safety apply to all fresh fruits and vegetables offered for sale in supermarkets. In advance of issuing a proposed rule, FDA should ensure that its standards are consistent with the National Organic Program and should work with the U.S. Department of Agriculture (USDA) to reconcile any conflicting requirements, but not at the expense of safety. Doing so will ensure that consumers continue to have broad access to organic fruits and vegetables.

D. FDA's Regulation Should Be Preemptive of Conflicting State Laws.

In order to ensure consistency, fairness and consumer confidence, FDA's produce safety regulation should be the preeminent national regulation in this area. Without coordination of produce safety requirements on federal, state, and local levels, it will be a significant burden for retailers to ensure their produce suppliers are in compliance with applicable laws. Retailers and consumers need national uniformity and consistency because they purchase produce grown throughout the United States. Furthermore, if FDA's regulation does not declare preemptive effect, states may implement produce safety standards for purposes of giving producers within the state competitive advantages in the marketplace, rather than on the basis of sound science. This occurrence would create a patchwork of standards contrary to the thoughtfulness with which FDA is endeavoring to establish this proposed regulation and may result in small farmers losing commercial viability because of their inability to meet differing state requirements.

To alleviate such concerns, FMI recommends that FDA issue a statement of its intention to preempt differing state requirements.[4] This will ensure that state law does not stand as an obstacle to the accomplishment and execution of the full purposes and objectives of this regulation. Additionally, preemption will prevent confusion for consumers and retailers. Food safety should not be a competitive program among regulatory jurisdictions.

III. Strategies to Ensure Compliance

FMI recognizes that a thoughtful and comprehensive produce safety regulation can only be useful if it is properly implemented and maintained by all fresh produce growers and packers. Compliance with the regulation is imperative in order for the rule to be effective. We believe that compliance can only be achieved through a concerted public-private partnership using a multi-pronged approach. Such an approach must include education and training, properly applied microbiological data collection programs, inspection and enforcement by Federal, State and local entities, and assessment of compliance through private-sector accredited third-party certification. Ensuring international compliance will present an even greater challenge, requiring all of these efforts plus partnerships with trading partners, accountability by brokers and importers, infrastructure support and building capacity.

A. Compliance Efforts Depend on Education, Outreach, and Training.

FDA's produce safety regulation will only be effective if producers and packers of all sizes understand what is expected of them. The agency should launch and support an aggressive approach to inform growers about the new regulation, one that involves education, training and outreach. There are many established networks that FDA can use to communicate the new requirements.

[4] FDA has previously taken this approach to establishing regulations with intended preemptive effect. *See, e.g.*, 47 Fed. Reg. 54750, 54756 (Dec. 3, 1982).

Given FDA's limited resources, FMI recommends that the agency coordinate with USDA's extension offices, state departments of agriculture, and land grant universities to engage in outreach efforts directly with the growing community. Our members have learned that small farmers are often more comfortable with these groups because they are known faces in the local community. Education efforts should include compliance guidance directed for small growers that clearly explain expectations in plain language. FDA should also develop training programs and materials aimed at this demographic and at producers of priority items.

Farmers, especially small growers, are likely to be more receptive to the new regulation if they understand that these standards will enable them to sell their products to a broader range of customers, including retailers, and enhance their image within the community and with consumers in general. The goal of compliance should be elevated above the role of inspection and enforcement since (1) FDA will have minimal ability to carry out inspections and enforcement and (2) compliance is more likely to be achieved if there is universal commitment rather than fear of punitive action.

FDA should take advantage of multiple avenues to disseminate information. Webinars, DVD's and other media tools can be used to share information. Trade associations and industry partners, including retailers, are all available to assist in training, education and outreach efforts.

We also think it is important that education efforts not stop with farmers. There is responsibility at all levels of the food chain, including end users. Consumer education and awareness are important to ensure the regulation is effective. Consumer mishandling of produce is a known cause of illness and a public awareness campaign may be effective to educate consumers as to their role in keeping produce safe. FMI, along with the Partnership for Food Safety Education, would be pleased to work with FDA to develop such consumer outreach materials.

B. The Role of Microbiological Testing.

Microbiological testing can be a useful tool, but given the enormous volume of product, the short shelf life and the low levels of pathogens, there needs to be a thoughtful plan regarding the requirements for and use of micro testing as part of the regulation. In determining testing requirements it is important to balance the value of the information against the cost. Millions of dollars can be quickly spent on microbial testing without having any impact on protecting public health if there is no plan for where to collect the samples and how to use the data.

Product testing at the end of the food supply chain will yield the least amount of value and the greatest cost. For example, testing at retail, wholesale or distribution centers is generally not useful for determining at what point contamination may have occurred. It does not provide information on the effectiveness of interventions, verification of control steps or validation of processes. Even if traceability systems can effectively lead back to a source or point of origin,

valuable time elapses and consumers are at risk. If a positive sample is found at retail, it is too late to protect the public since by that time most of the food has already been sold and consumed. Furthermore, out of an abundance of caution, retailers are likely to recall or destroy hundreds of thousands of dollars worth of perfectly safe food while waiting on investigation results as to the source and extent of the contamination.

Microbiological testing data will be more useful if it is collected at points where controls can be monitored and where interventions and corrective actions can be taken. Sampling earlier in the supply chain allows for the possibility of using test and hold programs, it can limit the amount of product represented by the sample and can narrow the possible causes of the contamination. When collected early in the process, micro data can be used as part of a prevention program rather than as a detection and response effort. Therefore, we recommend that FDA identify sampling sites early in the supply chain.

Identifying where samples will be collected can then be followed by a scientific determination regarding how to use the test results. Testing does not ensure food safety and given the low incidence rate of pathogens on huge quantities of fresh produce, many resources can quickly be spent on negative test results while food borne outbreaks still occur. When considering product testing, the old adage of finding a needle in a haystack does not even apply; this would be more like finding a needle in all the haystacks across the country. However, there are ways in which we believe micro data can be of value to improving food safety and in turn, protecting the public.

Microbiological testing can be used to validate the efficacy of processes and interventions. Food safety plans should help to identify the points where hazards are most likely to occur and these same control points can be monitored, and their effectiveness verified, via routine and recurring sampling plans. Although positive test results may lead to product destruction and even recalls, the information should also be used to assess what went wrong and why. FDA should develop a response plan for investigating positive results to learn from these instances and work with the produce industry to improve food safety management systems and industry-wide processes. Using micro data as part of a continuous improvement plan will result in stronger industry cooperation and support for the regulation, in addition to building a safer food supply.

The Microbiological Data Program (MDP) operated by the USDA's Agricultural Marketing Service (AMS) could be a helpful tool for FDA. The data collected by AMS provides a means for monitoring trends because the testing is done over time. MDP sampling targets particular produce items based on risk and therefore is consistent with FDA's intent to focus on priority commodities and assess the effectiveness of prevention programs. The samples currently collected for the MDP would be of more value if they were taken at or closer to the farm level, rather than at distribution centers for the reasons already explained above. AMS recently notified FMI that they are pilot testing a plan to move the sample collection further up the supply chain closer to the farm level and we applaud them for this effort. Furthermore, we

encourage FDA and AMS to work together to permanently relocate the collection sites for the MDP.

The MDP is not intended to be a regulatory or enforcement program and the time between the sample collections and reporting results can be significant. Therefore, we recommend this program be further developed into a National Fresh Produce Surveillance Program. As such, the data can be compiled and analyzed over time and used to assess trends. Furthermore, this data can be used for a variety of other purposes such as: (1) a measure of compliance with the regulation; (2) an assessment of the impact and success of the regulation in reducing food borne pathogens; (3) to help fill the gaps in data needed for risk assessments and risk rankings; and (4) to identify priority commodities. As a national surveillance program, individual test results would not be used for enforcement but rather to support a baseline monitoring program. Subsequently, national target goals could be set and measured.

It is important to remember the limits of microbial testing. Test results only provide a snapshot and negative results do not mean the absence of pathogens. Testing does not ensure safety. Rather, safety assurances can only come from implementation of food safety plans and good agricultural practices. While sampling may be an effective tool in certain circumstances, random sampling of produce especially at retail and distribution is of little value in our members' experience. Therefore, FMI recommends that microbial testing not be mandated and that alternatives, such as establishing a national baseline, are considered.

C. Inspection and Enforcement is a Governmental Responsibility.

FMI believes that enforcement is a government responsibility and is not the duty of retailers. We recognize that FDA faces enforcement limitations based on its finite resources, but it is important that the agency maintain its position and authority as the regulatory oversight body. Consumers want and expect FDA to act as the regulatory authority for food safety and consumer confidence depends on it. The retail sector will inevitably play a role in ensuring that farmers implement FDA's regulations, but they should not be "deputized" to carry out FDA's primary responsibility. The appropriate role for retailers is to supplement FDA's efforts to ensure safety by demanding accountability, but not to supplant FDA's enforcement efforts.

Likewise, we believe that state and local regulatory authorities can and should be used to assist FDA with inspections and enforcement. In addition to traditional inspection activities, novel approaches such as marketing agreements may be useful. USDA's AMS is currently considering a program to initiate national marketing agreements. Under these programs, state agriculture departments could form cooperative agreements with the produce industry to audit farms under marketing agreements. In these programs, farmers agree to implement and adhere to food safety practices which would be consistent with the FDA regulations. State inspectors audit the participating farms to assess compliance and report their findings back to an industry oversight board. FDA could delegate regulatory authority to the States to take enforcement action when deficiencies are found and to report back to FDA on their findings.

D. Role of the Retail Industry.

FMI supports an FDA-established system whereby third-party certifications may be used by produce growers to demonstrate compliance. Such certifications would not be a replacement for government inspections and enforcement, but can provide additional information to FDA for assessing risk. Independent certifications can be a tool used by FDA when determining how best to allocate resources to most benefit public health. Furthermore, the higher degree of compliance that is assured by third-party certifications may result in a lesser amount of enforcement activity that is needed from the agency.

FMI agrees with FDA's position as stated in their January 2009 *Guidance for Industry - Voluntary Third-Party Certification Programs for Foods and Feeds:*

> Ensuring the safety and security of food products is a shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but industry has the primary responsibility to ensure that food products intended for human and animal consumption in the United States are safe and meet applicable FDA requirements. Certification programs can help industry fulfill its responsibility by providing an independent evaluation of an establishment's food safety system and, if a problem is discovered, by providing information that can help a firm to fix the problem.[5]

This same approach can be applied to farms and packhouses.

Over eleven years ago, retailers from several countries, including the U.S. began working together to improve the standards and audit systems used by the private sector. By May 2000, this effort received recognition by major international retail CEOs who supported the need to establish a global approach to managing food safety. As a result, the Global Food Safety Initiative (GFSI)[6] was launched, a collaboration among some of the world's leading food safety experts from retailer, manufacturer and food service companies, as well as service providers associated with the food supply chain.

The primary role of the GFSI is to set requirements for food safety "schemes" and to determine, through a benchmarking process, which schemes meet the standard. In its global context, a "scheme" is a food safety certification program that includes both the recognized

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[5] U.S. Department of Health and Human Services, Food and Drug Administration: *Voluntary Third-Party Certification Programs for Foods and Feeds*, (January 2009).

[6] Global Food Safety Initiative, http://www.mygfsi.com/ (July 5, 2010).

standard and the delivery method for assuring compliance with the standard. To conform to the GFSI benchmarking document, a standard must include, at a minimum, these key elements: Food Safety Management Systems; Good Practices; and, Hazard Analysis and Critical Control Point (HACCP) principles, as defined by the Codex Alimentarius Commission or the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

Furthermore, the scheme must meet the requirements for the operation and delivery of a certification process, including auditing and certification only performed by accredited certification bodies. The standards for food safety management systems, along with the requirements for the delivery of Food Certification Systems, form the reference basis for the benchmarking of food safety management schemes and are in addition to any legal requirements for food in the countries of production and consumption. They are not intended to replace the requirements of any legislation.

Comprehensive programs recognized by the GFSI, such as FMI's Safe Quality Food (SQF), now offer fully accredited certifications to suppliers who can consistently and reliable demonstrate compliance with regulations and harmonized international standards for food safety. For many retailers, SQF certification of fresh produce suppliers provides an independent evaluation of a grower's food safety management system and, if a problem is discovered, the assurance that these suppliers will have the ability to respond to protect the public, implement corrective actions, and to use the information for continuous improvements in their systems.

We invite FDA to work more closely with FMI to further explore how retailer-supported initiatives such as the GFSI and certification programs such as SQF can supplement the compliance activities of FDA.

E. Importer Accountability is the Key to International Enforcement.

It is essential that FDA regulate produce safety both domestically and internationally. Because we recognize that it is not feasible to establish an effective regime of international inspections, FDA should develop a program whereby importers and brokers are responsible for providing assurance that the produce they bring into the country meets the U.S. requirements. It may be possible for FDA to fold this requirement into the existing Prior Notice requirements mandated of importers under the Bioterrorism Act. Demanding accountability of brokers and importers would provide uniformity and consistency, which are important for consumer confidence.

As with domestic produce, accredited third party certifications can play a complimentary role to FDA's regulatory authority. Retailers can require their suppliers to be certified to an international standard such as SQF regardless of where the product is grown or packed. Suppliers should be able to use accredited, FDA-recognized certification to expedite importation of their products and to demonstrate their compliance to the established standard.

IV. Conclusion

We believe the approach discussed above will enhance the safety of produce while also establishing a system that is not overly burdensome. Furthermore, this type of comprehensive produce safety program will increase consumers' confidence that the produce they buy at retail stores is safe. This request for comments is an important first step in a process that is certain to have a substantial dialog to come. FMI recognizes the challenges of balancing flexibility and accountability and looks forward to working further with FDA on this matter as the agency works to develop a comprehensive regulation.

Thank you for this opportunity to comment. If we may be of further assistance, please do not hesitate to call on us.

Sincerely,

Jill Hollingsworth, DVM
Group Vice President
Food Safety Programs