



July 20, 2010

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

Docket FDA-2010-N-0085

Re: FDA Preventive Controls for Fresh Produce: Request for Comments

The U.S. Apple Association (USApple) is the national trade association representing all segments of the domestic apple industry. Members include 36 state apple associations representing 7,500 apple growers throughout the country, as well as individual firms involved in the apple business. USApple welcomes this opportunity to provide a response to the Food and Drug Administration (FDA) Request for Comments regarding the development of food safety standards for fresh produce at the farm and packing house.

USApple has a longstanding policy supporting the utilization of a science-based regulatory framework that addresses risk scenarios in the produce industry and one that avoids inappropriate and unnecessary regulation on commodities that are not known to represent a high food safety risk. USApple believes food safety practices must be risk-based, commodity-specific and reflect sound science to help ensure that consumers are provided healthy and nutritious apples and other produce items. While apples, along with other tree fruit and vine crops fall within the category of fresh produce, their risk profile for potential microbial contamination is substantially lower than fruit and vegetable crops grown on or below the surface of the soil. It is from that standpoint that we offer our responses to the areas outlined in the *Federal Register* notice.

Role of the good agricultural practice guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”:

The FDA “Guide” is widely used by the industry as the basis for implementing and monitoring food safety programs. It has provided a framework for sound and workable plans such as USDA’s Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit process. The Guide should continue to be used as a primary source of guidance in individual food safety plan formulation and implementation.

Standards for domestic and foreign growers and packers:

USApple supports a science-based regulatory framework that is risk-based and commodity specific. When public health and safety is the basis for regulatory decision making, the source of the produce should make no difference in the approach taken. Failure to adopt an even handed regulatory approach to

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domestically produced and imported produce will result in two negative outcomes: 1) Domestic producers are put at an economic disadvantage by additional costs of compliance not borne by producers of imported produce, and: 2) Public health and safety could be compromised by allowing produce not subject to requirements equivalent to U.S. food safety standards to be imported and distributed in the U.S. marketplace. Any guidelines or regulation arising from that analytical basis should be applied equally to domestically produced and imported produce.

Identification and prioritization of risk factors:

The development of risk profiles for production, packing and processing should be scientific, risk-based and commodity specific. Involvement of the industry should be a very important part of the identification and prioritization process. The produce industry is quite diverse when cultural practices, crop growth characteristics and harvesting and packing operations are considered. Within the fresh produce classification are crops that vary widely in growth and production characteristics. Subgroups within the fresh produce designation vary widely with regard to their potential risk of microbial contamination. For example, apples and other tree fruit crops are fairly similar in nature, and could be examined as a subgroup, while crops such as leafy greens and other vegetables have significantly different risk profiles that require different types of evaluation in the development of guidelines or regulations to mitigate identified risks. Within the industry is a broad base of knowledge and expertise on production, harvesting and packing that can and should be utilized by the FDA in the process of identification and prioritization of risk factors.

Environmental assessment of hazards and possible pathways of contamination:

Assessment of potential hazards for contamination is a critical part of understanding and differentiating the need for control steps in the production, packing and processing function. Although tree fruits are included in the broad category of fresh produce, production of tree fruit represents a very low potential food safety risk. Apples are entirely hand harvested, so potential contamination from harvesting equipment is non-existent. Mechanical equipment used in orchards is of a secondary nature, such as forklifts to handle palletized bins of harvested apples, with tractors and trucks used to transport the palletized bins to packing or processing facilities. In addition, because of industry trends as well as packer and retailer specifications, a growing share of apple production currently falls under USDA GAP or one or more of a dozen independent GAP audit providers. A good example of this growing trend in the apple industry is outlined in comments submitted by Mr. Lee Showalter on behalf of Rice Fruit Company (See Docket FDA-2010-N-0085 “*Remarks on Produce Food Safety on the FDA’s Produce Rule May 13, 2010*”). As the FDA examines revisions to the existing GAP guidance, the agency should include guidance on how to perform environmental assessments of hazards, identify sources of contamination, and mitigation strategies.

The impact of scale of growing operations on the nature and degree of possible food safety hazards:

Consistent with our view that risk assessments should be scientific, risk-based and commodity specific, USAApple believes that exclusion or inclusion of a particular growing or packing operation based on size is a departure from a risk-based approach, and is inconsistent with program goals focused on public health and safety. The size of the operation should not be a reason for exclusion from food safety requirements.

Methods to tailor preventive controls to particular hazards and conditions affecting an operation:

The current FDA GAP guide has provided a sound blueprint that is widely used in the produce industry. The fresh produce industry has built upon the FDA guide and has incorporated additional guidance developed by academia such as land grant institutions in the creation of guidelines and standards, general and commodity-specific that could be used by the agency in revising the current guidance document. Preventive controls need not be complicated. They should be clear enough for producers to understand what is expected of them, but not be overly prescriptive.

Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations:

USApple believes that scalability is an essential component of a food safety plan incorporating preventive controls. In particular, for the tree fruit industry, where the overall risks of food borne contamination are low, the risk based assessment should take into account the size and nature of the operation and the resulting scope of actions or procedures would likely be far less for the small operation. For many apple producing operations, the entire “staff” consists of the grower and his family. For the food safety plan to be effective – employed by the maximum number of producers – the agency should keep in mind that resource limitations of producers has a significant influence on their willingness and ability to implement the food safety program. Failure to take into account the economic aspects of compliance risks losing the opportunity to have the broadest possible participation by producers.

Coordination of produce food safety practices and sustainable and/or organic production methods:

If food safety is the basis for the development of a regulatory framework, whether the commodity is produced under an organic or conventional production system should not differentiate the assessment or implementation of a food safety program. The need for a particular food safety measure should be no different simply because of the modality of production. Further, in the tree fruit industry, it is not uncommon for a producer to have conventional and organic production practices in the same operation. Having different requirements depending upon the practice could result in confusion and additional unnecessary paperwork that is not warranted by food safety concerns.

Coordination of produce food safety practices and environmental and/or conservation goals and practices:

As noted above, we believe that food safety should be the underpinning of the framework. Interjecting “conservation” or “stewardship” components to a food safety framework unnecessarily duplicates obligations of other federal agencies (such as USDA’s responsibilities in the area of soil conservation and resource management). Including those outside components also dilutes and unnecessarily complicates the food safety program with standards and requirements unrelated to food safety.

Coordination of produce food safety practices and federal, state, local and tribal governmental statutes and regulations:

Like most markets in the United States, the fresh produce market is not delineated by state or local government political boundaries, but is a national market. Along with other trade associations, the FDA, USDA, and state food regulatory officials, USApple was a participant in the development of the Association of Food and Drug Officials’ (“AFDO,” the organization of state-level food and drug regulatory bodies) “*Model Code for Produce Safety*.” Uniformity among federal and state food regulatory officials in their approach to food safety oversight is essential to preventing wasteful and unnecessary fragmentation of the national market. The AFDO model code and the inclusive process by which it was drafted serve as an example of how a coordinated program could work.

Microbial testing:

Application of a sound, science-based approach is essential to addressing the issue of microbial testing. Experience in the food industry has clearly demonstrated that, on its own, even the most pervasive (and cost prohibitive) microbial testing regime cannot itself guarantee food safety. In regard to apple production, there is no evidence of the need for microbial testing of the fruit, thus it should not be mandatory.

Post-harvest operations and the role of the current good manufacturing practices in 21 CFR part 110:

As noted earlier, industry trends and customer demand has led to the current situation where the vast majority of packinghouses have established HACCP plans appropriate for their operations. However, to avoid confusion by using terminology applied to Current Good Manufacturing Processes (cGMPs), any new post-harvest fresh produce rules applying to growers, packers or shippers should be included within the Good Agricultural Practice framework.

Records and other documentation that would be useful to industry and regulators in ensuring the safety of produce:

There are many third party audit processes currently used in the fresh produce industry. From the numerous guidances and standards currently being utilized, both general and commodity-specific, the FDA could relatively easily determine what records and documentation would be useful in verifying adequate preventive controls, compliance and traceability. However, the agency should also avoid creating a “paperwork overload” that imposes a significant financial burden – especially on smaller operations - and one that could be counterproductive to the goal of obtaining the maximum number of operations participating in a food safety regime.

Strategies to enhance compliance:

Consumer demand and industry led efforts have been a powerful influence in moving the fresh produce industry, including the tree fruit sector, to formalized food safety programs. In addition to working with state agencies with food safety authority, for the broadest possible acceptance, the FDA should utilize the expertise of industry associations and the extension service to reach out to the grower/packer/shipper community. The foundation of an effective food safety program is education. Training materials applicable to nearly all sizes of operation are available from many sources, and the FDA should tap those existing resources wherever possible. USApple pledges continuing commitment to working with the agency in the development and implementation of food safety rules and procedures that can be accepted and employed by a broad cross section of the tree fruit industry.

Please contact me by telephone at (703) 442-8850 or via e-mail at mseetin@usapple.org should you have any questions or require additional information.

Sincerely yours,



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