



October 29, 2013

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

Re: Docket FDA-2011-N-0921

RIN 0910-AG35 “Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption”

The U.S. Apple Association (USApple) is the national trade association representing all segments of the domestic apple industry. USApple’s members include state and regional apple associations representing 7,500 apple growers throughout America, as well as more than 400 individual firms involved in the apple business. USApple welcomes this opportunity to provide a response to the Food and Drug Administration (FDA) on the proposed rule entitled *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, as published on January 16, 2013, in the *Federal Register*.

The United States is the world’s second largest producer of apples, behind the People’s Republic of China. With a USDA estimated farm gate (wholesale) value of nearly \$3 billion in 2011¹, apples are the third most valuable fruit produced in the U.S behind only grapes and citrus. According to the USDA, per capita consumption of fresh apples is roughly 16 pounds or approximately 43 fresh apples per capita annually².

Roughly 29 percent of the 2012 U.S. fresh apple crop was exported with a value of over \$1 billion³. USDA estimated China apple production in 2011-12 at 35 MMT (1.8 billion bushels)⁴. Further, according to USDA statistics, the world’s second largest producer, the U.S, has averaged 225 million bushels over the past 5 years, making China’s apple production 8 times that of the U.S. While Chinese apple production is the world’s largest, it is the product of many small farms that make less than \$25,000 U.S. per year⁵. Under the small farm exemptions in the proposed rule, the vast majority of apples imported from China would be exempt from the proposed rule,

¹ USDA, National Agricultural Statistics Service, Noncitrus Fruits and Nuts Summary 2011

² USDA, Economic Research Service, Crops Branch July 2013

³ USDA Foreign Agricultural Service Global Agricultural Trade System (GATS) August 2013

⁴ China - Peoples Republic of Fresh Deciduous Fruit Annual, USDA Foreign Agricultural Service Dec 2011
http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Fresh%20Deciduous%20Fruit%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-2-2011.pdf

⁵ Follow your labels: American apple juice is a product of China, Christian Science Monitor July 2013
<http://www.csmonitor.com/World/Global-Issues/2013/0721/Follow-your-labels-American-apple-juice-is-a-product-of-China>

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putting U.S. producers at a significant competitive disadvantage, and U.S. consumers a differential and confusing system of food safety regulation. Thus, with a significant share of the U.S. apple crop being exported, and the potential for imports to be subject to a much less stringent regulatory regime, USApple approaches the produce rule proposals as they impact out domestic producers and the potential impact on international trade.

Apples in the U.S. are entirely hand harvested by workers using ladders to reach higher placed fruit or standing on the ground for lower placed fruit. While research continues on mechanical harvesting equipment, it has not yet proven to be practical. The harvested fruit does not come into contact with the ground. Workers place the picked fruit into canvas bags secured to their body by straps. The picking bags are carefully emptied into wooden or plastic harvest bins placed in the orchard row. Forklifts are employed to handle the bins of harvested apples, with tractors and trucks used to transport the palletized bins to packing or processing facilities. In general, the bins are the property of the packinghouse.

Apples are grown in every state in the U.S., but are grown commercially in 29 states. Washington State produces about 60 percent of the apples in the United States. Other leading states include New York, Michigan, Pennsylvania, California and Virginia⁶. The growing environment in the U.S. varies widely from the more arid western growing areas to the temperate and higher rainfall areas in the east, which in turn influences the usage pattern of agricultural water. In the east where rainfall is generally higher, when irrigation is employed, it is done by drip or micro sprinkler irrigation underneath the tree without the water contacting the crop. However, because of disease and insect pests, crop protection chemicals are applied periodically throughout the growing season. Crop protecting chemical sprays involve the use of agricultural water which contacts the developing crop. There is little use of overhead sprinkling in the east for either frost control or sunburn prevention. Water used in the east typically comes from wells or surface water from ponds or streams. Sprays can be applied up to within a few days of harvest.

In the west, arid conditions require the use of both irrigation and cooling. Overhead irrigation is used not only to provide necessary water for tree health and fruit growth, but also to cool the fruit and prevent sunburn. Losses from sunburn can be a significant economic factor. According to research conducted at Washington State University, if no protective practices are used, Washington State apple growers would lose about 10 percent, on average, of their crop to sunburn damage⁷, which would translate to a loss of more than \$200 million annually for that state alone. Similar to practices in the east, crop protection chemicals are applied periodically throughout the season. Water used in the west is from streams, ponds, deep wells, and open irrigation canal systems. Agricultural water is typically applied up to harvest from whatever water source is available. In many instances there are no alternatives to the existing sources which has implications should a regulatory change regarding microbial presence lead to the inability to obtain agricultural water from a particular source.

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

⁶ AgMRC, Iowa State University http://www.agmrc.org/commodities_products/fruits/apples/commodity-apple-profile/ and USDA NASS.

⁷ L. Schrader et al, Washington State University, Sunburn Research http://hort.tfrec.wsu.edu/pages/Sunburn_Research

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 at affordable prices.

While apples, along with other tree fruit falls 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. When Congress passed Public Law 111–353 the “Food Safety Modernization Act” (FSMA), they recognized that different produce commodities have different risk profiles and directed the FDA to identify and focus on foods identified as “high risk” as provided for in the statutory language:

- (A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and thereafter as the Secretary determines necessary, the Secretary shall designate high risk foods for which the additional recordkeeping requirements described in paragraph (1) are appropriate and necessary to protect the public health. Each such designation shall be based on—
- (i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
 - (ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
 - (iii) the point in the manufacturing process of the food where contamination is most likely to occur;
 - (iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
 - (v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
 - (vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.⁸

The FDA states that the proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. It would address microbiological risks from all agricultural inputs (people, agricultural water, biological soil amendments, and tools and equipment), from unsanitary conditions in buildings, and from contact with wild and domesticated animals during growing, harvesting, packing, and holding activities of covered produce.

“As we explained in Section IV.C, we tentatively concluded that an approach that considers both the risk associated with the commodity and that associated with the agricultural practices applied to the crop under the conditions in which it is grown, would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. Under this approach, we considered available information on outbreaks and contamination as well as existing evidence on characteristics of the commodity (such as whether the commodity

⁸ PUBLIC LAW 111–353—JAN. 4, 2011 124 STAT. 3932

grows on trees or has a smooth rind). This evidence informed the proposed requirements, but we have tentatively concluded that limiting the scope of this rule based on outbreak data or on the levels of frequency of pathogen detection alone would not adequately address the risk of serious adverse health consequences or death. Therefore, as discussed in section V.A.2.a. of this document, we are proposing to cover apples, citrus fruits, watermelons, and tree nuts in this proposed rule. . . .⁹

As noted earlier, the USDA estimates that 16 pounds or approximately 43 fresh apples are consumed per capita per year¹⁰ indicating a substantial consumption of fresh apples by the general population. In light of the significant consumption of apples in the U.S., it should be noted that there are no documented cases of foodborne illness associated with the consumption of fresh apples in the United States. Similar findings were published in a January 2013 report from the European Food Safety Authority (EFSA). In their report, *Scientific Opinion on the Risk Posed by Pathogens in Food of Non-Animal Origin*, researchers reported no illness outbreaks linked to whole, fresh tree fruits.¹¹

With its blanket regulatory approach that encompasses commodities like apples with no documented cases of foodborne illness, FDA's rationale as described above does not employ a "science-based" approach, rather it more closely resembles the "precautionary principle" where even the most unlikely and undocumented possible risk can be factored in. The precautionary principle approach will lead to excessive regulation while offering little or no benefit of enhanced food safety in the case of apples and will most likely drive up costs.

USApple believes that the FDA should conduct a more comprehensive analysis. In the proposed rule there is inadequate analysis to establish the current state of food safety practices and the description provided in the proposal fails to adequately link those practices and public health. The FDA has not presented a thorough economic modeling of what an optimal set of rules for food safety practices would look like. Rather, the FDA wants to impose a "one size fits all" approach on all covered commodities rather than one that focuses on those commodities or farms that pose the greatest risks. The FDA states that it is required by law, by the Food Safety Modernization Act, to develop these standards. The FDA should rethink its approach of lumping apples and similar tree fruit and nut commodities into the proposed regulation since there is little to suggest that the increased and costly regulations will improve public health.

Request for Revised Proposed Rule Subject to Additional Comment

USApple joins with the National Association of State Departments of Agriculture (NASDA), the United Fresh Produce Association (United Fresh) and other groups in requesting that, following consideration of public comments on the initial produce food safety regulations, the FDA issue a revised proposed rule and allow for additional public comment on the revised rule. Our association has a longstanding commitment to providing consumers with an abundant, high quality and safe food supply. We support a science-based, commodity-specific approach to food safety

⁹ Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption pg 122

¹⁰USDA op. cit. p. 1

¹¹ Scientific Opinion on the risk posed by pathogens in food of non-animal origin. Part 1 (outbreak data analysis and risk ranking of food/pathogen combinations) January 2013. EFSA Panel on Biological Hazards (BIOHAZ) pg 51 <http://www.efsa.europa.eu/en/efsajournal/pub/3025.htm>

regulation that is focused on the highest public health priorities. The produce food safety rule proposal represents the most sweeping change in produce regulation in over 70 years, and it has major operational and cost impacts on growers, packer/shippers and marketers of apples and apple products. We believe that it is incumbent upon the FDA to do the most thorough examination possible before implementing a rule with such a profound impact on the food system. For those reasons, we join NASDA, United Fresh, the Northwest Horticultural Council (NHC) and others in requesting that the FDA issue a revised proposed rule subject to public comment prior to issuing the final rule.

Responses to specific provisions

1. **Subpart A Section 112.4(a)** – Consistent with our view that risk assessments should be scientific, risk-based and commodity specific, USApple 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. As noted earlier in this document, apples grown in China would likely be largely exempt for this regulation because the operations there are small and growers would fall below the \$25,000 annual threshold.
2. **Subpart B Section 112.12** – We support the ability to develop alternatives to the rule delineated requirements. In addition, clarification should be made that alternatives developed by the USDA, state agricultural departments, land grant universities, and other federal research institutions are acceptable
3. **Subpart C Section 112.21** – The vast majority of apples in the U.S. are harvested by migrant workers who work on multiple crops and work sites and for different employers. To avoid expensive and wasteful duplication, we recommend that the FDA develop a process or system whereby once workers are trained through an FDA approved process, that training can be verified via a “training certificate” that the workers can take with them. The certificate should be valid for a harvest season, and should be valid for similar crops such as deciduous fruit.
4. **Subpart D Section 112.32** – This section is overly prescriptive. The requirement for “washing hands thoroughly with soap and running water” in an orchard setting following a ten minute break by harvest workers as described in Section 112.32 (b) (3) (iv) is unnecessary.
5. **Subpart E Section 112.42 (a)** - The “reasonableness” standard described here should be that which could be expected of the grower/orchardist.
6. **Subpart E Section 112.42 (d)** - Overhead irrigation is used not only to provide necessary water for tree health and fruit growth, but also to cool the fruit and prevent sunburn. In the arid production areas of the west, losses from sunburn can occur rapidly and be a significant economic factor. According to research conducted at Washington State University, if no protective practices are used, Washington State apple growers could lose about 10 percent, on average, of their crop to sunburn damage (op cit). In the eastern and western areas, crop protection chemicals are applied periodically throughout the season to control imminent threats from insects and diseases. Donna Pahl, University of Maryland food safety specialist and GAPs educator has filed comments in the docket related to this issue discussing research on survival of E. coli in agricultural water;

“In our own research, we found that the levels of *E. coli* present in water used for the application of crop sprays did not have a significant impact on the microbial load on the surface of tomatoes. The two publications listed below¹²¹³ are linked field studies completed by our lab. Water sources of significantly different water quality (groundwater and ponds) were used to prepare and apply pesticides to tomatoes. Twenty-four hours after the pesticide application treatments, tomatoes were harvested, rinsed, and massaged to elute surface bacteria. The resulting washwater was tested with conventional microbiological and molecular methods. Even after performing the non-recommended practice of applying water with high levels of fecal indicator organisms, there were no significant differences in the microbial load on the tomatoes.”¹⁴

When the imminent threat of insect or disease infestation occurs, timing is critical. An insect such as the newly invasive pest the Brown Marmorated Stink Bug (*Halyomorpha Halys Stahl*) can cause losses of 2-3 percent per day in the late season, so it is critical that growers apply crop protection chemicals as soon as possible when the pest is discovered. Similar situations exist with the 100 or so diseases and insect pest species that attack apples. A delay in the availability of agricultural water caused by a microbial count above the standard that causes application water to be unavailable could be catastrophic. The potential loss of critically needed water for irrigation, cooling or spray application is an enormous potential economic cost, particularly in view of the fact that, as noted earlier, apples do not have a single documented case of food borne illness attributed to the consumption of fresh apples.

7. **Subpart E Section 112.43** - This requirement could be problematic for orchardists. In Western U.S. production areas, apple production requires the application of as much as 3 acre-feet (36 inches) of irrigation water annually. Chlorine treatment of water in the volume needed for irrigation and cooling is a daunting logistical challenge. Worse, chlorine in the water has the potential to damage the fruit. Chlorine interacts with many crop protection chemicals producing erratic results from crop damage to reduced efficacy.
8. **Subpart E Section 112.44** - In view of both the historical experience with the third largest fruit crop in the U.S. for over a hundred years of production without a documented case of food borne illness attributable to the consumption of fresh apples, and the research cited earlier on microbial survival on fruit, we believe that it is unwarranted from the standpoint of food safety to require that water usage be halted immediately. Research has shown that apples exposed to air temperatures exceeding 105 degrees Fahrenheit (a relatively common occurrence in high desert production areas of the Pacific Northwest) will sustain damage after as little as one hour of exposure.¹⁵ Should the detection of a violative level of bacteria occur during a period of high temperatures, it would be impossible for growers to implement a remediation process before significant damage to their apples would occur. Given the real potential for significant crop losses in such a situation, that requirement would also translate to a reduction in the food supply, and dramatically increase the regulatory cost burden.

¹² Teliás, A, J.R White, D.M. Pahl, A.R. Ottesen, C.S. Walsh. 2011. Bacterial community diversity and variation in spray water sources and the tomato fruit surface. BMC Microbiology 11: 81.

¹³ Pahl, D.M., A. Teliás, M. Newell, A.R. Ottesen, C.S. Walsh. 2013. Comparing source of agricultural contact water and the presence of fecal indicator organisms on the surface of ‘Juliet’ grape tomatoes. Journal of Food Protection. In press

¹⁴ Donna M. Pahl comments <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0145>

¹⁵ Schrader Sunburn of Apples: Causes and Suppression of Sunburn Damage. Washington State University 2009 <http://ashs.org/db/horttalks/detail.lasso?id=696>

9. **Subpart E Section 112.45 (a)** - This provision should be clarified to indicate that irrigation district testing certification is sufficient to comply with this provision.
10. **Subpart E Section 112.45 (b)** - In view of both experience and scientific research, this provision is extremely onerous and should not be applied to apple production. Requiring testing of surface water every 7 days during the growing season places a costly compliance burden on growers without a clear examination of why it might be necessary. Apples are harvested once – at the end of the growing season. The growing season is 6 months or more in length. Previously cited research on the survival of microbial pathogens on the surface of fruit would argue that such a requirement for apples is excessive and extreme. Research conducted at Washington State University and published in the Internet Journal of Food Safety demonstrated that even when high concentrations of E. coli treated to be environmentally resistant were applied to apples, populations were reduced to undetectable levels on apples collected just 1 day after spraying.¹⁶ With research indicating such short retention times on apples, if the FDA requires water testing at all, it should be limited to a short period immediately before harvest.
11. **Subpart E Section 112.50** - The expansive new recordkeeping requirements proposed are burdensome and create a significant additional workload, particularly for smaller, family owned and operated orchards. A sizable and increasing majority of orchards are already subject to one or more GAP compliance audits. We believe that the GAP records and recordkeeping requirements should be sufficient.
12. **Subpart F** – USApple supports comments submitted by The Organic Trade Association on standards applying to organic soil amendments.
13. **Subpart I Section 112.83** - This is another example of unnecessary regulation arising from a “one size fits all” approach to regulation. While orchardists have a significant economic incentive to prevent animal intrusion and subsequent damage to the crop, feral animals will, from time to time, enter orchards. Those occasional intrusions do not represent a threat given that the fruit is located well above ground level and is hand harvested and placed directly into harvest bins. This has been the situation for generations of commercial apple production without a single case of foodborne illness arising from consumption of fresh apples.
14. **Subpart K Section 112.112**. - Fruit that has been harvested is transported to packinghouses where it is cleaned and inspected. We suggest that changing the wording to “harvesting covered produce that is visibly contaminated with animal excreta should be avoided to the extent practicable.”
15. **Subpart L Section 112.123 (d) (1 & 2)**. - Harvest bins are typically located in orchard rows prior to the commencement of harvest, and are cycled from the orchard to the packinghouse and back to the orchard throughout the harvest. Ladders and picking bags are transported to the orchard and used by workers harvesting the fruit. Harvest and transport is done in the open and in conditions ranging from clear skies, to dusty winds or rain. While workers can and do identify and deal with equipment contamination during the harvest, the typical usage pattern and continual exposure to the elements makes a scheduled sanitation program ineffective.

When congress passed the FSMA, it represented the most sweeping regulatory change in food safety in generations. At the same time, congress provided the FDA with flexibility to tailor newly developed regulations in a science-based manner based on a commodity specific risk-based

¹⁶ Sun-Young Lee and Dong-Hyun Kang. Longevity Studies of Escherichia coli on Apples from Tree. Internet Journal of Food Safety, Vol. 5, 2005, p 35-440. <http://www.internetjfs.org/articles/ijfsv5-6.pdf>

approach. USApple believes that the agency has not taken that approach, but instead developed a set of “one size fits all” proposals that will likely have serious unintended consequences. Those consequences come in the form of overregulation, increased costs on growers to comply with the regulatory proposals, and a significant risk of serious economic losses directly resulting from the regulations. For example, agricultural water regulations that could force growers to unnecessarily cease using water critically needed for irrigation, cooling and crop protection chemical application due to microbial standards. That situation could result in major losses from heat injury to fruit, and losses from insect and disease infestations that routinely attack the apple crop and damage the crop in just a few hours or days. All of this for a crop (apples) for which there is not a single documented case of foodborne illness in either the U.S. or Europe.

With its blanket regulatory approach that encompasses commodities like apples with no documented cases of foodborne illness, FDA’s rationale does not employ a “science-based” approach, rather it more closely resembles the “precautionary principle” where even the most unlikely and undocumented possible risk can be factored in and result in additional regulation. The precautionary principle approach will lead to excessive regulation while offering little or no benefit of enhanced food safety in the case of apples.

In the proposed rule there is inadequate analysis to establish the current state of food safety practices and the description provided in the proposal fails to adequately link those practices and public health. The FDA has not presented a thorough economic modeling of what an optimal set of rules for food safety practices would look like. Rather, the FDA approach imposes a “one size fits all” approach on all covered commodities rather than one that focuses on those commodities or farms that pose the greatest risks. The FDA should rethink its approach of lumping apples and similar tree fruit and nut commodities into the proposed regulation since there is little evidence to suggest that the increased and costly regulations will improve public health. USApple believes that the FDA should conduct a more comprehensive analysis and seriously reconsider a commodity based, risk-specific approach to the regulations.

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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