



December 12, 2014

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” (Revision to Original Proposal of January 16, 2013)

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”, or the “Agency”) on the revisions to the proposed rule entitled *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, as originally published on January 16, 2013, in the *Federal Register*.

On October 28, 2013, USApple filed comments with the Agency on the rule as it was originally proposed. In our earlier comments, we noted that 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 at affordable prices. The comments below address general issues followed by our response to the revised standards for agricultural water.

General comments:

Standards should be expressed as guidance – The revisions to the standards for water testing are an improvement, but are not science or food-safety based. With the science on water and food safety still evolving, the standards should be **expressed as guidance** rather than being embedded in the rule itself. Guidance can be more easily adjusted as science provides answers, whereas altering standards embedded in a final rule can be a difficult and cumbersome process.

Cost benefit analysis – We continue to believe that the cost/benefit analysis understates the costs and overstates the benefits of the rule proposals in general. In particular, for apples, where no documented case of foodborne illness from the consumption of fresh apples exists, the “lumping together” of all produce commodities – both high and low risk – in the analysis significantly distorts the real world situation. For growers, many of whom utilize multiple water sources, costs associated with labor for gathering and maintaining custody of multiple samples at varying intervals



throughout the season added to the cost of testing the samples is substantial. Further, with a commodity like apples with no documented case of foodborne illness from fresh apple consumption, the public benefits are zero. Based on more than a century of commercial apple production experience, the proposed rule adds significant costs which growers will be forced to incur while providing no known benefits to the public in the form of safer food.

Commodity risk profiles - When Congress passed Public Law 111–353 the “Food Safety Modernization Act” (FSMA), it was recognized that different produce commodities have different risk profiles. The legislation called for the FDA to identify and focus on foods identified as “high risk” as provided for in the statutory language. 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. We believe that the Agency should heed the FSMA directive of the Congress to establish commodity risk profiles that allow for a focus on those areas presenting the highest food safety risk instead of a “one size fits all” that imposes significant costs on growers without a corresponding benefit to public health. Establishing food safety regulation based risk profiles would allow the Agency to focus its (often limited) resources on improving food safety in the areas of greatest concern.

Exemptions – 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. Further, a food safety incident – even from a small “exempt” grower - reflects on the entire industry in the eyes of the public. The size of the operation alone should not be a reason for exclusion from food safety requirements.

The bulk of our comments on the amendments to the previously proposed rule will focus on Proposed Subpart E – Standards Directed to Agricultural Water.

B. Proposed Subpart E--Standards Directed to Agricultural Water

To provide a context for our response to the proposed amendments to §§ 112.44(c), 112.44(d), and 112.50(b), included below is our response to the original proposals as contained in the USApple comment letter¹ filed on October 28, 2013, followed by comments on the proposed amendments.

Original comment

“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;

¹ USApple Comment Letter “USApple Comments on FDA Produce Safety Rules” filed October 28, 2013

“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 below²³ 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.”⁴

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 foodborne illness attributed to the consumption of fresh apples.

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.

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 foodborne 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)

² Talias, 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.

³ Pahl, D.M., A. Talias, 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

⁴ Donna M. Pahl comments <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0921-0145>

will sustain damage after as little as one hour of exposure.⁵ 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.”

Proposed amendments to §§ 112.44(c) and 112.44(d)-

We commend the Agency for considering comments on the produce food safety rules as originally proposed and providing a revision that is available for additional comment. The revisions related to agricultural water are an improvement over the original proposals. However, they are complicated and somewhat confusing. The terms “statistical threshold value” or “STV” and “geometric mean” are not readily understandable by those outside of the scientific community, and the methodology involved in calculating STV and GM values is similarly foreign to the vast majority of growers. We strongly feel that an effort should be made to simplify the process of arriving at the data necessary to implement alternate approaches to dealing with water that exceeds the EPA recreational water standard that the Agency has chosen as the agricultural water benchmark. The Agency should consider making available to growers the methodology required to calculate the values necessary to make decisions on agricultural water. One example would be an easily downloadable software program that could be installed on a laptop or desktop computer – or even a downloadable application that could be run on a cellphone - that would take growers’ water test data and output the statistical values delineated in the proposals, followed by the calculation of the day interval between the last application of water and when harvest could commence.

Another approach to simplifying the process of determining the day interval might be the development of a “lookup table” containing a column where the range of the generic *E. coli* appears, where the grower could find the range that fits the operation’s water test results. The column(s) to the right would indicate the day interval required between last use of irrigation/cooling water and when harvest could begin.

We would also like to suggest the addition of another option that would be added to the alternatives offered in the revised rule proposal. A number of packer/shippers, mostly in the Eastern U.S. have adopted a requirement for their growers that requires growers who experience a water test in excess of the EPA recreational water standard to use only “potable” water for 14 days prior to harvest. Using the .5 log per day die off suggested by the Agency, even a 14 day period is extremely conservative. The Agency should consider adding an alternative such as use of “**water that meets the microbial standard for drinking water**” for a period of days (such as 7 days) prior to harvest based upon a single water test taken (for example) 30 days prior to harvest. This alternative would be in lieu of the expensive process of creating a water profile and periodic testing of the water supply that is called for in the revised proposal.

Proposed amendments to §§ 112.45(b) (1); Agricultural water testing -

The costs associated with water testing can be extremely burdensome depending upon the number and type of water sources used - such as for multiple orchard sites. The ability for growers to share

⁵ Schrader Sunburn of Apples: Causes and Suppression of Sunburn Damage. Washington State University 2009
<http://ashs.org/db/horttalks/detail.lasso?id=696>

water tests from common water sources is a welcome improvement. However, while the revisions are a significant improvement over the original proposal, parts of the description are still vague and require clarification. The definition of “water source” needs to be clarified regarding how it is applied to multiple irrigation districts using a common open irrigation ditch. This is especially important for growers with multiple blocks or orchards. Additional clarification or guidance is also necessary regarding the sampling process in terms of what is an acceptable sampling procedure for the 5 samples required “as close to harvest as practical.” May they be taken from the same location on the same day but at different times? In the case of a common irrigation ditch, where should the sampling be done and is there a geographic limit that would require additional sampling of the ditch? What time interval is appropriate between samples? Depending upon how water source is defined, the number of samples could be very large for orchards with multiple blocks or locations, so clarification is necessary on the nature and scope of water testing.

The requirement to establish a new water quality profile every ten years is unnecessary and burdensome. The provision begins by calling for establishment of the water quality profile using two years of sampling data with a minimum of twenty samples. Once established, annual testing (five samples per year) is required. If the annual survey indicates that the existing water quality profile no longer represents the quality of the water, the baseline must be adjusted. The annual testing and adjustment (if required) of the baseline amounts to a “dynamic” profiling, and makes a 10 year adjustment unnecessary and redundant.

§§12.45(e) – The revision allowing agricultural water testing by a third party for the benefit of several operations is also an improvement over the original proposal. However, this provision also needs to be clarified as described in the preceding paragraph.

USApple appreciates the opportunity to comment on the proposed revisions to the Produce Safety Rules as originally proposed. We continue to strongly urge the Agency to utilize the authority given by Congress in the FSMA to identify and categorize commodities based upon risk in the development of food safety regulations. While we believe the revisions represent an improvement over the original proposals, we also believe that important clarification is necessary on the agricultural water provisions. We also strongly feel that the standards encompassed in the revisions should be in the form of **guidance** to allow for timelier adjustment as the science evolves.

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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