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TO: Division of Dockets Management (HFA-305)
Food and Drug Administration
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FROM: Carolyn McQuiston, President
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RE: **Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption**
Docket No. FDA-2011-N-0921
RIN 0910-AG35

I am submitting comments on the proposed rule for "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption" on behalf of the State Horticultural Association of PA. Established in 1859, SHAP represents orchardists and states in its mission "to preserve and enhance the viability of the commercial fruit industry". These comments are offered because aspects of the Proposed rules of the Food Safety and Modernization Act (FSMA) represent a threat to that mission.

The fruit industry has been very progressive with regard to food safety and food security in recent years. A significant number of our members have been certified under the USDA GAP audit and, more recently, many growers have also been certified by the Primus Audit for both their Ranch and Harvest Crew categories. Although these initiatives are largely market-driven, these audits require a substantial investment in time and record keeping. The new regulations under the Food Safety and Modernization Act promise to increase the overhead expenses for compliance with another set of federal regulations.

Overview

As growers we are not microbiologists or experts in the area of food science. In looking at these Rules, we often find that it's what we don't know that causes us pause in responding to the proposed regulations. We find that in talking to food scientists that

there has been little research done on microbial activity for whole fresh tree fruits. It is because there have been no indicated problems that there is little existing research. If a scientist does not know the exact answer to the question, they default to assuming that there could be a potential issue.

Our industry is and will continue to be a strong advocate for doing all of the necessary things to ensure that our fruit is safe.

We feel that we have to approach a response to the proposed regulations using our food borne illness outbreak history as a basis for commenting. In short the recent CDC data shows no indications of whole, fresh tree fruits being implicated in food borne illness outbreaks.

There was a similar finding in a recently released 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,*** there were no illness outbreaks linked to whole, fresh tree fruits.

In response to an inquiry in 2011, the USDA stated that the USDA Microbial Data Program had never tested any fruits. This would seem to be an indication that government had not seen any particular risks in tree fruits. These indicators of the lack of risk are a basis for questioning the proposed regulations.

While there are specific exemptions by grower sales volumes mandated by the law, we feel that when final regulations are released, all growers will be impacted. It is our opinion that existing Good Agricultural Practices (GAP) audit systems will move quickly to make their audits align with the law. Therefore any grower in a supply chain where GAP audits are mandated by customers will need to comply with the FSMA regulations as well as the audit requirements.

The Produce Rule

The Produce Rule contains 5 main component areas:

1. Equipment, tools, buildings, and sanitation
2. Biological soil amendments
3. Domesticated and wild animals
4. Personnel qualifications, training, and health and hygiene
5. Agricultural water

The proposed rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. (Sprouts are covered by somewhat more stringent requirements.) It does not apply to raw agricultural commodities that are rarely consumed raw (potatoes), those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern.

Agricultural water

In addressing specific concerns about the Rule, Agricultural water rises to the top of the list. The FDA states that water can be a carrier of many different microorganisms of public health concern. Agricultural water is defined as water that is intended to, or likely to, contact covered produce or food-contact surfaces. For our growers, drip or micro sprinkler Irrigation water is not agricultural water. However water used in crop protecting sprays is Agricultural water and therefore becomes subject to regulation.

We have learned that Penn State recently conducted an Agricultural water survey in which it was determined that 60-70% of currently used surface water sources would fail to meet the proposed recreational water standard. This is a significant problem for our growers and our industry. The FDA states that generic E. coli serves as the most appropriate microbial indicator of fecal contamination of water. The proposed rule states that when there is a finding of 235 colony forming units (CFU) (or most probable number (MPN) as appropriate) generic E. coli per 100 ml. or more that the grower must immediately discontinue use of that source of agricultural water and/ or its distribution system. It is our opinion that this is an inappropriate rule for our industry based on our indicated risk profile.

The FDA goes to some length in its preamble discussion to give a rationale for its approach to Agricultural water. The agency states that they thought about proposing a drinking water standard for covered produce but felt that it would be unnecessarily restrictive. They state that it would not account for the forces driving pathogen die-off.

We feel that this is an admission by the FDA that there is indeed degradation of pathogens when exposed to environmental conditions of sun, temperature, rainfall, etc. pg. 244. They further acknowledge that the EPA recreational water standards were developed from epidemiological studies that correlated the risk of gastrointestinal disease for exposure to marine and freshwater by swimmers ***rather than*** to consumption of produce.

In our opinion, this is a speculative approach not based on focused scientific studies on produce. The FDA further acknowledges that their proposed standard is much more stringent than the World Health Organization (WHO) standard which recommends a standard of 1,000 CFU generic E. coli per 100ml. for water used on root crops eaten raw and 10,000 CFU generic E. coli per 100ml. in leaf crops.

In our opinion this is where the FDA's *not commodity-specific-by-risk* approach is most troubling. One size does not fit all produce commodities. Indeed, they do use the phrase "tentatively conclude" in summarizing remarks concerning whether produce exposed to water that violates the proposed water standard would necessarily establish evidence of adulteration of covered produce. Nor would it mean that the food was contaminated.

The FDA states that in specific circumstances an alternative standard (e.g., a standard that applies an application interval time between application and harvest) but is specific to a specific commodity or commodity group and region may be appropriate (Pg. 247-

248) if the alternative standard is shown to provide the same level of public health protection as the proposed regulation. In our opinion if we could prove substantive degradation of pathogens from a known water source with a defined level of contamination then we would have solid grounds for proposing an alternative standard. There are currently existing food safety programs which state that within 14 days of intended harvest, only potable water will be used for spraying. What we lack is research.

Another problematic Agricultural water provision is the frequency of testing. Untreated Agricultural water from any source where a significant quantity of runoff is likely to drain into the source e.g., steams or streams feeding ponds, must be tested every 7 days during the growing season. From any source where underground aquifer water is transferred to a surface water containment structure, constructed and maintained in a manner that minimizes runoff drainage into the containment, must be tested at least once each month during the growing season.

In our opinion, these testing frequencies are much too stringent for our commodity risk profile. We would suggest that testing three (3) times per growing season should be an adequate number of tests to determine water quality, particularly since we are only using Agricultural water for spraying.

Biological Soil Amendments of Animal Origin

This part of the Rule deals with soil amendments of animal origin, such as manure because manure can contain pathogens of public health concern. The Rule proposes three (3) types of measures to reduce risk. The proposed Rule also has provisions for handling and storage of biological soil amendments of animal origin. This section should not pose a big problem for our growers unless they are organic and using manure.

Health and Hygiene

The proposed Rule would require that farm personnel use hygienic practices, including hand washing and maintaining adequate personal cleanliness. The provisions are quite similar to what current GAP audit programs require and should not cause growers any problems.

Domesticated and wild animals

The Rule addresses where there is a reasonable probability that animals will contaminate produce, that there are certain restrictions. For our industry, bird excreta would be the main concern. The Rule states that produce contaminated by excreta not be harvested. Current GAP food safety plans say the same thing, so industry should not have problems complying with this section.

Equipment, tools, and buildings

There is really nothing of concern for our industry in this section. Growers that have been doing GAP audits are familiar with most of the provisions.

Recordkeeping provisions

The FDA says that they would not require duplication of records to document that certain standards were being met, e.g. those kept for GAP audits. This position is acceptable. However, we would emphasize that every effort should be made to avoid the needless duplication of record keeping requirements between the new FDA rules and existing GAP audit rules for documentation that is substantially similar in scope and content.

Agricultural Water

Overview

The proposed agricultural water regulation in the FDA's Produce Rule is flawed. It is flawed because it does not address risk specific to produce commodities but lumps all produce under one standard.

The FDA's use of the EPA's recreational water standard does not reflect any specific science that relates to consumer consumption of produce commodities. The FDA acknowledges that the proposed standard is much more restrictive than the World Health Organization (WHO) standard.

One size does not fit all produce commodities. In many FDA stakeholder meetings produce industry representatives told the FDA staff that there were differences in risk by commodity as well as differences in cultural practices for the same commodity grown in different regions.

The FDA seemingly acknowledged this fact at the time but the Produce Rule as released is not specific by produce commodity. It does not recognize the total lack of food borne illness outbreaks from consumption of whole, fresh tree fruits. There is no risk evidenced by an event likely to occur based on illness outbreak history, and risk evaluation is at the heart of food safety protocols.

The tree fruit industry is in strong support of delivering safe, wholesome fruit to the consumer. The industry will be compliant with whatever is issued as the final Produce Rule. However we do not want to see our Agricultural water sources put at risk if it is not necessary to protect the public health.

Some have said that we only need to treat the water. However upon investigation, a PhD chemist from a large corporation offered that a number of commonly used crop protecting chemicals could "react rather quickly and destructively with hypochlorite, even at normal use dilution". So for a grower who must immediately discontinue the use of a water supply due to a finding that exceeds FDA's generic E.coli limit, there is no immediate solution.

An Alternative Approach For Tree Fruit Agricultural Water

In recent public meetings the FDA continues to ask industry for alternatives to their proposed regulations. Based on that desire, we would propose the following:

Agricultural water used on tree fruits is not a public health risk until 14 days before intended harvest. It is not a health risk because the fruit is basically hard, bitter, and inedible. If there is no likelihood that it will be consumed, contact by agricultural water is not a risk.

Testing of agricultural water should be done 3 times during the growing season to establish a baseline for a given source. If contamination levels are present which exceed the regulated limits then an alternate, conformant source must be used within 14 days of harvest.

We are unaware of any science which would contradict this approach. The FDA acknowledges pathogen degradation when exposed to sun, temperature, and rainfall. Our approach would substantially address risk and allow continued use of a water source that showed non-conformant levels of generic E.coli until 14 days of intended harvest.

It is also important to note that a vast majority of whole, fresh tree fruit offered to the consuming public goes to packers who have rigid food safety protocols in place.

Summary Conclusions

Protection of the public's health is our number one concern. However the implication that agricultural water on whole, fresh tree fruits is a public health issue has not been demonstrated. The USDA in response to an industry inquiry in 2011 stated that the USDA Microbiological Data Program (MDP) had never tested any fruits. This is certainly because there have been no identified microbial problems in tree fruits. Application of a rigorous standard to a commodity of such low risk is inappropriate.