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DATE: July 22, 2013

TO: Division of Dockets Management (HFA-305)
Food and Drug Administration
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FROM: Carolyn McQuiston, President
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RE: **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**
Document ID FDA-2011-N-0920-0013
RIN 0910-AG36

I am submitting comments on the proposed rule for "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food " 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 Preventive Controls Rule

This rule will impact commercial packers and on- farm facilities that pack produce other than their own.

“Preventive controls” means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. “Current scientific understanding” is subject to interpretation by commodity risk profile.

Hazard Analysis and Risk-based Preventive Controls (HARPC)

HARPC is being introduced by the FDA to address the biological, chemical, physical , and radiological hazards that might be expected to occur. It is a broader-based approach than our industry's current Hazard Analysis and Critical Control Point (HACCP) based plans. It is based on 7 principles established by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

A "reasonably foreseeable hazard" is defined as a potential biological, chemical, physical, or radiological hazard that may be associated with the facility or the food. The words "potential" and "associated" would seem to have significance.

If a pathogen is known to have caused a health problem in a certain commodity, e.g. Listeria monocytogenes in cantaloupes, it could well be interpreted as a hazard for other produce commodities by the FDA. There needs to be commodity-specific guidance which the FDA is currently unwilling or unable to provide.

Written plans and documentation are required for each facility. You must:

- Conduct a hazard analysis
- Determine critical control points
- Establish critical limits
- Establish monitoring procedures
- Have corrective actions
- Establish verification procedures
- Establish record keeping and documentation procedures.

The Rule also requires that the owner, operator, or agent of the facility is responsible for preparing and implementing a written food safety plan. It must be someone who has been trained in the development and application of preventive controls or has gained this knowledge through work experience must be responsible for executing the plan.

The plan must be facility specific. The plan must be reanalyzed every year, whenever there is a significant operational change that might create a new hazard, or whenever there is new information that emerges on potential hazards, or when a preventive control is found ineffective. All changes must be documented.

We feel that this rule will add significant burdens to our industry's packing operations. Those which have already established HACCP plans in operation will have to modify them to adjust to the FSMA regulations. The costs and time spent in training employees to become qualified in performing these tasks are not inconsequential.

The rule is not commodity-specific by risk and adds numerous complications to small produce businesses in achieving compliance. The real question is what is necessary for our relatively low risk whole, fresh tree fruit profile? We lack research in our industry because we have had no indicated problems.

“Ready-to-eat food” (RTE food) means any food that is normally eaten in its raw state or any other food including processed food, for which it is reasonably foreseeable that the food would be eaten without further processing that will significantly minimize biological hazards. If tree fruits are categorized as RTE as opposed to raw agricultural commodities (RAC food), then the FDA could force packers to do mandated product testing.

Any finding of a pathogen of public health significance on the product is reportable to the FDA. The product would have to be quarantined and held for retesting. In our opinion this represents an unnecessary and costly process that should not be backed by our industry. The produce industry has already proven that you can’t test your way to safety.

Another area of significant concern is environmental testing of equipment or facility sites to determine the presence or absence of potentially harmful pathogens. The FDA has suggested this would be a good verification procedure for checking sanitization effectiveness. We oppose environmental testing because science has not indicated a need for our low-risk whole, fresh tree fruits.

There are many aspects of the Preventive Controls Rule that are currently being addressed by industry audit programs. But there are many packers for which this Rule will represent major changes. In some instances packing facility structures may have to be reconstructed to make them enclosed and therefore less vulnerable to intrusion by rodents, etc.

Exclusions by packer size may not matter as audit systems will have a tendency to align their elements with the provisions in the Rule. It is our opinion that research is needed to provide solid guidance on what is necessary by commodity and by risk profile.