

***Idaho State Department of Agriculture  
02.05.01 Rules Governing Produce Safety  
May 15, 2018 at 9 a.m. in Ontario, Oregon  
Pamela Juker, Facilitator***

Present: Brad Carlsen, Capital Press; Candi Fitch, Idaho-Oregon Fruit and Vegetable Association; Ann Jacobs, Idaho-Oregon Fruit and Vegetable Association; Theresa Bond, Champion Produce; Jeff Robins, Champion Produce; Brad Dines, Champion Produce; Jackie Williams, Williams Fruit Ranch; Bryce Marvin, Snake River Produce; Terry Willis; JC Watson Company; Jon Watson, JC Watson Company; Paul Arrington, Idaho Water Users Association; Bob Simerly, McCain Foods; Megan Huls, Owyhee Produce; Patrick Guzzle, Idaho Health and Welfare; Pamela Juker, ISDA; Janis Perry, ISDA.

**AGENDA ITEMS**

**WELCOME**

Pamela Juker convened the meeting at 9:05 a.m. at the Clarion Inn in Ontario, Oregon. She explained that minutes of the rulemaking session would be recorded. Along with the minutes, the draft rule and the notice of rulemaking would be available on the ISDA website. She encouraged participants with questions to contact her, Brigitta Gruenberg or Jaclyn Evans in the ISDA office. She also announced that several outreach and education materials were available for participants to take include: a placard listing exemptions to the Produce Safety Rule, pocket size copies of the federal rule, visitor procedures poster, and additional outreach and education materials.

Pamm stated that it appears that this is a well-educated audience, many who have been through the Produce Safety training, so she would be brief in the background of the Food Safety Modernization Act. She indicated that copies of House Bill 537 that was passed by the 2018 Idaho legislature and the strawman draft rule were distributed to participants. She explained that participants could sign up for an on-farm readiness review that would be conducted this summer to help people comply with the rule before regulatory inspections begin next year. This review would not involve pictures taking and any notes and reference manual would be left at the farm upon completion of the review. The intent of the review is to help producers come into compliance with the rule. An audience member asked if the FDA would be invited. Pamm stated that the review would be conducted by a team of three people including U of I staff, Ariel Agenbroad or Rebecca Mills, and ISDA staff, Pamm, Brigitta, or Jaclyn. She stated that it would be up to the operator whether to invite the FDA. She indicated that the intent of the review is to educate operators.

Pamm explained that the purpose of negotiated rulemaking is not to change or negotiate the federal rule, since it will be incorporated by reference into the Idaho rule in its entirety. ISDA has been monitoring the federal Produce Safety Rule since 2013, as part of the seven rules proposed and eventually adopted by FDA. A Food Safety and Modernization Act (FSMA) Advisory Committee was formed with members representing not only produce, but transportation and other involved industries. This group of thirty members recommended that ISDA apply for an FDA outreach and education grant which was received in 2016 and a compliance and enforcement grant received in 2017. In 2018 HB 537 gave ISDA

statutory authority to take on enforcement of the Produce Safety Rule. This allowed for a state presence, not FDA presence, on farms and facilities.

Pamm provided a brief overview of the FSMA Rules (See powerpoint presentation slides 5 and 6). The Produce Safety Rule covers produce general consumed raw. Some produce commonly grown in Idaho would include onions, tree fruit, hops and grapes. (Slide 7) For an exhaustive list of produce not covered by the rule see 21 CFR 112, Section 112.2. The FDA is currently working on record keeping procedures for hops and wine grapes for assurance that they will be processed to eliminate microorganisms. Potatoes, sweet corn, and sugar beets are not covered. In response to an audience question, Pamm explained that the ISDA is currently not authorized to enforce the FSMA Sanitary Transportation Rule, only the Produce Safety Rule. A packing shed may be covered if it meets the definition of a primary or secondary farm as defined in the Produce Safety Rule. She explained that the human food industry has asked for FSMA inspections for the Preventive Control for Human Food Rule. However, currently that is handled by Health and Welfare inspections. Patrick Guzzle stated that Health and Welfare has conducted seventy-five contract inspections this year. He indicated that if an operation is subject to an FDA inspection, it would not be inspected by the state. By 2020, these inspections could be contracted with FDA to ISDA.

Pamm read from the definition of farm from the Code of Federal Regulations (CFR) including a “primary production farm” and a “secondary activities farm.” She indicated that if a packing shed is part of the farm, it does not have to be registered with the FDA. The Produce Safety Rule limits what activities, not manufacturing, can be done to the produce including dehydrating, treatment to enhance ripening, and packaging and labeling. The FDA is currently reviewing the water standards in the rule.

Pamm continued to explain:

- Who must comply (Slide 8);
- Qualified exemption (QE) and QE modified requirements (Slides 9 and 10);
- Key Requirements (Slide 11);
- Compliance Dates (Slides 12 and 13) – FDA postponed inspections to 2019;
- Variance (Slides 14 and 15) – FDA is working on guidance.

Bill Simerly commented that onion growers through Malheur County may seek a variance. He asked who should be contacted at ISDA regarding a variance and who would be reviewing the scientific evidence. Pamm indicated that she would be the ISDA contact and the FDA would be the reviewer if all components of the variance are complete. She stated that another industry group had contacted the ISDA about submitting a variance so she checked with the FDA on guidance documents. She referred to §112.176 for instructions on a citizen’s petition requesting a variance.

Since HB 537 gave ISDA authority to promulgate rules related to produce safety, Pamm explained that ISDA has created a draft rule for discussion. Page one of the draft rule includes items that all rules contain. The rule incorporates by reference the entire federal Produce Safety Rule, CFR, Title 21, Part 112. Pages two and three deal with the variance process. Pamm explained that ISDA will need the petitioner’s assistance in defending a submitted variance if FDA should have questions directly related to the variance’s scientific evidence. This section explains that procedure and timelines.

She stated that unlike the Organics Rule, this draft does not include: fees since the grant will cover the cost, a seal, or how to apply. She then asked for input from the participants.

Jon Watson questioned whether a seal, a certificate or some sort of validation, from the state of Idaho indicating that an operation had met the criteria and had complied with the Produce Safety rule would be helpful. Pamm asked when this seal would be applied, since there would be times when the findings during an inspection would need corrective action. She said that with this rule an operator is either in or out of compliance, since all key requirements must be met. She cited training as an example. Documentation of training could involve corrective action if it did not meet the rule requirements. She also indicated that an inspection frequency may eventually be included in the rule since the frequency may not be every year.

In response to a participant question, Pamm indicated that she would double check on how USDA GAP audits will interface with operators who must comply with the Produce Safety Rule. She indicated that GAP audits, which are market driven, and Produce Safety inspections are different and both will continue.

Pamm explained that this rule was made from scratch. Written comments to the draft rule will be considered up until May 31. The same negotiated rulemaking process would apply to changes in the rule.

Jon Watson asked if Oregon has taken on the job of Produce Safety inspections. Candi Fitch stated that she thought that in Oregon the FDA will conduct the inspections. Jon indicated that he appreciated the state of Idaho taking on the task of inspections. He felt that it will be very disruptive for growers since a large number of onion growers are growing in Oregon so must deal with two different types of inspections or “annex Malheur County into the state of Idaho.” Patrick Guzzle stated that everyone would still be subject to the same rule, no matter who did the inspections. Bill Simerly indicated that he hoped the grant money does not run out since this is a big job. Pamm encouraged participants to read the bill regarding funding. Enforcement would cease if the funding is no longer available unless industry were to decide on another funding mechanism, perhaps a fee. The grant is for five years and we are currently in year three. Idaho could receive up to \$575,000/year for outreach and education and \$180,000/year for compliance. Oregon received an outreach and education grant, but did not apply for the compliance part of the FDA grant.

Pamm reiterated that ISDA is poised to help operators comply. She is optimistic. If there is an egregious situation that affects human health, it must be fixed today. She sees fines only for those operators who are not willing to comply. The Idaho statute includes the authority to fine, but the wording is “may”, not “shall.” Patrick Guzzle stated that the FDA can charge for a re-inspection.

Pamm indicated that unlike some states, Idaho has not included a farm registry into the rule. That is something that could be considered, if participants are interested. Patrick Guzzle stated that third party audits may be generating some questions about registering facilities.

Pamm Juker adjourned the meeting at 10:35 a.m.

Next meeting: May 22, 2018 at 10 a.m. PDT in Moscow, Idaho.

Respectfully submitted by Janis Perry