Idaho State Department of Agriculture 02.05.01 Rules Governing Produce Safety May 22, 2018 at 10 a.m. in Moscow, Idaho Pamela Juker, Facilitator

Present: Jaclyn Evans, ISDA; Pamela Juker, ISDA; Janis Perry, ISDA.

AGENDA ITEMS

WELCOME

Pamela Juker convened the meeting at 10 a.m. Fairfield Inn and Suites in Moscow, Idaho. Since no participants, other than ISDA staff, were present, Pamm previewed her presentation for Jaclyn Evans. She stated that this was the second negotiated rulemaking session for the Produce Safety Rule. The last one will be in Burley, Idaho on May 29, 2018 at 10 a.m.

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. Potatoes, sweet corn, and sugar beets are examples of commodities that are not covered. 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.

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.

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 fees will not be included in this rule because the cost of the program is being funded by the FDA grant.

Pamm explained that 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.

Pamm indicated that ISDA, along with the University of Idaho, is providing outreach and education for the Produce Safety Rule. This includes an anonymous decision tool for producers to determine if they must comply with the federal rule. 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 picture 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. Produce Safety training will be available in the fall of 2018. She also announced that several items were available for participants to take including: a placard listing exemptions to the Produce Safety Rule, pocket size copies of the federal rule, and additional outreach and education materials.

Pamm Juker adjourned the meeting at 10:40 a.m.

Next meeting: May 29, 2018 at 10 a.m. in Burley, Idaho.

Respectfully submitted by Janis Perry