Food Safety Advisory Committee Meeting Summary
July 7, 2016

Attendees

Ashley Hynes, Oregon Cattlemen's Association
Shawn Miller, NW Grocery Association
Jenny Dresler, Oregon Farm Bureau
Brian Campbell, NW Food Processors' Association
Ivan Maluski, Friends of Family Farmers
Gail Greenman, Oregon Farm Bureau
Rebecca Landis, Oregon Farmers Markets Association
Antone Mickelson, Darigold
Monica Durazo, ODA
John Burr, ODA
Karel Smit, ODA
Frank Barcellos, ODA
Amanda Wright, ODA
Dave Wright, Pacific Seafood
Jack Noble, ODA
Stephanie Dukovic, Ever Fresh Fruit
Joy Waite-Cusic, OSU
Dave Martin, Oregon Health Authority
Tami Kerr, Oregon Dairy Farmers Association
Lisbeth Goddik, OSU
Paul Cieslak, Oregon Health Authority
Annaliese Koehler, Oregon Food Bank
Dave Eisenhut, NORPAC
Bill Burich, NORPAC
Stephanie Page, ODA

Budget subcommittee report

Stephanie Page and Jack Noble provided an update on the last budget subcommittee meeting. They briefed the subcommittee on the budget projections for the program as well as staffing. Based on Jack's projections, it appears that there is sufficient funding to add two Limited Duration positions. These are positions that need legislative approval to continue beyond the end of the current biennium. Jack explained that his projections are showing a $6M balance at the end of the current biennium. With the additional 2 positions, that balance is projected to get back down to $4.5M at the end of the 2017-2019 biennium.

Rebecca Landis added that ODA has been researching the costs of a large-scale outbreak to help verify the assertion that the program needs a relatively high Other Fund

balance in case of emergency. Jack explained that the minimum is to have 3 months' operating cash available for a program. The concern that others have mentioned is that we are going into a Legislative session when the funds could be swept - this has happened before.

Dave Wright asked whether firms are charged for ODA FSP for the additional time.

John Burr explained the FDA can assign a fee to recalls. That's one of the FSMA rules to allow FDA to charge a fee associated with additional inspections. It should be an hourly fee (but that is rarely enforced) Dave Wright commented that seems to be a new piece in the play book. John Burr added that the ODA Food Safety program does not charge for reinspections, recalls and follow-ups.

John Burr mentioned that there was an account number set up so he asked our financial analyst to go back and research the costs associated with that. This is the largest coordinated effort to come up with a dollar amount. Committee members encouraged ODA to continue researching the costs of a large-scale outbreak and talk to other states.

Ivan Maluski asked about ODA's role in voluntary versus mandatory recalls. John Burr talked about the Peanut Corporation of America recall - FDA had the lead and the states assisted. Paul Cieslak added that nearly all of these recalls are voluntary and that OHA nearly always asks ODA to assist with effectiveness checks.

Stephanie Page provided some statistics in response to the budget subcommittee's request for information at its earlier meeting.

- The total number of overdue inspections for the Food Safety program is 1775 – that includes firms that are overdue by one year and a day. FSP licenses about 12,000 firms.
- Of those 1775, 408 are between 0-90 days over due (20%). The program wouldn't consider those over due because staff could work them in over the next few months during other routine inspections in the same area.
- 395 are more than 730 days past due.
- The number of high risk firms past due has been tracked over the last 6 months and is on a downward trend. The program did see an increase between May and June, but believes this was due to data entry by staff and is more of a "correction" rather than an indication the program is falling further behind.
- Factors that are affecting being able to catch up include cannabis, which at this point is a wild card on how much time is being used up. Currently we have about 250 firms pending at OLCC to be licensed for cannabis products. Plan review is required for retail firms. For other types of firms, consultations will add a significant load to FSP inspectors. Fee structure will be the same for cannabis as for other ODA licensed firms. Other factors to take in to consideration on catching up are when inspectors retire, Vacation. FSMA is taking a lot of time

and the inspections will take more time than a normal routine inspection (FSP/ODA will not take it on FSMA until the money is granted).

- Some of the FSP inspectors are only assigned retail firms which enables them to do 500 to 600 per year. Dairy inspections are more complex do and require more training on a annual basis but one dairy inspector does about 200 routine inspections per year which is typical.

ODA staff provided some additional updates. The Secretary of State's office has selected Food Safety Program for an audit and will be working on that over the next few weeks. The auditors have met with managers, staff and stakeholders, and have requested and been provided a variety of documents and information. Some of the questions have looked at the program's workload and how many inspections are overdue, how inspections are scheduled efficiently, and how the program ensures consistency between regions. The audit has given the Food Safety Program some good issues to think about.

The program will be working on rules to include all of its license fee schedules. Currently, shellfish fees, egg millage fees, and one of the dairy licenses are the only fees outlined in rule; the rest were deleted from the statute but have not yet been incorporated into rule. Stephanie Page asked if any committee members would be willing to participate on a rulemaking subcommittee and the following committee members volunteered: Shawn Miller, Rebecca Landis, Brian Campbell, and Jenny Dresler.

ODA and Oregon Health Authority have signed a new Memorandum of Understanding on combination facilities, updating the last MOU which was signed in 1986. Combination facilities are firms that conduct activities regulated by both ODA and OHA, for example, selling food for both immediate and later consumption. To determine who licenses each of those firms and avoid duplication of efforts, the agencies look at what the predominant activity. If the majority of sales are for immediate consumption, the county licenses the firm, and vice versa. If the predominant activity clearly changes over time, the agencies can come to agreement to transfer a firm to the other agency's jurisdiction.

John Burr explained that one significant change with the new MOU is when a OHA firm is also conducting a high risk activity, for example restaurants making juice and selling it wholesale, that the restaurant would still be licensed by the county and ODA would license the juice production activity. Dave Martin with OHA said when dealing with high risk activities such as juice and seafood, it makes more fiscal sense for ODA to license rather than training one county inspector for one firm. John Burr added that the agencies still have work to do on making clear guidelines. Rebecca Landis asked about where that line will be. Stephanie Page said that for firms that are combination facilities, if business has drastically changed that is when we transfer to county, if its 49/51 we

don't quibble on the change. FSP continues to work closely with county inspectors when a firm changes.

Sanitary Transportation overview - Veronica Nigh, American Farm Bureau Federation

Veronica explained that the final rule is more flexible than the proposal and hopes to codify industry best practices. The regulations set forth requirements and general expectations. This is the 6th major rule under FSMA.

The rule is trying to prevent practices during transportation that create food safety risks. It is important to remember where this rule came from. In 2005, Congress amended the federal Food, Drug and Cosmetic Act by setting up a section that required FDA to adopt practices regulating sanitary transport. In 2010, FDA published an advance notice of that rule making and then it got rolled into FSMA which was passed in 2011. This rule only addresses motor vehicle and rail transportation, not boat or airplane transportation. For Oregon, talking about trade and the amount of product sent via air, this does not apply given the statutory limitations.

Who is covered?

- With some exceptions, the final rule applies to shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. It also applies to:
    - persons, e.g., shippers, in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the United States.
- The rule does not apply to exporters who ship food through the United States (for example, from Canada to Mexico) by motor or rail vehicle if the food does not enter U.S. distribution.
- Companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border.

The rule applies to both human and animal food. There is a new category of "loaders" compared with the proposed rule. Key changes - focus of the rule is now food safety, not spoilage or quality. Nevertheless, the rules focus on transportation practices that could make food unsafe and broad statutory regulations against adulteration still apply.

FDA has changed the definition of the parties involved in transportation operations to account for various business arrangements and roles and activities during transportation operations. Primary responsibility is placed on the shipper. Shippers can rely on contractual agreements to assign responsibility to other parties.

Exempt from the Rule

- Shippers, receivers, or carriers engaged in food transportation operations that have less than $500,000 in average annual revenue
- Transportation activities performed by a farm
- Transportation of food that is transshipped through the United States to another country
- Transportation of food that is imported for future export and that is neither consumed or distributed in the United States
- Transportation of compressed food gases (e.g. carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products), and food contact substances
- Transportation of human food byproducts transported for use as animal food without further processing
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety
- Transportation of live food animals, except molluscan shellfish

Question - So if a farmer is harvesting green beans or sweet corn and hauling them to a processor, are those activities exempt? Answer - yes.

Key Requirements

Specifically, the rule would establish requirements for:

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
- **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
- **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.
- **Records:** Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.

Temperature control requirements are more flexible – the shipper and carrier can agree to a monitoring scheme in advance and avoid constant monitoring. Large record keeping component - shippers have to retain written records and it is good to know that the rules specify that you can have a written agreement that lays out the plan and if the parties remain the same and folks are educated to what that agreement states, you wouldn't have to have a separate agreement for every shipment.

Scope of foods covered by the rule is narrower. Foods refrigerated for quality reasons are not covered by the rule.

Waivers

The Sanitary Food Transportation Act allows the agency to waive the requirements of this FSMA rule if it determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health.
The FDA announced in the proposed rule that it intended to publish waivers for two groups of people/businesses (see below). The agency intends to publish these waivers in the Federal Register prior to the date firms are required to comply with this rule.
The FDA also received comments asking for a waiver for transportation operations for molluscan shellfish for entities that hold valid state permits under the National Shellfish Sanitation Program. The agency continues to review comments on this request, and will issue a determination in the near future.

The agency intends to publish waivers for:

- Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety program. This waiver only applies when Grade A milk and milk products—those produced under certain sanitary conditions—are being transported. FDA acknowledges that controls for such transportation operations already exist under the NCIMS program, with State enforcement and FDA oversight.
- Food establishments holding valid permits issued by a relevant regulatory authority, such as a state or tribal agency, when engaged as receivers, shippers and carriers in operations in which food is relinquished to customers after being transported from the establishment. Examples of such establishments include restaurants, supermarkets, and home grocery delivery operations. FDA acknowledges that controls for such transportation operations already exist under the Retail Food Program, with state, territorial, tribal and local enforcement and FDA oversight.

Compliance dates – the general compliance date is April 6, 2017. The small business compliance date is April 6, 2018 (small businesses defined as having less than 500 FTE, except that for motor vehicle carriers, if they are not also shippers and/or

receivers, a small business is defined as a business is less than $27.5M in annual receipts).

Overall, Farm Bureau is fairly pleased with what we saw in the final rule. It appears that FDA really took industry comment and scaled it back so it is more focused on food safety rather than marketing issues.

How will rule be implemented? US DOT is responsible to notify FDA during transportation safety inspections; FDA plans to work with US DOT to support their inspection efforts. Even though DOT has authority to perform the inspections, FDA has said it will take the lead on enforcement. So, sounds like it will be a joint effort with US DOT and FDA.

Other updates

Stephanie Page explained that ODA had applied for a FSMA produce rule implementation grant, requesting funds for outreach, education, technical assistance, and inventory, but not inspections/compliance activities. Ivan Maluski asked when we will know when Oregon will get the funds. Stephanie Page responded that FDA will notify us sometime in August. Committee members asked about the feedback ODA is receiving on its role in implementing FSMA and Stephanie Page said there have been a variety of perspectives. Jenny Dresler mentioned that most seem like they would prefer ODA vs FDA to inspect.

John Burr provided a summary of compliance and enforcement actions for the last year in the Food Safety program. Stephanie Page explained that the program is no longer issuing C & D orders because we do not have the authority to be issuing them. The program stopped doing them earlier this year, so the committee would still see some identified. The program will not issue them going forward and is not pursuing the C & D legislative concept.

About 74% of the actions involved the retail industry (74%), and about 15% involved manufacturing. John explained the different types of actions, i.e. a sanitation warning would be issued for sanitary issues in a firm. A recall and embargo could take place at the same firm. We had one license suspension which was temporary. An agreement for disposition is typically a minor problem, i.e. a product is not sellable because it is out of temperature. We did very few closures. A warning letter is related to sanitation, while a file review letter is for other issues where we ask for the firm's response.

Bill Burich asked if the program does not have C & D authority, what other tools are available? John described the tools that are available, such as civil penalties.

Shawn Miller asked if there is a breakdown by firm size, and John said it is not in his summary but we can further break that out.

Rebecca Landis asked about agreements for disposition and whether that could include re-processing. John explained that if a product can be re-processed it would not show up on the disposition category.

Dr. Cieslak asked if firms are asked to keep logs or if the temperature violations are all observed during the inspection. John explained that these are observed during the inspection but that we recommend that firms keep logs.

Frank Barcellos explained the actions related to dairy firms. He explained that Oregon uses sanitation warnings to help alert producers of issues. He said that generally there are not a lot of other actions, that the program works well in Oregon and that firms are generally doing a good job remaining in compliance. He also explained that the shellfish actions were sanitation warning (66.7%) and product recalls (33.3%).

ODA staff announced that Christina Springer has been hired as the new ODA Retail Specialist. Christina has worked for ODA for several years as an inspector and the program is excited to have her in the new role.

Intentional adulteration rule

The final rule takes a Hazard Analysis and Critical Control Points approach. Very small businesses, defined as less than $10M in annual sales, are exempt from the rule but must keep records documenting that they are exempt. Covered firms must conduct a vulnerability assessment and for actionable process steps, identify mitigation strategies to significantly minimize significant hazards to human health.

For covered firms, the rule requires monitoring, verification, corrective actions, and record keeping. In addition, firms must keep records of training or experience for employees.

FDA is developing guidance for this and other rules, and training is being planned as part of the Preventive Controls Alliance.

Additional tools are also in the works to assist firms with gaining the education required as part of the rule and developing food defense plans.

Several committee members had questions about the scope of the rule and whether it covered activities such as economically motivated adulteration, or activities that are not intended to harm human health but result in harm. ODA staff will do some follow-up research on these questions and get back to the committee members.

Next meeting

The committee scheduled its next meeting for November 15, 2016 at the Farm Bureau office building in Salem.

Possible topics:

- Director Burbach, FDA, how large firm FSMA inspections are going
- FSMA updates
- Follow up briefing on retail violations and what size firms they are occurring in
- Temp logs and recordkeeping

Legislative Concepts and Program Option Packages

The group reviewed the current list of Legislative Concepts and Program Option Packages. The Cease & Desist authority concept has been removed from the list of concepts; the rest of the concepts and the Program Option Packages (new funding requests) remains the same.

Rebecca Landis asked about the FSMA concept and whether getting statutory authority to inspect farms would also involve getting the authority to require farms to register. Stephanie Page explained that ODA is not planning to ask for authority to require farms to register.

The group discussed the disincentive for farms to voluntarily identify themselves because it may make them more likely to receive an inspection, and ODA staff affirmed that this will likely be a challenge.