

April 7, 2016
Food Safety Advisory Committee
Meeting Summary

Budget subcommittee report

Shawn Miller gave an overview of the budget subcommittee meeting. The financial outlook is good and the program is in good shape. The subcommittee discussed some options because of the high ending balance – it is growing to a level that may generate a target on the program in terms of fund sweeps. The program had a similar ending balance in 2005 when we last restructured fees, and the legislature's proposed and Governor's budget proposed taking general fund. There were several sweeps during that session and we were looking at an over 100% fee increase because of that. You can quickly have a very good financial position with that ending balance and very quickly having the legislature asking the industry for 100% fee increases.

The program currently has \$3.948 million in General Fund. For fiscal year 2016 we are looking at about a \$4.237M end balance and in fiscal year 2017 the ending balance will grow to 6.356M. The Oregon Department of Administrative Services and the legislature look at an appropriate ending balance to have in reserve. When you are looking at an excess of \$4.8M, that is a pretty big target; it is larger than what general fund takes in. We could be right back into a situation where we are looking at industry to fully fund.

The subcommittee asked the agency to look at 3 options:

1. Creation of emergency fund for food-related outbreaks
2. Adding staff to meet the goals; also learned at the meeting that the agency currently (for a variety of reasons) is not meeting its inspection interval goals. To help catch up, Food Safety would need to increase the number of food safety inspectors. The subcommittee asked the agency to look at how many full-time equivalent (FTE) staff it would take, and rather than waiting, would be good to go to E-Board, explain that we are behind, and ask for additional positions. We discussed a 2 FTE possible addition - ODA will do some more work on what it will take to catch up. That still doesn't cut into that ending balance.
3. Another option was adjustment of fees; the agency has great difficulty adjusting fees. Another option would be asking the legislature to direct the agency to give a credit to licensees. What we would ask is, if there were a 2%, 5%, or 10% rebate, what would those ending numbers be. Think it would be good to ask the agency about that and what the impact on the ending balance would be.

If we don't come up with a good sound plan for next session, we will be in trouble if we don't get ahead of it.

Rebecca - also in favor of some kind of proactive action; it would behoove us to get on that. Whenever you hire someone, they don't go out and start inspections on their own right away if they are not trained. On the other hand, it doesn't seem to us that we will be able to get to those goals without adding staff. I'm not taking it lightly that this is a simple fix that ODA can just go out and grab bodies and make that happen – staff require significant training to get up to speed to start doing inspections.

Emergency fund – the debate is how to do it; our perspective is that if we can identify a portion of the existing balance that would be ready for an outbreak that would be a good thing. Another thing staff is doing that's important is quantifying, for example, when there is a large-scale emergency, how much resources are needed to adequately respond. Simply adding 2 FTE is not going to take it all down. There are so many uncertainties when you have an outbreak. The peanut outbreak case from 2008-2009 is an excellent example – peanuts and peanut butter were in lots of products that went all the way down to the gas station store level.

Bill Burich commented that an important take-home is that the revenue is increasing because more firms are out operating and also because of the online system of renewing fees. Staff are not able to meet inspection goals currently; we are working through that and trying to make some kind of equitable situation.

Stephanie Page explained that there are emergency board meetings in the Legislature in May and August – we think August would be good timing, and we could request positions at that meeting.

Shawn Miller said the agency also said that as quickly as they need more help, because of decreased licenses in a downturn, we don't want to get in a position where you hire people and then have to lay people off. That's what we want to learn from the agency at our next meeting. It is the agency's decision regarding whether they want to go to the E-Board in August.

Jack Noble explained we are realizing that the online renewal system is affecting how money is coming in. Last year will be a slight anomaly in the high income because license holders took advantage of the online renewal process. A lot of people jumped on that and paid at the end of June, so it skewed the fiscal year numbers a bit. We are starting to get our hands around it which will help us with lowering the projections. The fund balance is still going up and I think the things we have discussed, we will still need to talk about.

Jenny Dresler asked how ODA is funding anything to do with cannabis, and what the fees will be.

Stephanie Page explained that the fees for cannabis edible business will be parallel to the fees for non-infused businesses. She also provided an update on the time that Food Safety staff are spending on cannabinoid businesses. They are tracking their time with an accounting code and from November to February, about \$2,700 in staff time was spent assisting cannabinoid businesses. This is not a lot of time, but we expect it to increase significantly in March and April.

Stephanie Page added that ODA inspectors have been ask to give general info regarding cannabinoid edibles and the relevant laws and rules that apply to a particular business, but avoid going onsite until businesses have passed the initial OLCC or OHA screening process. We hope that achieves a balance of providing customer service while also protecting our staff time to do routine inspections and other Food Safety program work.

Food Safety Modernization Act Overview

Stephanie Page gave an introduction to the Food Safety Modernization Act produce rule and how we got to where we are today. Congress passed FSMA in 2011 and proposed draft rules to implement the act in 2013. ODA and many other organizations commented on the proposed rule, including aspects of the irrigation water rule that were unworkable for pacific northwest irrigators. FDA adopted final rules for 5 of the rules in 2015, adopted the sanitary transport rule in 2016 and plans to adopt the intentional adulteration rule in 2016.

Components of the produce rule include: agricultural water, biological soil amendments, domestic and wild animals, worker health and hygiene, equipment, tools, buildings, and sanitation, and growing, packing and harvesting of produce.

FDA has received \$19M in its base annual budget to support produce rule implementation at the states. ODA is considering applying for this funding - for nearly all participating states, this means creating an entirely new program.

Final produce rule: ag water and alternatives - Joy Waite-Cusic, Oregon State University

Joy reviewed the criteria under which a farm would be subject to the irrigation piece of the produce rule. Criteria are: growing, harvesting and packing covered produce, and applying water to covered produce. She reviewed some examples of “covered” produce and produce that is exempt because it is rarely consumed raw. Examples of covered produce include onions, sweet cherries, blackberries, marionberries, plums, blue berries, walnuts, cabbage, broccoli, and kale.

FDA made major revisions to the irrigation water rule based on input from stakeholders in the public comment period. The final rule requires growers to conduct water quality monitoring to establish two numeric values: the statistical threshold value and geometric mean. Growers will need to establish an initial water quality profile and then conduct supplemental monitoring every year to update that profile.

Joy reviewed the water quality requirements for produce at different steps in the production and harvesting process. She also reviewed some of the exemptions from testing requirements. If a farm irrigates with potable water from a public water system, or with treated water, they are not required to conduct testing. Untreated groundwater must be monitored, with an initial profile requirement of 4 samples in the first year and then 1 sample for each subsequent year. If well water is free of *E. coli*, it may be used for both pre and post harvest. If it does contain *E. coli*, it can be used for pre-harvest only.

For untreated surface water, the grower must collect 20 samples over 2 years, as close to the harvest as possible. Joy provided two example sets of water quality monitoring results and displayed the statistical threshold value and geometric mean.

If the values are over the allowed thresholds, the rule allows for some mitigation strategies. One is a time interval between irrigation and harvest, and the other is a time interval between irrigation and the end of storage. The second option requires supporting data and record keeping.

Another option is water treatment; there is not a lot of information available on this option. And another option is discontinuing irrigation, which is not an option for most growers.

The rule gives quite a bit of freedom in terms of the time to be in compliance. It gives growers some room to make a change. There is not evidence that the current numeric criteria are tied to public health protection.

Joy summarized her research on onion dry-down practices in the Treasure Valley and evaluation on how these practices would assist onion growers in complying with the irrigation water rule. Her study concluded that the finishing practice are effective in mitigating risk associated with poor water quality.

She has submitted a Specialty Crop Block Grant application to look at water variability and the potential for data sharing between farms.

Stephanie Page and Lindsay Eng asked for feedback on ODA's role in FSMA produce rule implementation and where such a program should be housed within

the agency. Current thinking is that Market Access & Certification would conduct on-farm inspections and that they would work with Food Safety on the compliance/enforcement side of things. From what we have heard from our stakeholders, they are saying if someone is going to be inspecting their farm, they are more comfortable with the state doing it. But some say that they don't believe FDA will have the capacity to inspect, so they would rather take their chances and not have Oregon set up a program.

FDA has released a funding opportunity announcement to build state capacity for produce safety programs. The opportunity includes two sources of funding, Competition A and Competition B. Competition A focuses on capacity building, outreach and education, and creating a farm inventory, while Competition B focuses on developing an on-farm inspection program and conducting the inspections. Based on the feedback ODA has received so far, the department is planning to apply for Competition A funds only this year, and may apply for Competition B in the future based on ongoing stakeholder feedback.

Stephanie Page and Lindsay Eng explained that for the inventory part of the project, FDA expects states to provide a list of farms, which ODA recognizes is a challenging concept for our stakeholders. They are not sure if FDA expects a list of covered farms only or both covered and non-covered farms.

A committee member commented that education and outreach needs to be no cost for folks to be willing to participate. Stephanie and Lindsay also explained that they believe outreach and education should be directed at both covered and non-covered farms because a farm's status could change over time, and because markets may cause non-covered farms to need to meet the requirements.

Rebecca Landis asked if FDA give us more guidance before 2017 for FSMA. Privacy is a huge concern.

Ivan Maluski asked if it is premature to expect farms to follow FSMA if we don't have the clear understanding of the rules.

Stephanie Page said that the largest farms have 2 years to be compliant from final notice; most farms will start to be expected to be compliant by 2019 but there is additional time for the irrigation water requirements.

Ivan Maluski asked how far along ODA's FSMA-related legislative concept is in terms of actual language.

Stephanie Page explained that ODA is working on draft language, which won't be final until after legislative counsel review. There is no funding for states from

FDA for onsite inspections unless we agree to adopt the entire produce rule (all provisions) outright. We can choose to get authority later.

Discussion of legislative concepts

Stephanie Page reviewed an updated list of legislative concepts in ODA's Food Safety, Animal Health & Animal ID program area. Advisory committee members discussed the proposed legislative concept regarding "stop work" orders, situations in which they could be used, and how ODA sees these orders working with the other regulatory tools that the agency already has. She described an example in which an unlicensed firm was selling products that required a license to sell. The local inspector had the ability to embargo the product, but that does not stop the firm from continuing to produce the product. The inspector would need to stop by the firm on a regular basis to continue embargoing product, which is time-intensive with the inspector's office 30 miles away from the firm.

Advisory committee members commented that they would like to see a quick turnaround on the appeal process for a stop work order so that someone's entire product is not tied up – really solid sideboards are needed on this authority. They also commented they would like to see Director approval required for stop work orders.

A committee member asked what ODA's options are if someone does not pay a civil penalty. Stephanie Page said she would find out and report back to the committee.

Several other questions came up during the discussion – ODA staff will report back to the committee on these questions. They are:

- Statistics on how frequently the other types of enforcement actions are issued.
- Who regulates hemp extracts for joint pain and other similar products that are used for medicinal purposes.
- Could a store with 3 licenses have different risk classifications for each license?

Next meeting

The next advisory committee meeting will be July 7, 2016. Committee members identified the following possible topics:

- Legislative Concepts
- FSMA transportation rule
- Intentional adulteration rule

