Food Safety Advisory Committee
January 9, 2019
10 am – 1 pm

Meeting Summary

Attendees

Advisory Committee members:
Shawn Miller, NW Grocery Association, Co-Chair
Jamie Wiggins, Food Northwest, Co-Chair
Jerome Rosa, Oregon Farm Bureau
Tami Kerr, Oregon Dairy Farmers
Paul Cieslak, Oregon Health Authority
Dave Martin, Oregon Health Authority
Jovana Kovacevic, OSU
Shannon McFadden, Oregon Food Bank
Hilary Styles, Pacific Seafood
Karen Samek, Darigold/NDA
Bob Beck, Columbia River Inter-Tribal Fish Commission
Steve Ramsey, Safeway
Mark Wustenberg, Dairy Veterinarian
Rebecca Landis, Oregon Farmer's Market Association

Staff:
Isaak Stapleton, ODA
John Burr, ODA
Karen Apiado, ODA
Rusty Rock, ODA
Karel Smit, ODA
Frank Barcellos, ODA
Mary Al-Telaihi, ODA
Robert Wilson, ODA
Kent Widdicombe, ODA
Sue Davis, ODA
Jack Noble, ODA
Kathryn Nelson, ODA

Other attendees:
Curtis W. Martin
Will Weis

Public Comment: Shawn

There was no public comment.

Budget Overview: Kathryn Nelson & Jack Noble

Definitions:
Fiscal year (FY) is July 1 through June 30 of the following year.
Appropriation year (AY), also known as Biennium, is July 1 of odd year through June 30 of the next odd year. It includes two fiscal years and is what our state budget is based on.
Other funds are funds that are received by fee payers, federal contact work, or other miscellaneous revenue sources such as interest on accounts.
General Fund is money appropriated by the legislature for use in this program.
Federal Funds are money received directly by the Federal Government for specific grant work are federal funds.
Operating reserves are other fund balances set aside to stabilize the program in case of an unexpected increase in expenses or revenue shortages. Our program is required to maintain a reserve amount is equal to three months of program expenses.
Administrative overhead is a percent of the program's expenditures transferred out of Other Funds to support the administrative functions for the agency (i.e. Payroll, IT services, licensing, etc.).
Other fund expenses are personal services, salaries, benefits, retirement, supplies and services, travels. Lab services expenses, Food Safety pays a flat fee for the lab program.

Administrative overhead is a percentage of overall expenses, as a result administrative costs were a little higher in Ay 15. The current rate is 15% and we do anticipate that rate to stay the same. Other fund revenue primarily comes from licenses, federal contract work, and an OHA contract. We had minimal "fee for service" work such as 'Machinery and Equipment certification' (market access now has this) with $40,000-50,000. We're estimating about $8 million to come from license fee revenue this biennium. Food safety Program fee structure was established in 1987 and then revised 2002-2003 through several special legislative sessions that significally reduced general fund for the program and then in 2005 the industry introduced house bill 2539 which established the current food safety fees and statue and also established the fee structure we use today. A 3% fee increase was provided in July of 2009, but the program didn't exercise the increase because the other fund cash balance was sufficient enough to cover expenses. Fee increases have been implemented recently when the legislative adopted budget reduced the program's general fund $1.4 million. This year we enacted our final ability to raise fees 3% and did that on July 1st 2018. The increase does not cover for the $1.4 million fund shift. The agency has submitted a legislative concept to extend our ability to raise fees 3% per year and have also requested a POP which is a policy option package to reverse the $1.4 million that was not approved in the governor's budget.

Federal funds grants with reduced program's need to spend to other funds. Wages, hiring freezes furloughs those kinds of things helped keep other fund spending down. With the economy improving and number of licenses increased we have seen an increased in revenue in this last biennium. The two new positions were approved in our budget but we were subjected to an Other Fund shift of 1.4 million. When you add all those things together it really hit our other fund cash budget. General fund and other cash correlate with each other. We are predicting that in AY 23, that we will have a negative cash balance or 1.3

million. We anticipate that the 19-21 biennium we will be able to maintain program services however if we don't get general fund or raise fees 2023 by we will anticipate the need for a substantial fee increase to maintain our current service level. Program budgets are still on downward trajectory unless we see an increase in Other Funds.

Licensing Compliance Enforcement Update - Isaak Stapleton

For the firms who are refusing to pay license fees, we are increasing enforcement to either close firms out in systems or start the civil penalty process. There are about 598 firms that have not renewed their license, with 89 of them being more than a year past due. Before entering the civil penalty process, we must confirm they are still in operation. Staff determined the total dollar amount of license fees due to be 60,000.00, that is including late fees. We are working with the Department of Justice to roll out expedited enforcement offer telling firms what they owe and deadline to pay. If we do not receive payment within 20 days of the enforcement action letter is sent, or firm decides not to sign and accept offer, we will move on to issuing civil penalties. Range of what firms owe are between $300 and $2,000. We don't anticipate to have a large number of people contesting the offer and it will not be easy to dispute needing a license. Firms will be looking at paying around $9,000 if they choose to take the civil penalty route. It is a goal to contact the 89 firms who are more than one year past due before renewal for the 2019-2020 period opens. This is purely due to needing these firms in compliance.

Our licenses expire June 30th of each year. Firms are not charged a late fee until 60 days after that. This is a grace period for a late fee being accessed, NOT a grace period to renew or to be licensed. Firms are not in compliance if they miss the June 30th window to renew. We can-not close a business for not being licensed, we can only do that in the event of unsanitary conditions. This will be our first time issuing civil penalties for licensing compliance as we have not done so in the past.

The process of notifying firms that it is time pay their license fees start with our licensing department sending out a postcard in the mail mid-May to let firms know it is open online to renew their license. Then a second notice is sent early July to notify their license still needs to be renewed. A third and final notice gets sent in September letting firms know we still have not received payment and there is now a penalty fee assessed. The licensing department does not send out any other notification after that and it goes to the Food Safety Program to reach out to the delinquent firms. Mary and Sabrina go down the delinquent firms list and attempt contact by phone and email.

A specific breakdown of the license types that are past due are: about 150 retail food establishment, 130 food processor, 81 shellfish, 74 meat, 74 bakery, 37 cannabis, 24 dairy, and 11 egg handlers. We have about 12,000 licenses in total.

Inspection Update (Rusty Rock)

Since our last meeting, two additional inspection types have been added to our list of contacts considered as routine: Dairy device inspections and milk truck inspections. Dairy device inspections are inspections that consist of equipment checks that have a regulatory requirement to occur on a quarterly basis.

Of the 12,000 licenses, roughly 30-40% are low risk, 35-50% are medium risk, and about 20-25% are high risk. However, 50% of inspections conducted are associated with a high-risk firm. High-risk facilities have a 6 to 12-month inspection frequency. We will be continuing to prioritize high risk inspections. Our next is step in the process of addressing the overdue inspections is to start spending time with individual inspectors that may have a work load conflict. For example, right now our inspectors on the coast are struggling under their workload due to crab season starting, which consists of a ton of sampling for them. The drive alone to do this is can be up to 6 hours.

Overall, we have seen the back log has dropped from about 1689 firms being overdue to about 1182 since the implementation of our "Routine Thursday" policy. Using four years of actual inspection data we found that there had been a trend towards reduced routine work with an increased emphasis on consultative / outreach visits. The implementation of the Routine Thursday initiative has shifted the balance of work back towards routine regulatory inspections.

Preventative Controls Status Update (John Burr, Kent Widdicombe, Robert Wilson)

(John)At the last Advisory meeting we announced we had just adopted the 2017 version of the CFRs which basically sunset CFR 110 and adopted 21 CFR 117. We have been able to send all of our staff except for two people to the PCQI course. We are looking to getting the remaining two into a class as soon as we see one available. Thus far we have sent five field staff and one manager to the seven-day FDA Preventive Controls for Regulators (FD-254) course. The people who have taken the FD-254 course include our FDA contract reviewers and John Burr which is a seven-day course. In May we will be able to send five additional people to the seven-day FDA training course. In December we received a list of firms the FDA would like us conduct Full Scope Preventive Controls inspection as part of the FDA contract agreement. This year we will conduct eight Full Scope Preventive Controls inspections for the FDA. We plan on having two inspectors conduct each inspection during the learning phase of Full Scope PC inspections. All other inspections will be Limited Scope Preventive Controls inspections. Training by FDA for the Regulator course has been limited and this is an issue in getting all staff members training in Full Scope Preventive Controls inspections.

(John) I want to give a special thanks and credit to Kent Widdicombe for taking the lead on implementation of the Preventive Controls project and also give thanks to Liz Beeles in our publications department for her help on developing the guidance documents Kent will talk about next. The Preventive Controls guidance documents are now available on our website.

(Kent) Due to training and the slow process of adopting the Preventative Control type of inspection, to begin with we will only be doing GMP Subpart A, B, and F for ODA inspections. If a firm has questions about preventative controls or their food safety plan, or has implemented Preventive Controls, we will look at the plan and provide advice. With respect to GMP's, 117 is not a big change from 110 but the language has changed and there are different interpretations on some language.

Kent discussed one recent Full Scope Preventive Controls inspection with Subparts C & G investigated, where we found the firm conducted a hazard analysis but did not develop a preventative control for the hazard and the associated monitoring. What we are trying to reinforce is that preventative controls require firms that identify a hazard to develop a control step.

In terms of time, a typical FDA inspection has been taking 4-days, but we would like to get that down to 4-6 hour physical inspection and then start identifying the hazards, specifically looking in 3 areas: ingredients, processing, and storage. After the physical inspection the 2 inspectors will go offsite and determine and identify hazards and take back to the firm and determine best actions and next steps. The plan is to try and identify 1 or 2 hazards and get process controls in place with monitoring. We will also be working with firms that have HACCP plans for high risk foods such as juice, seafood, LACF, and dietary supplements that exempts them from Subparts C & G where they are controlling micro-organisms of concern through other sections of the CFRs, but still need to address issues such as GMPs and labeling.

We had one comment from a small firm that stated they had gone to a training where it was recommended everyone file an exemption if they qualify. There's an Attestation exemption 3942A which talks about a small firm under a million dollars that can be exempt, but the form talks specifics about the requirement for implementing preventive controls and monitoring, but the exemption from providing records. We will be working with firms to better understand exemptions.

Dairy program will be sending out a letter to dairy producers and dairy plants that details qualifications for exemptions of subpart C and G of preventative controls.

(Frank) Back on August 20 – 23, 2018, state rating officers and state program managers were invited by FDA to come to the FD378 Preventative Controls for Grade "A" Milk Plant Regulators course to bring states up to speed with the new rules and requirements put in place for the new Appendix T that was added to the 2017 Pasteurized Milk Ordinance. All milk plant regulators attended at locations across the nation. FDA was ready to move forward with lifting the exemption that was given to the dairy industry that expires Sept 17, 2018.
FDA is also working on a pilot program concept to see how plant inspections will be done where there are grade A products and non-grade A products being processed in the same plant. The purpose of the pilot is to remove the need for these inspections to fall under two regulations that are not completely similar. The industry has pushed against FDA consumer safety officers (CSO's) coming in to their plant and doing half of inspection and state folks

coming in and doing the other half. There are 7 states involved with this pilot program. Initial trial inspections to see how to adjust to this new inspection process took 7 days. In reality we expect to return to 3 or less days working in the plant.

Hemp Rule Change - Rusty Rock

There has been some commotion involving industrial hemp and the farm bill that was signed and how it theoretically freed up the ability for interstate commerce. FDA then followed up with a "no" to CBD stating it is still a drug in their per view. The important thing to know is that Oregon law says the by-products of industrial hemp which are similar to marijuana are not to be considered an adulterant in food. Because industrial hemp is not subject to the same rules as marijuana it can be processed in manufacturing facilities and sold in conventional markets. It is likely you will see and CBD enhanced products at grocery stores. There were some changes that happened to the industrial hemp program that people should be aware of that strengthen the testing requirements. Industrial hemp growers and handlers are required to be registered with ODA which includes specific testing. At this time no health benefits have been scientifically supported but a lot of food and beverage processors are following popular market trends. Under the prior rules, after you bought the concentrate and it went into the product, there were no additional testing requirements. The updated testing requirements for retail products that are not registered with the industrial hemp program, now are subject to testing requirements, but there is currently no agency assigned over sight. Our staff will not be going out and checking CBD manufacturing firms to ensure they are doing testing because that would be additional staffing resources that we don't have available.

Reused Water in Processing (John Burr)

Over the last couple of months, the ODA has received a few requests for the ODA to evaluate and approve reuse water in processing facilities. These requests are coming as firms seek to reduce their overall water consumption and as they receive pressure from buyers to who ask processors to reduce their "carbon and water footprint".

Firms have long sent water from cleaning and production to flumes to flush waste, but the water is sent to a waste water system for treatment and eventual irrigation.

A few strategies have emerged
1) Reduce water use through developing conveyor systems to move product
2) Reduce uncontrolled water usage/over usage
3) Recycle or reuse through reconditioning

Past recycle/reuse has been limited to non-food contact surfaces and activities. The new request is to recondition water for food contact surfaces or even as an ingredient.

As the OHA Drinking Water Program will not get involved, we've reached out to our counterparts in California, Washington, and Arizona for their comments/approach on the

issue. They have asked firms to provide documents on how they will remove adulteration. We are also considering the Codex Alimentarius 1999 document encouraging firms to take a HACCP approach to implementation of a water reuse program. At this time, we have communicated this position to firms, but we have not had any responses.

Working lunch: OCA Lab Created Meat LC (Jerome Rosa), Open discussion

There was legislation that was brought by Missouri legislature regarding lab created meats that changed the legal definition of meat for labeling purposes. We have a legislative concept that is being worked on. The definition of what meat animal is in Oregon is any vertebrate animal except fish and aquatic mammals, not otherwise prohibited by law for sale for human consumption. When we look at what our state definition is versus MO, we have far more descriptive definition:

> The term meat or meat product means any edible muscle, except any muscle found in the lips, snout, or ears, of meat animals, which is skeletal or found in the tongue, diaphragm, heart, or esophagus, with or without any accompanying and overlying fat, and any portion of bone, skin, sinew, nerve or blood vessels normally accompanying the muscle tissue and not separated from it in the process of dressing or as otherwise prescribed by the department.

Part of what the discussion that has been going on is who is going to be regulating this product. Is it going to be FDA or USDA? The current regulation state that the USDA regulates all the processes in plants making sure everything gets inspection and meets quality standards. Recently there was a federal decision stating USDA and FDA both will be regulating this skin cell culture products. 90-91% of all the meat handled in the United States is handled by 4 main processors and 2 of those large companies have invested heavily in this Lab grown product. The future concern really is confusing consumers that a hamburger product may come out being 70% real meat and 30% this product without properly identifying the source of the proteins present. We are trying to protect the term and language of what it actually is to allow consumers to make an educated decision. We have proven that this product as it is doesn't not mimic exactly what meat is. We want federal law to act on this, if that doesn't occur, we are looking for some protection within the state.