



Creating a State of Health

MINUTES OF SPECIAL MEETING

PUBLIC BODY: MEDICAL MARIJUANA AUTHORITY FOOD SAFETY STANDARDS BOARD

DATE: TUESDAY, AUGUST 14, 2018 and WEDNESDAY, AUGUST 15, 2018

ADDRESS: OKLAHOMA STATE DEPARTMENT OF HEALTH

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Day 1 – Tuesday, August 14, 2018; 9am – 5pm

Agenda Item 1:

Call to Order, Welcome & Introductions

Board members present: Becky Johnson, Ravirajsinh Jadeja, Scott Yates, Scott Scheffer, Fenton Rood, Mark Woodward, Kara Berst, Ray Jennings, Travis Splawn, Troy Skow, and Edd Rhoades

Board members absent: Bud Scott

Staff present: Phillip Jurina, Rocky McElvany, Amanda Morgan, Kim Bailey, Nicole Nash, Buffy Heater, and Teresa Martinez

Others present: George Richardson, Marcus Wray, Alison Tock, Adam Tock, David Howard, Stephen Corbin, Jennifer Boyle, Lezli Engelking, Sean McClelland, Jessica Badsky, Huston Hulse, Mark Fisher, Patricia Crater, Sherry Jenkins, Matthew Campbell, Carter Burleson, Collin Rockett, Jason Fisher, Toby Lee, Kareena Hardt, and Jeremy Applen

Agenda Item 2:

Purpose & Charge of Board per State Question 788 <http://omma.ok.gov/rules-regulations>

a. Discussion & Questions

State Question 788 and the rules set forth in OAC 310:681 (the “Rules”) provide the duties and authority of this Board. According to the Rules and State Question 788, the Board should have food safety standards recommendations within 60 days of its passage. The deadline to make these recommendations available is August 27, 2018. They will thereafter be submitted to the Board of Health for adoption and, if adopted, to the Governor for approval. The Board’s charge per State Question 788 is to recommend food safety standards for the processing of any edible marijuana product. The food safety standards should be in line with existing standards and should not be excessive or punitive.

A copy of the text found in State Question 788 was provided to Board Members. The Rules state that by July 1 each year, the Board will review regulations and standards and, if necessary, submit recommendations for changes and/or additional standards. A question was asked if this can be done more often. This can be done more often, as long as it is done by this date each year.

Agenda Item 3:**Overview of Existing Oklahoma Statutes and OSDH Rules Regarding Food Safety**

- a. Definitions of “Food”**
 - i. Title 63 O.S. § 1-1101 et seq. <http://www.oklegislature.gov/osstatuestitle.html>**
 - ii. Oklahoma Administrative Code (OAC) 310:260 & OAC 310:257
[https://www.ok.gov/health/Protective Health/Consumer Health Service/Foods/](https://www.ok.gov/health/Protective%20Health/Consumer%20Health%20Service/Foods/)**
- b. Food Processing Rules – OAC 310:260**
 - i. Good Manufacturing Process (GMP)**
 - ii. Labelling & Packaging**
 - iii. Quality Assurance & Testing**
- c. FDA Good Manufacturing Practices**
- d. Discussion & Questions**

Phillip Jurina provided an overview of statutes and regulations that pertain to a food license, the definitions of food, good manufacturing practices/processes, labeling/packaging, quality assurance/testing, and FDA GMPs. There are close similarities concerning the definition of food within Title 63, OAC 310:260, and OAC 310:257. Title 63 and OAC 310:257 provide the following definition of food: “The term ‘food’ means (1) articles used for food or drink for man, (2) chewing gum, and (3) articles used for components of any such article.” OAC 310:257 defines food as “any raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.”

OAC 310:260 also loosely follows the language of the Code of Federal Regulations Title 21, part 110 (21 CFR 110). This covers various types of products like jellies, pickles, and wine. It provides language for a range of tasks, from making the item to breaking it down into smaller portions and re-packaging. Meat products fall under the Oklahoma Department of Agriculture’s jurisdiction.

The labeling/packaging within OAC 310:260 loosely follows 21 CFR 101, which is general labeling and allows for trace back and recall of the product. Other than process authority, pH control, and water activity control, testing is industry driven. The industry tends to use a higher standard since they ship products out of the state and must adhere to federal regulations to do so. This will not be the case with medical marijuana.

OAC 310:260 incorporates by reference several federal guidelines. These include but are not limited to several sections of 21 CFR. The incorporation was done in 1991, so must adhere to the language as it was written at that time.

A question was raised regarding implementation of the Food Safety Modernization Act (FSMA). There was no information to give, as the agency has not moved forward under this act. This originates at the federal level.

A question was raised regarding expiration dates. This is more a use by date for tracking as quality declines and risk inclines.

A question was raised regarding exemptions. OAC 310:260 really doesn’t have any exemptions. OAC 310:257 does have exemptions if they meet certain requirements. One of the requirements

is the HACCP (Hazard Analysis and Critical Control Plan). The HACCP finds critical control points within the process.

A question was raised regarding regulations concerning use of flammable products in processing. There is no current regulation regarding this.

A copy of OAC 310:260, Good Manufacturing Practice Regulations, was provided to Board members. Phillip Jurina provided a walk-through of this language and gave a brief overview of each section. Subchapter 5 will not pertain to cannabis as it is for an unrelated specific product. There were some questions as to whether cannabis would be an additive or an ingredient. Depending upon the type of product and associated processing methods, it could be used as either additive or ingredient. State Question 788 used the term “additive”. The board recognizes it is a component of food products.

There was some discussion regarding the extraction of marijuana and the infusion into food products. It was agreed upon that there is a need to have standards to ensure safety of products for both extraction and infusion.

Agenda Item 4:

Overview of FOCUS <https://www.focusstandards.org/> - Qualitative Overview (Attachment A)

- a. Industry, Other State, Other Country Relevant Experiences**
- b. Determination of Applicability of Available FOCUS Standards Core Areas**
- c. Discussion & Questions**

Lezli Engelking, Sean McClelland, and Jeremy Applen from the Foundation Of Cannabis Unified Standards (FOCUS) were present and provided some background information of the foundation to include facilities and processes within the cannabis industry. FOCUS is a non-profit organization that develops cannabis standards. They work with boards and individual companies within multiple states. They brought forth their written standards regarding the cannabis industry for the Board to review. They will not be making recommendations for this Board, only providing information. Lezli Engelking did make a request that if this Board should adopt any part of their standards, the regulations note that they were from FOCUS.

Agenda Item 5:

Overview of FOCUS Infused Product Standards <https://www.focusstandards.org/cannabis-standards/> (Attachment B)

- a. Discussion & Questions**

The FOCUS Cannabis Infused Products standards provide language concerning several topic headings. These included management, training, worker practices, health/safety, product quality/safety, product specifications/packaging/labeling, HACCP plan, foreign materials control, allergens, operational procedures, production equipment, water use/quality, product/raw material testing, product traceability/recall/withdrawal, product storage, receiving/transport, facility maintenance, pest control program, sanitation/cleaning, sanitary facilities, waste management, business viability/sustainability, and security program.

The board reviewed the FOCUS Infused Product and Manufacturing standards language per section to determine if it was applicable to Oklahoma needs, if there was any corresponding language found in OAC 310:260 or 257, and to identify if there were any gaps. It was determined that the sections on business viability/sustainability and security did not fall under the jurisdiction of this Board.

Two areas were identified that had gaps in language as a cross walk between the FOCUS infused product standards and OAC 310:260 and OAC 310:257.

1. The explicit references to testing and lab in OAC 310:260 and 257 were not perhaps as specific or developed as the FOCUS standards.
2. Packaging and labeling in OAC 310:260 and 257. The Board may want to consider the FOCUS standards language in this area.

Agenda Item 6:

Overview of Other Core Areas Standards <https://www.focusstandards.org/cannabis-standards/> (Attachment C)

a. Discussion & Questions

This was discussed in combination with Agenda Item 5.

Agenda Item 7:

Day 1 Wrap Up

a. Outstanding Questions

b. Follow Up Activities

There were several points of discussion obtained during the meeting that will need further information or follow-up to be brought back before the Board when they reconvene tomorrow August 15, 2018.

1. A matrix by Lezli Engelking comparing the FOCUS Infused standards with 21 CFR 110.
2. Phillip Jurina to create a solid crosswalk between the FOCUS infused standards, OAC 310:260, and OAC 310:257.
3. The explicit references in OAC 310:260 and 257 as they pertain to testing or any possible laboratory protocols.
4. The explicit references in OAC 310:260 and 257 as they pertain to packaging and labeling.
5. Outstanding question regarding HACCP. To discuss and consider the possible burden on processors and what changes in might be necessary for cannabis.

Agenda Item 8:

Call for Recess

Fenton Rood made a motion to call for recess and reconvene at 9:00 am on August 15, 2018. Ray Jennings seconded the motion.

Roll call

Aye: Becky Johnson, Ravirajsinh Jadeja, Scott Yates, Scott Scheffer, Fenton Rood, Mark Woodward, Kara Berst, Ray Jennings, Travis Splawn, Troy Skow, and Edd Rhoades

The motion carried.

The August 14, 2018 special meeting of the Medical Marijuana Authority Food Safety Standards Board recessed at 3:00 pm.

Day 2 – Wednesday, August 15, 2018; 8am – 5pm

Agenda Item 1:

Call to Order, Welcome

Ray Jennings made a motion to bring the Medical Marijuana Authority Food Safety Standards Board out of recess at 9:08 am on Wednesday August 15, 2018. Fenton Rood seconded the motion.

Roll call

Aye: Becky Johnson, Scott Yates, Scott Scheffer, Fenton Rood, Kara Berst, Ray Jennings, Travis Splawn, Troy Skow, and Edd Rhoades

The motion carried.

Board members absent: Ravirajsinh Jadeja, Mark Woodward (arrived at 11:15 am), and Bud Scott

Staff present: Phillip Jurina, Amanda Morgan, Nicole Nash, Buffy Heater, Teresa Martinez, Spencer Kusi, Lynnette Jordan, and Gary Rutherford

Others present: George Richardson, Anthony Winner, Sheri Winner, Jennifer Boyle, Lezli Engelking, Sean McClelland, Drew Grimes, Huston Hulse, Jason Fisher, Jacklyn Lock, Han Ben Zvenis, Mark Grimes, and Jeremy Applen

Agenda Item 2:

Review and Discussion Questions

A crosswalk was provided by Phillip Jurina to compare the FOCUS infused product standards with current regulations. OAC 310:260-3-6 provides information concerning general sanitation requirements, raw materials and other ingredients, and manufacturing operations. This is where language can be found that will speak to any testing or HACCP plans as well as packaging. A HACCP plan is not a requirement in this language.

There was an extensive conversation concerning HACCP plans and whether or not they should be required for use or only on a voluntary basis as a recommended best practice.

Ray Jennings made a motion to use OAC 310:260 as written with no additional documents or requirements, to encourage and recommend that all new businesses follow a HACCP plan. Becky Johnson seconded the motion.

Roll call

Aye: Becky Johnson, Scott Yates, Scott Scheffer, Fenton Rood, Kara Berst, Ray Jennings

Travis Splawn pointed out that the way this motion was made it could possibly restrict the Board from adding any other recommendations along with OAC 310:260.

After discussion among the board members, Ray Jennings rescinded the motion.

A suggestion was made to create a list of recommendations that would be provided to the lead person who would then draft them into rule/regulation language. The list of recommendations could then be voted on as a whole or one at a time.

Lezli Engelking gave an overview of the Extraction and Concentrate Production standards from FOCUS. These included product safety/quality, equipment installation/operation training, production training, emergency evacuation, water-based extraction, water quality, food grade chemicals, CO₂- based extraction, CO₂ monitoring, use of dry ice, ethanol or alcohol-based extraction, food-grade ethanol, solvent-based extraction, solvent safety, solvent recovery, food grade solvents, and waste solvent disposal.

A point was made that it appears the FOCUS standards for extraction did not address the contamination risk in the final product. It was identified yesterday under the infusion standards that there was a gap in what is currently provided for in OAC 310:260 and the level of specificity provided as it relates to testing. It seems that at least some of the FOCUS standards on extraction do not provide readily available recommendations as it pertains to food safety and are more concentrated on requirements that are not under the purview of this Board.

Language in OAC 310:260 does require testing where necessary to identify sanitation failures or possible food contamination. The FOCUS infused standards takes this further and list out specific agents that could be of interest concerning contamination and provides thresholds.

There was extensive discussion concerning labeling. The discussion included batch labeling, individual serving labeling, what information to place on the label, and multiple labels on products.

Concerns were raised about whether someone could decide to become a cannabis processor with food products and operate out of their home. This would allow external contaminants like pet fur.

Concerns were raised that testing for THC levels would not be a requirement. It is understood that with this industry being new, there is not enough time to set up a system for testing. This is something that can be discussed further at a future meeting. It will also allow for research from other states regarding testing and gather more information as to how it would impact the assessment of excessive or punitive impact to processors.

There were conflicting opinions concerning the poison control number to be placed on the package. There was discussion about whether to place it on the back of the card, place it on the package, place the number only without stating who the number is for, placing Poison Control, placing for adverse reactions, for adverse effects, accidental ingestion, and state to call 911.

Agenda Item 3:

Discussion of Food Safety Standards

- a. Identification of Those Applicable to Oklahoma**
- b. Prioritization of Applicable Standards**

The Board, through discussion of different talking points, standards, and regulations determined that these should be the recommendations for draft regulations.

1. Applicability of Existing Food Manufacturing and Food Establishment Laws

It is not the intent of the Food Safety Standards Board to relieve cannabis processors of the existing requirements in Oklahoma Administrative Code, Chapter 257 and Chapter 260, to the extent they are applicable and do not conflict with State Question 788.

2. Voluntary Adoption of the Hazard Analysis and Critical Control Plan (HACCP) Standards

The Food Safety Standards Board recognizes, but does not require HACCP Standards for licensed cannabis processors. As a best practice, OSDH shall encourage cannabis processors to voluntarily adopt HACCP templates and receive training on implementation.

3. Oklahoma Adoption of Most Recent Code of Federal Regulations (CFR) Standards

Upon the Oklahoma Board of Health or Commissioner of Health adopting updates to food processing standards, including but not limited to Title 21 of the CFR, licensed cannabis processors shall be subject to the more recent standards. The Food Safety Standards Board shall meet regularly to determine necessary action to change any standards pursuant to its authority under State Question 788.

4. Incorporation of FOCUS Manufacturing Standards, Section 12(D) – (J)

The Food Safety Standards Board recommends guidance for cannabis processors on laboratory threshold limits for testing based on an annexed list produced by the Food Safety Standards Board. The purpose of the guidance shall be to educate cannabis processors on consistent testing thresholds. The contents of the list shall adopt applicable language from the FOCUS Manufacturing Standards, Section 12(D) – (J).

5. Incorporation of FOCUS Packaging and Labeling Standards

The Food Safety Standards Board recommends that manufacturing labels for foods containing cannabis be labeled with all applicable requirements in Oklahoma Administrative Code 310:257 and those incorporated by reference. The Food Safety Standards Board recommends adding the FOCUS Manufacturing Standards found at Section 13(D), and at minimum specifying the product contains THC. Manufacturing labels for foods containing cannabis may specify the strain(s) of cannabis within the product; and must specify the batch(es).

6. Oklahoma Poison Control Center Information

The Food Safety Standards Board shall recommend that the Oklahoma Poison Control Center telephone number is placed on the product package, and on OSDH-developed education materials, including the words “for accidental ingestion call 1-800-222-1222”.

7. Individual Food Labeling Standards

The Food Safety Standards Board shall recommend incorporating by reference 21 CFR 101 for individual food labeling standards.

8. Oklahoma Uniform Symbol

The Food Safety Standards Board shall recommend a uniform, unique symbol developed for Oklahoma to be placed on medical marijuana food products. Staff from the OSDH shall submit symbol designs to the Board for consideration at a future meeting. The size of the symbol placed on the product shall be 0.5 by 0.5 inch. All individual product units, including but not limited to those from bulk packaging, must be labeled with the Oklahoma Uniform Symbol.

9. Pregnancy and Warning Labels

The Food Safety Standards Board shall recommend adding the words “or while breastfeeding” to the current labeling requirements set forth in OAC 310:681-7-1(4).

10. Living Quarters Requirements per OAC 310:257-11-21 and OAC 310:257-11-22

The Food Safety Standards Board shall recommend that OAC 310:257-11-21 and OAC 310:257-11-22 pertains to all food manufacturers, including but not limited to licensed cannabis processors. Nothing in the recommendation is intended to conflict with existing local zoning and other applicable regulations.

Ray Jennings made a motion to move forward on recommendations 1-10 that is outlined, with noted changes documented by Buffy Heater. Fenton Rood seconded the motion.

Roll call

Aye: Becky Johnson, Scott Yates, Scott Scheffer, Fenton Rood, Mark Woodward, Kara Berst, Ray Jennings, Travis Splawn, Troy Skow, and Edd Rhoades

The motion carried.

Agenda Item 4:

Development of Plan to Establish Food Safety Standards Recommendations

a. Timeframes

b. Action Plans and Assignments

It was determined, with the advice of Nicole Nash, that the recommendations voted on at this meeting should be placed into draft rule format. The draft rule language would be prepared by OSDH staff. In order for the board to meet the date requirement of State question 788, this would require a meeting before August 27, 2018 for this Board to review, modify, and approve the initial draft. The consensus was to meet on Friday August 24, 2018 at 9:00 am. If it is available, the initial draft will be sent out 24 hours before the meeting.

Agenda Item 5:

Day 2 Wrap Up

a. Outstanding Questions

b. Follow Up Activities

None

Agenda Item 6:

Establishment of Future Meeting Schedule

a. Outstanding Questions

None

Agenda Item 7:

Closing, Adjournment & Dismissal

Ray Jennings made a motion to adjourn. Becky Johnson seconded the motion.

Roll call

Aye: Becky Johnson, Scott Yates, Scott Scheffer, Fenton Rood, Mark Woodward, Kara Berst, Ray Jennings, Travis Splawn, Troy Skow, and Edd Rhoades

The motion carried.

The August 15, 2018 special meeting of the Medical Marijuana Authority Food Safety Standards Board adjourned at 5:34 pm.

Acronyms and References

[OAC 310:257 – Food Establishments](#)

[OAC 310:260 – Good Manufacturing Practice \(GMP\) Regulations](#)

[OAC 310:681 – Medical Marijuana Control Program](#)

[Hazard Analysis and Critical Control Points \(HACCP\) – Food and Drug Administration](#)

[Oklahoma Medical Marijuana Authority](#)

[Oklahoma State Department of Health – Consumer Health Service](#)

[Foundation of Cannabis Unified Standards \(FOCUS\) – Manufacturing Standard Index](#)