

Montana Food Modernization Project

A product of HB 630 Sponsored by Representative Kathleen Williams.

(Portions of the appendices are the work of Chuck Munson of the Attorney General’s Office who provided amazing minutes of the public meetings (appendices B-E). We offer him our heartfelt thanks. It would not have been possible to do this without him.)

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Background

House Bill 630 Sponsored by Representative Kathleen Williams (Appendix A) funded a public process to gather input about Montana's food regulation and how it could be improved. A series of food-related bills were introduced and debated in the last legislative session on topics from hot coffee sales, eggs at farmers' markets, pickle exchanges, the transportation of meat, and raw milk indicating that public interest in food regulation was high. Changes to federal law, which include the Food Safety Modernization Act (FSMA) and a new version of the federal model food code, further motivated everyone involved to reexamine what was and wasn't working with Montana's food laws with an eye towards the future.

HB 630 tasked the three departments (Agriculture, Livestock, Public Health and Human Services) responsible for food regulation and advocacy to assess food laws and develop a report addressing the following issues:

- (a) potential changes in Montana laws and administrative rules necessitated by the passage and implementation of the federal Food Safety Modernization Act pursuant to Title 21, chapter 27, of the United States Code;
- (b) the extent to which home kitchens can be used to prepare foods for sale that are not potentially hazardous while maintaining food safety for the public;
- (c) the relative availability of community-based commercial kitchens and their use; and
- (d) inconsistencies and inefficiencies in Montana's food laws that could be improved and streamlined.

The agencies were instructed to coordinate, hold a public meeting and gather comments and suggestions on the above subjects.

Review of Current Law

A brief overview of the current food law will assist readers' understanding of the comments and suggestions that follow. Food law is generally split into three separate paths, with three levels of regulation. Path one is for foods derived from animals (meat, milk, eggs); path two is food for animals (feed and pet food); path three is for all other foods. The three levels of regulation are federal, state, and local.

Path One: Animal (meat, milk, eggs)

Federal Level – United States Department of Agriculture (USDA) law and regulation - which govern to the extent these products cross state lines.

State Level – Montana Department of Livestock law and rules - which generally mirror federal regulation, govern in-state livestock and poultry processing, and slaughter, as well as eggs. Retail sale as human food is still covered by Montana Department of Health and Human Services laws and regulations (see Path Three).

Local Level – If sold into the retail human food chain (grocery store, direct sale, restaurants, etc.), their sale is subject to the jurisdiction of county sanitarians consistent with state Department of Health and Human Services laws and regulations.

Path Two: Animal Feeds and Pet Food

Federal Level – Food and Drug Administration (FDA) law and regulation – is primary but certain things are also covered by USDA laws.

State Level – Montana Department of Agriculture law and rule, with one limited exception which is covered by the Department of Livestock involving vegetable waste fed to pigs.

Local Level – none.

Path Three – All Other Foods

Federal Level – FDA is the federal regulatory agency -- produces a model food code (set of rules) that states may voluntarily adopt.

State Level – Montana Department of Public Health and Human Services -- is the licensing and rule maker at the state level.

Local Level – County Sanitarians -- are the ones that must enforce and implement the food laws and regulations on businesses that are in their county.

In addition, the Montana Department of Agriculture has certain duties as they relate to the production and first sale of fresh produce (fruits and vegetables). Certain foods have special rules that apply only to them (huckleberries for example) as do certain growing practices (organic and natural beef programs).

While Montana does not have existing law or regulation under the moniker of a “cottage food” law, it does have a series of exemptions found in MCA 50-50-202 that several outside legal reviewers have deemed a “cottage food” law. This particular law played a large role, both in the public comments but also the departmental discussions, so it is included below in its entirety.

50-50-202. Establishments exempt from license requirement -- farmer's market records. (1) Establishments owned or operated by the state or a political subdivision of the state that employ a full-time sanitarian are exempt from licensure but shall comply with the requirements of this chapter and rules adopted by the department under this chapter.

(2) (a) A license is not required to operate an establishment if it is operated by a nonprofit organization for a period of less than 14 days in 1 calendar year. An establishment exempt from licensure under this subsection:

(i) must be operated in compliance with the remaining provisions of this chapter and rules adopted by the department under this chapter; and

(ii) prior to each operation, shall register with the local health officer or sanitarian on forms provided by the department.

(b) Nonprofit organizations or persons selling baked goods or preserves exclusively for a charitable community purpose are exempt from registration if they notify the local health officer or sanitarian, by phone or in person, before the event. The notification required is limited to the date and time of the event, items planned to be sold, and an estimate of the number of people expected to be served at the event.

(3) (a) (i) A license is not required of a gardener, farm owner, or farm operator who sells raw and unprocessed farm products or whole shell eggs at a farmer's market.

(ii) Whole shell eggs sold at a farmer's market by a farm owner or operator must:

(A) be clean, free of cracks, and stored in clean cartons;

(B) be kept at a temperature established by the department; and

(C) carry a label indicating the name and address of the farm owner or operator selling the eggs.

(b) A license is not required of a person:

(i) selling or offering hot coffee or hot tea at a farmer's market; or

(ii) selling baked goods or preserves at a farmer's market or exclusively for a charitable community purpose.

(c) Coffee or tea exempted under this subsection (3) may not be prepared or served with fresh milk or cream.

(4) (a) A farmer's market that is an organized market authorized by a municipal or county authority shall keep registration records of all individuals and organizations that sell baked goods or preserves at the market.

(b) The registration records must include but are not limited to the name of the seller, the seller's address and telephone number, the products sold by the seller, and the date the products were sold.

(c) The registration records must be made available to the local health officer or the officer's agent.

The use of home kitchens to prepare foods for sale and the availability of community-based commercial kitchens

One of the requirements of HB 630 is to assess the current availability of community-based commercial kitchens. These kitchens may be used under existing statutes and rules to produce food items for sale. This survey did not address "cottage food" kitchens specifically, but does identify sources that may be available to entrepreneurs who are interested in expanding their operation. This survey identified 394 community-based commercial kitchens throughout the state, including 266 that are currently licensed (requiring inspections). Some counties were not able to determine how many existed in their areas or did not respond to survey questions. These kitchens may be available to individuals for use in food manufacturing. DPHHS recognizes the interest by entrepreneurs who are in need of a facility to rent or lease. There are also facilities that may be interested in making their operation available for rent or lease. DPHSS will work with owners of licensed establishments to make this information readily available to entrepreneurs via the DPHHS website.

The departments agreed that production of potentially non-hazardous foods in home kitchens and community based kitchens could be safely accomplished under the proposed **Health, Agriculture, Livestock (HAL) Recommended Approach to Cottage Foods – HB 630** detailed on page nine of this report. For more information on the availability community based kitchens please see Appendix I.

Collaboration between Agriculture, Livestock and Public Health and Human Services

The three departments have been meeting for over two years on a quarterly basis to informally work on improving how the food regulation system functions. The passage of HB630 formalized this process. The bill also called for a facilitator, and the departments agreed on Joan Miles, who was a former Director of Public Health and Human Services, an attorney, and a former county sanitarian. The departments began a series of meetings to work together to look at all of the state laws and rules involving food to see what was working, what was confusing, and what could be done more effectively. These discussions looked closely at all food laws, particularly laws that overlapped with each other or contained complicated exceptions and/or exclusions and resulted in the following:

State Agency Improvement Efforts Already in Place:

- The three agencies have quarterly interagency meetings to discuss food manufacturing/food purveyor issues such as complaints, overlapping authorities, gaps in regulations, etc.
- Agencies are encouraging more communication, collaboration, referral of problems to appropriate agency representatives.
- DPHHS
 - Nearing completion of comprehensive revisions to food service regulations that are consistent with FDA Model Food Code. This will bring the Department's regulation into a more contemporary status.
 - DPHHS is conducting periodic review of county inspection reports – this is both an educational opportunity and an effort to improve consistency throughout the state.
 - Development and distribution of the *Montana Wholesale Food Licensing Guide* to help prospective applicants comply with local, state and federal requirements for a wholesale food business.
<http://www.dphhs.mt.gov/publichealth/fcs/documents/LicensingGuide.pdf>
 - Provided training and access to the state licensing data base to county Sanitarians – allowing Sanitarians to access and update information on specific food service establishments or food manufacturers
 - Development of a state sponsored website for the public to register complaints. These are referred to the appropriate county, and DPHHS can follow up where appropriate or provide technical assistance in resolving issues.
 - Promotions of accreditation through the Public Health Accreditation Board – this will bring more standardization, consistency and quality to various public health operations.
 - Improvements in licensing of food manufacturers and reviews/approvals of products of licensed food manufacturers to prevent delays that impact business operations.
- Department of Agriculture – Preparing a “Direct Marketing Guide” for potential and new or expanding ag businesses. This will walk them through the process, identify all requirements,

refer to other agencies when necessary, etc. This manual has been drafted but is waiting for the new version of the food regulations by DPHHS so as not to refer to outdated rules.

Public Meetings

While HB 630 called for at least one meeting for public input, it was clear from early discussions among the three agencies that multiple meetings would be preferable if meeting facility costs were kept low. We were able to hold three public meetings: Missoula (Appendix B), Bozeman (Appendix C), and Billings (Appendix D). Chuck Munson from the Attorney General's office kept excellent minutes of the events that we have included (Appendix F). He also prepared a summary of the major points that arose during the public meetings (Appendix E).

The public meetings served not only to allow people to express their views to the regulators in person, but also to discuss areas of concern and confusion with them one-on-one before, during, and after the meetings. While each meeting ended up with a slightly different tone and composition based on those in attendance, we cannot state enough how positive the experience seemed to be for everyone involved. Providing public forums to allow discussion on issues like this is a useful expenditure of time and money when the area of law is complicated or where a variety of viewpoints can exist without being in direct conflict. It is less useful where there are diametrically opposed viewpoints on core issues, such as raw milk regulation.

Written Comments

We have included all of the written public comments we received (Appendix F). They cover a lot of different topics, and many have suggestions on how the laws and regulations could be changed. They include comments from consumers, regulated businesses, and regulators. We did not include comments that simply asked questions about the location of the public meetings or thanked us for providing the process.

Advisory Group

In addition, the departments met twice with a small advisory group composed of various stakeholders in the current food system, including county sanitarians, farmers, an institutional buyer of local food, a food and agriculture development center, and local food advocates. The notes from these meetings are included (Appendix G and H).

Consensus Recommendations from the Three Participating Departments (HAL)

In addition to the work already being done by the various departments, the following are recommendations endorsed by all three of the departments, and are at least consistent with many of the public comments received and the majority of the advisory committee as well. At least the first four would require changes to existing legislation.

- (1) Expand/create the Montana “cottage food” law by amending MCA 50-50-102 to allow the sale of non-potentially hazardous foods (including foods currently listed) anywhere as long as it is a direct sale within the state. Additional details are provided below, please see: *Health, Agriculture, Livestock (HAL) Recommended Approach to Cottage Foods – HB 630*
- (2) Raw agricultural products (fruits, grains, vegetables) would be regulated by the Department of Agriculture, and could be sold anywhere and to anyone (including grocery stores, schools, and restaurants) subject only to limits set by local jurisdictions for time and manner. The federal FSMA would govern larger operations. Additional funding might be required as the Department of Agriculture is primarily a fee for service agency. To be consistent with federal regulations, honey should be added to the list of raw agricultural products found in MCA 50-50-102 (16).
- (3) Give greater rule-making flexibility to the Department of Public Health and Human Services by moving food regulatory details from law into rule. This would make the department’s interactions with their local counterparts more consistent. It would also allow the regulations to address the realities of modern farmers’ markets (weekly reoccurring events), mobile food operations, food sampling, and catering issues in a manner that is consistent in how the regulation is applied, while providing flexibility to change over time without involving the legislature on an individual food by food basis.
- (4) Currently, food rule-making requires the participation of a “special” oversight committee mandated under **MCA 50-50-103. Department authorized to adopt rules -- advisory council.** Our suggestion is to replace this group with representatives from health, agriculture and livestock, along with representatives from among the county sanitarians, and appointed members of the public.
- (5) The public also expressed an intense desire for more food safety and regulation trainings. The departments will work with MSU Extension and county sanitarians to make educational opportunities available about state and federal food law and food safety in general.
- (6) The exemption in 50-50-202 (b) for non-profit baked goods and fruit preserves should remain the same so as not to complicate charitable fund-raisers.

Health, Agriculture, Livestock (HAL) Recommended Approach to Cottage Foods – HB 630

The consensus of this group is to recommend revision of the current farmers’ market exemption in MCA 50-50-202 to include cottage foods and allow for direct sales of “non-potentially hazardous foods” (NPHF) at any direct sale venue. We also recommend MCA 50-50-103 be changed to allow DPHHS to adopt rules without the requirement of a special oversight committee.

- WHAT CAN BE SOLD:

- Non-potentially hazardous foods (NPHF). Cottage food operations may only produce “non- potentially hazardous foods,” including: (1) Baked Goods; (2) Candy; (3) Preserves; (4) Honey; and other products specified in rule;
 - Need to add “may include but is not limited to” and list general examples of allowed and prohibited products;
 - Specify that the 2013 exemptions for hot beverages and whole shell eggs should be maintained;
 - Specify that "Raw and unprocessed farm products" (suggest changing to “raw agricultural commodities”) are not regulated under this statute.
- HOW WILL PRODUCERS PARTICIPATE:
 - Require a one-time registration of each cottage food operation. Local health authorities will review and approve application and submit registration form to DPHHS, similar to what is done now for licensure. Changes to the operation will require re-registration and approval;
 - Require a one-time registration fee be established in rule (proposing \$35). This fee will be submitted to local jurisdictions. Subsequent re-registration and fees may be required when an operator modifies or expands their products. DPHHS will maintain a database of registered operations.
 - No additional fees may be imposed on these operations.
 - The registration will be recognized throughout the state, with no additional requirements imposed by the local health authority, if operating as approved.
 - Require an education component (developed by DPHHS and MSU Extension Service), which may include on-line training specific to cottage foods;
 - No monetary limit to total annual sales is proposed;
 - Grant authority to DPHHS to write rules pertaining to types of foods that can be sold, safe food handling training, registration with local health department, etc.;
 - No inspection of home kitchens be required, however allow for investigations by the local health department in the event an illness or complaint is associated with the facility;
 - Food production and processing will be limited to home kitchens in domestic residences.
 - WHERE CAN PRODUCTS BE SOLD:
 - Direct to consumers in public and private venues;
 - No sales to restaurants or other licensed establishments which include but are not limited to retail food establishments, wholesale food establishments, and public accommodations;
 - No shipment of products;
 - No consignment sales.

- **SAMPLING:**
 - Rules would allow cottage food businesses to provide free samples of products to customers without the need for a retail food license.

Suggestions from the Departments Individually:

Department of Agriculture

The Department of Agriculture recommends looking at salsas, barbecue sauces, and pickles to create clear frameworks on what types of these products (if any) might be considered for sale under a modified MCA 50-50-102.

The Department of Agriculture also recommends that honey be added to the raw agricultural products exemption in 50-50-102(16).

The Department of Agriculture would also like to see clearer rules/laws on eggs and poultry, as those currently in place tend to confuse producers, county sanitarians, food retailers and food service providers.

Department of Public Health and Human Services

During public meetings held in early 2014, information was collected regarding Montana food regulations, types of food establishments and licensing of establishments. The licensing and regulation of temporary and mobile food establishments were identified as a concern for regulators and operators.

The department proposes the following to address these concerns by simplifying and standardizing regulations related to mobile and temporary food establishments to ensure uniform application throughout the state:

Mobile Food Establishments

1. Adoption of the 2013 model Food Code published by the United States Food and Drug Administration (FDA), and its accompanying modifications, additions and deletions, as proposed by the department. Adoption of the Food Code will update state standards using the most recent science, better align the rules with other states, and improve uniform application of food safety principles throughout Montana;
2. Clearly state in retail food establishment rules adopted by the department that a state-issued mobile food establishment license will be honored by all local health officers and their designees, without additional licensure fees, provided the mobile food establishment meets all applicable state requirements;
3. State in statute that plans for mobile food establishments will be approved by DPHHS in coordination with local jurisdictions;

4. Authorize in statute a fee for mobile food establishment plan reviews.
5. All licenses will be issued and all inspections (i.e. pre-licensing, routine, complaints) will be performed by the county health authority where the mobile unit is based.

Temporary Food Establishments

1. DPHHS would no longer issue temporary food establishment licenses;
2. Authorize in statute that local health officers or their designees may issue temporary food establishment permits to be effective for one calendar year;
3. Permits are valid for the calendar year or until the last scheduled event, and only within the county that issued the permit.
4. Authorize the department in statute to establish rules setting maximum permit fees, application procedures and general standards;
5. Adopt the proposed rule change for the definition of a “temporary food establishment,” which means *a food establishment that operates at a fixed location for a period of no more than 14 consecutive days in conjunction with a single event or celebration*;
6. Create and adopt a definition for “Multiple-event temporary food establishment” which means *a food establishment that operates at a series of events, each for a period of no more than 14 consecutive days*. The purpose of creating this category is to enable operators that do not or cannot meet mobile food establishment standards the opportunity to buy one license in a calendar year, rather than multiple licenses in a year, if they operate within a specific county;
7. Multiple-event temporary food establishments would be required to list each proposed event location for that county during plan review. If additional events or a change of venues are proposed, the establishment owner would be required to notify the local jurisdiction at least 7 days before the proposed event date;
8. Each local jurisdiction will set its own permit fees (not to exceed maximum amount set by rule);
9. Each local jurisdiction will process such permits and keep the entire permit fee;
10. Permits would only be valid in the county where the permit was issued;
11. Each local jurisdiction may add local requirements;
12. Plan review would be performed by the local jurisdiction and required each year, since a temporary food establishment permit would be valid only for the calendar year.

License Fees

The department proposes the following to modernize retail food service fees to reflect the complexity of food service and offer relief to taxpayers who pay for the vast majority of the system that keeps food safe in Montana.

1. The department proposes changing license fees authorized in statute to correspond with the department’s proposed “Establishment Complexity” categories;
2. This new fee structure will better reflect risks of specific establishments and reflect the complexity of inspections required of the local sanitarian.

3. County sanitarians will be directly involved with assisting cottage food participants in food safety, including plan review, label development and issuing approval for registration. The purpose of the registration fee is to supplement the costs to the local jurisdictions for the resources necessary to provide training and review applications.

Department of Livestock

The Montana Department of Livestock, Meat and Poultry Inspection Bureau, recommends growers of small poultry flocks utilize the 1,000 Bird Exemption to produce poultry for Montana consumers. In order to meet the likely demand, the bureau is developing procedures and assessing staff resources.

The Montana Department of Livestock recommends developing consistency among county sanitarians regarding meat establishment requirements and what is considered an acceptable product.

Additional Perspectives

The report includes the Departmental recommendations and the various comments collected in this information gathering process (including in the appropriate appendix). In addition Grow Montana prepared further comments based on the legislative suggestions of this report and their participation in the advisory group discussions. The entirety of their comments is included in Appendix J, but they are summarized below.

- A. Make up of advisory committee: essential to include a diverse range of stakeholders
- B. Comments regarding cottage food proposal:
 - I. Impact on producers currently selling under MCA 50-50-202
 - II. Allowed products: Strongly encourage expanded list of allowed products
 - III. Product registration: re-registration seems unnecessary
 - IV. Product labeling: a reasonable way to ensure public knowledge
 - V. Production in home vs. commercial kitchens: production should not be limited to only homes
- C. Poultry processing: input for implementation of 1000-bird exemption

Conclusions

The public input process was a success. It created an environment in which consumers, businesses, regulators, and educators could talk and discuss the issues surrounding food. All three departments plan to continue meeting on a regular basis to continue the positive experiences that came out of this process.

We would like to thank all of the people who participated in the public comment processes and the advisory group. We would like to thank the public sanitarians for their thoughtful comments and participation in this process.

As to the four primary purposes of HB 630:

1. As to the FSMA, the federal Food Safety Modernization Act with currently enacted and proposed regulations does not appear to require changes to Montana laws or rules. By providing more food safety training throughout the state those growers affected by the act will have an easier time complying with it.
2. As to the “Cottage Food” Law, an expansion of Montana’s current “Cottage Food” Law (MCA 50-50-202) is our recommendation.
3. As to identifying the availability of “Community” Kitchens in Montana, DPHHS has compiled a list in Appendix I, and is working on creating a more detailed version to make it easier to find licensed food businesses willing and able to provide facilities that would allow a business to engage in licensed food manufacturing.
4. As to streamlining and improving the food regulations in Montana, the three Departments have included their suggestions in this report, and are working on updating rules and processes to make it easier for businesses to understand and comply with the food regulations of Montana.

With intended updates to the food regulations of Montana, coupled with some additional regulatory flexibility that we hope the legislature will grant in the food regulatory enforcement arena , we think Montana can create a system that is easier to understand, relatively painless to use, and maintains consistent safety standards for all. All three of the agencies involved are committed to working with local sanitarians and county extension offices to provide quality food safety training that the public made clear it needs and desires. While the changes proposed will not fix all issues that some have with food regulation, they represent a positive step that will make the requirements easier to understand and compliance easier to achieve.